CASE AUTH/2810/12/15

ANONYMOUS v TEVA

Promotion of DuoResp Spiromax

An anonymous, non-contactable complainant, who described him/herself as a general practitioner, complained about an advertisement for DuoResp Spiromax (budesonide/formoterol fumarate dehydrate) placed in the Primary Care Respiratory Update by Teva UK.

The advertisement featured the claim 'The moment I picked it up I knew how to use it*' next to the photograph of a patient. The claim 'Intuitive design' appeared under the photograph and both claims were referenced to Rychlik *et al* (2014) and Plusa *et al* (2015). 'Intuitive to use' was also so referenced. The asterisk referred to a statement in small, grey font at the very bottom of the advertisement (below the prescribing information) 'Instructions for use should be followed as per the patient information leaflet'.

The complainant stated that he/she often used budenoside/formoterol inhalers and noticed from the advertisement that DuoResp Spiromax was easy for patients to use. If retraining was not required it would save a considerable amount of time. The patient information leaflet told a different story. Although it looked like a metered dose inhaler it should not be shaken and an air vent in front of the patient's lip could easily be blocked so it was likely that many patients might incorrectly use this inhaler without training. The complainant considered that the inhaler did have a place, but was disappointed that the reality of clinical usage did not match the initial impression.

The detailed response from Teva is given below.

The Panel noted that the headline claim 'The moment I picked it up I knew how to use it' and the strapline 'Intuitive design' were both referenced to Plusa *et al* and Rychlik *et al*. The Panel noted, however, that Rychlik *et al* was a presentation on incremental innovation and consisted largely of a preview of Plusa *et al* which was a qualitative market research study in which asthma/chronic obstructive pulmonary disease (COPD) patients and health professionals were interviewed to obtain opinions on DuoResp Spiromax and compare it with a currently used Turbohaler or Accuhaler. The main goal of the study was to answer two questions: How likely health professionals and patients were to use and even switch to the Spiromax and which benefits/features of Spiromax should be communicated to maximize its potential in the market?

One part of the study involved interviews with 181 health professionals experienced in the treatment of asthma and COPD across 9 European countries. The other part of the study involved 261 interviews with 80 asthma/COPD patients from mostly these countries. The patients must not have used Easi-Breathe before and must use a Turbohaler or an Accuhaler. It was not explained in the study when or why the patients were interviewed on more than one occasion. The Panel queried whether 261 was the sum total of interviews with 80 patients and 181 health professionals. The study stated that respondents (health professionals and patients) evaluated the DuoResp Spiromax after they had seen a demonstration video, tried an empty device and in the case of health professionals had additionally read the product profile. In that regard the Panel disagreed with Teva's submission that the study clearly supported the intuitive nature of the Spiromax device and the ability to handle it without any instruction. Further the Panel noted that the study concluded that training could not be completely eliminated '…but the easy training use of the inhaler is a step in the right direction …'.

The Panel noted the authors' findings and queried statements such as '76% of patients handled [Spiromax] correctly without receiving any instruction' given that they had all seen a demonstration video. The Panel considered that some important detail was missing from the published report as in its absence readers could not fully understand the study methodology nor the importance of its outcomes. Nonetheless, the Panel noted that whilst the majority of patients and health professionals were positive about Spiromax, there were still 25% of patients and 13% of health professionals who did not find it intuitive or very intuitive.

The Panel noted that the advertisement portrayed a patient's perspective of Spiromax and that Plusa *et al* had interviewed only 80 patients vs 181 health professionals. The Panel considered that readers would assume from the advertisement that all patients would immediately know how to use DuoResp Spiromax from the moment it was dispensed and would not need to be counselled in the correct use of the device. This was not so and in that regard the Panel was very concerned about the possible risk that some asthma or COPD patients would lose control of their symptoms for want of adequate training. The advertisement stated in small, grey font, below the prescribing information, that instructions for use should be followed as per the patient information leaflet. In the Panel's view this statement was easily missed. The Panel noted that Teva acknowledged that some patients had difficulty in using inhalers and it recommended that health professionals refer patients to the patient information leaflet. The Panel considered that the reference to the patient information leaflet for instructions on how to use the Spiromax device contradicted the headline claim 'The moment I picked it up I knew how to use it'. Further, that patients were required to follow instructions as per the patient information leaflet meant that the

device was not unequivocally intuitive as implied. The Panel considered that in the circumstances, the claims 'The moment I picked it up I knew how to use it' and 'Intuitive design' in the advertisement were misleading as to the ease of use of Spiromax and ruled a breach of the Code. The Panel considered that high standards had not been maintained and ruled a further breach of the Code.

