GENERAL PRACTITIONER v TEVA

Promotion of Qvar

A general practitioner and ex-employee of Cephalon (UK) complained about an advertisement for Qvar (CFC-free beclometasone dipropionate) issued by Teva and published in the BMJ, 10 September 2011. Qvar was indicated for the prophylactic management of mild, moderate or severe asthma.

Cephalon had been acquired by Teva on 14 October 2011.

The detailed response from Teva is given below.

The complainant was concerned that omitting information about the confidence limits in relation to a claim 'Qvar Easi-Breathe has real-life data from real-life patients. It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' which was referenced to a poster by McKnight *et al* 2010, could be misleading if the confidence intervals suggested much smaller or no differences were also likely. Secondly, no p values were presented which could further impact prescribing decisions. Therefore, overall, the statistical information was insufficient to make a clear prescribing decision and the omission of key statistical information was potentially misleading.

The Panel noted that the Code did not require the inclusion of statistical information. It required that claims were not misleading and were capable of substantiation but the omission of statistical information was not in itself necessarily misleading. The supplementary information advised that care be taken to ensure that there was a sound statistical basis for all information, claims and comparisons. Differences which did not reach statistical significance must not be presented in such a way as to mislead.

The Panel noted that one of the three results from McKnight *et al* compared patients using breath activated inhaler (Qvar Easi-Breathe) and pMDI beclometasone (Clenil pMDI). Patients were in three categories, controlled, partly controlled and uncontrolled. McKnight *et al* stated that in this population Qvar Easi-Breathe was associated with better control than Clenil pMDI (p <0.04). The Panel noted that the claim at issue 'It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' was different to the conclusions of McKnight *et al* which used the phrases 'appeared to result in better control' and 'is associated with better control'.

The Panel had some concerns about the claim. However, it did not consider that it was misleading due to the absence of confidence intervals or p values as alleged. No breach was ruled.

The complainant noted that whilst not obligatory, it would have been helpful to provide a telephone number and/or email address to report possible adverse events, or to request further information, without recourse to another source.

The Panel noted that the statement in the advertisement that 'Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Teva UK Limited' was in line with the Code. The supplementary information stated that a telephone number or email address could be included but there was no requirement to do so. The Panel therefore ruled no breach.

A general practitioner and ex-employee of Cephalon (UK) Ltd complained about an advertisement (Ref QV/11/003d) for Qvar (CFC-free beclometasone dipropionate) issued by Teva UK Limited and published in the BMJ, 10 September 2011 (Ref QV/11/003d). Qvar was indicated for the prophylactic management of mild, moderate or severe asthma.

Cephalon had been acquired by Teva on 14 October 2011.

1 **Claim 'Qvar Easi-Breathe has real-life data from real-life patients. It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …'**

The asterisk took the reader to the footnote 'Pressurised Metered Dose Inhaler. Percentage controlled on Qvar Easi-Breathe 64% (0.64). Percentage controlled on Clenil Modulite = 54%. Therefore ARR is 0.64 – 0.54 = 0.1. Numbers needed to treat = 10'.

The claim was referenced to a poster by McKnight *et al* presented at the European Respiratory Society congress, 2010.

COMPLAINT

The complainant was concerned that there was not enough information to make a decision on the clinical utility of Qvar, in breach of Clause 7.2.

No confidence intervals were provided to determine how large or small an effect was observed, and whether the confidence intervals for each group overlapped, which raised the possibility that there was no difference between the groups. The complainant alleged that omitting this information could be misleading if the confidence intervals suggested much smaller or no differences were also likely. Secondly, no p values were presented to interpret what level of statistical significance was used which could further impact prescribing decisions in combination with confidence intervals. Therefore, overall, the statistical information was insufficient to make a clear prescribing decision and the omission of key statistical information was potentially misleading in breach of Clause 7.2 and a comparative claim in breach of Clause 7.3.

RESPONSE

Teva submitted that the allegation about insufficient information was a misrepresentation due to oversimplification of Clause 7.2 which stated:

> 'Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.
>
> Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.'

Teva considered that the advertisement complied with Clause 7.2 as it was accurate, balanced, fair, objective and unambiguous and based on an up-to-date evaluation of McKnight *et al* (2010) and clearly reflected that poster presentation. It did not mislead and was sufficiently complete to enable a health professional to form his/her own opinion of the therapeutic value of the medicine as detailed in McKnight *et al*. All claims were clearly referenced and were capable of substantiation.

Confidence intervals were not included as they were not presented in the poster for the measure quoted in the advertisement, as the analysis did not calculate confidence intervals.

With regard to the p value, Teva submitted that the Code did not require statistical numerical data such as the p value to be provided. The Code clearly stated in Clause 7.4 that 'Any information, claim or comparison must be capable of substantiation'. The p value and statement of significance was substantiated by the poster cited in support of the claim.

Teva submitted that the claim at issue was clear, concise and referenced appropriately and reflected McKnight *et al*.

Teva denied that the advertisement was misleading. The advertisement used an appropriate comparator product, detailed claims that were substantiable in the original reference, created no confusion, reflected trademarks, took no unfair advantage in the reputation of the trademark and was not presented as an imitation or replica. It reflected the original reference and therefore did not breach Clause 7.3.

Teva submitted that the Code did not require the level of detail highlighted by the complainant and the advertisement was factually correct, unambiguous and referenced accordingly. The Code required that claims must not be misleading and be capable of substantiation, which was so for the advertisement at issue.

PANEL RULING

The Panel noted that the Code did not require the inclusion of statistical information. It required that claims were not misleading and were capable of substantiation but the omission of statistical information was not in itself necessarily misleading. The supplementary information to Clause 7, statistical information, advised that care be taken to ensure that there was a sound statistical basis for all information, claims and comparisons. Differences which did not reach statistical significance must not be presented in such a way as to mislead.

The Panel noted that McKnight *et al* predominantly focussed on retrospectively evaluating asthma control and how it was influenced by inhaler technique. One of the three results compared patients using breath activated inhaler (Qvar Easi-Breathe) and pMDI beclometasone (Clenil pMDI) using a modified form of the Global Initiative for Asthma (GINA) control tool. Patients on Clenil were compared with patients on Qvar in three categories, controlled, partly controlled and uncontrolled. McKnight *et al* stated that in this population Qvar Easi-Breathe was associated with better control than Clenil pMDI ($p < 0.04$). The Panel noted that the claim at issue 'It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' was different to the conclusions of McKnight *et al* which used the phrases 'appeared to result in better control' and 'is associated with better control'.

The Panel had some concerns about the claim. However, it did not consider that the claim at issue was misleading due to the absence of confidence intervals or p values as alleged. No breach of Clauses 7.2 and 7.3 was ruled.

2 Provision of contact details

COMPLAINT

The complainant noted that whilst not obligatory, it would have been helpful if Teva had provided a

telephone number and/or email address to report possible adverse events (Clause 4.10 supplementary information), or to request further information, without recourse to another source.

RESPONSE

Teva stated that a company telephone number and/or email address to report adverse events was not obligatory, therefore it did not understand why the complaint had been made. Teva submitted that it had provided the necessary obligatory information and it reserved the right to include/exclude supplementary information. This would be reviewed when the company revised its procedures with the introduction of the 2012 Code.

PANEL RULING

The Panel noted that the statement in the advertisement that 'Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Teva UK Limited' was in line with the requirements of Clause 4.10. The supplementary information stated that a telephone number or email address could be included but there was no requirement to do so. The Panel therefore ruled no breach of Clause 4.10.

Complaint received **17 November 2011**

Case completed **9 January 2012**