An anonymous, non-contactable complainant, who described him/herself as a general practitioner, complained about an advertisement for DuoResp Spiromax (budesonide/formoterol fumarate dehydrate) placed in the Primary Care Respiratory Update by Teva UK Limited.

DuoResp Spiromax was indicated in adults 18 years of age and older in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) was appropriate; in patients not adequately controlled with inhaled corticosteroids and as needed inhaled short-acting β_2 adrenoceptor agonists or controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists. The medicine was also indicated in the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD) (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who had significant symptoms despite regular therapy with long-acting bronchodilators.

The advertisement featured the claim 'The moment I picked it up I knew how to use it*' next to the photograph of a patient. The claim 'Inuitive design' appeared under the photograph and both were referenced to Rychlik *et al* (2014) and Plusa *et al* (2015). Another claim 'Intuitive to use' was also so referenced. The asterisk referred to a statement at the very bottom of the advertisement (below the prescribing information) 'Instructions for use should be followed as per the patient information leaflet'. The statement appeared in small, grey font.

COMPLAINT

The complainant stated that he/she often used budenoside/formoterol inhalers and noticed the advertisement for DuoResp Spiromax. Apparently it was easy for patients to use; the advertisement included the claim 'The moment I picked it up I knew how to use it' and referred to an intuitive design. The complainant noted that getting patients to use inhalers was increasingly difficult given the number of new options and he/she was pleased that this would save him/her a considerable amount of time if retraining was not required. The complainant alleged that the patient information leaflet told a very different story. Although it looked like a metered dose inhaler such as the often used Ventolin, it should not be shaken and an air vent which would be in front of the patient's lip could easily be blocked so it was highly likely that there would be a large number of patients who would incorrectly use this inhaler without training. The complainant considered that the inhaler did have a place, but was disappointed that the reality of clinical usage did not match the initial impression.

When writing to Teva, the Authority asked it to respond in relation to Clauses 9.1 and 7.2 of the Code.

RESPONSE

Teva queried what the substantive proposed complaint was. Teva noted that the complainant compared the 'reality of clinical usage' to the advertised claims but Teva's impression was that the complainant had not actually handled or prescribed the product.

Teva submitted that the advertisement in question referred to the intuitive nature of the Spiromax device, as substantiated by the references and also referred the reader to the need to read the patient information leaflet for instructions of use. The summary of product characteristics (SPC) stated that use of DuoResp Spiromax followed three simple steps: open, breathe and close.

Teva submitted that the advertisement headline 'The moment I picked it up I knew how to use it' and the strapline 'Intuitive design' were referenced to Plusa *et al* and Rychlik *et al* which clearly supported the intuitive nature of the Spiromax device and the ability to handle the device without any instruction.

Teva recognised that some patients had difficulty in using inhaled medication and therefore, albeit having supporting data on the intuitive nature of the Spiromax device, it still recommended that health professionals referred patients to the patient information leaflet.

Teva submitted that although it could not comment on the complainant's perception, it had been fair and balanced in the promotion of DuoResp Spiromax; it had recommended health professionals refer patients to the patient information leaflet and accurately referred to published data. Teva therefore, refuted the allegation that the advertisement in question was inconsistent with the reality of clinical usage and such data referred to.

PANEL RULING

The Panel noted that the headline claim 'The moment I picked it up I knew how to use it' and the strapline 'Intuitive design' were both referenced to Plusa *et al* and Rychlik *et al*. The Panel noted, however, that Rychlik *et al* was a presentation on incremental innovation delivered at a world respiratory conference in May 2014. The presentation consisted largely of a preview of Plusa *et al*. Thus, although two references had been cited in support of the claims, they both only referred to one set of data ie that from Plusa *et al*. The Panel noted that Plusa *et al* was a qualitative market research study in which asthma/COPD patients and health professionals were interviewed to obtain opinions on DuoResp Spiromax and compare it with a currently used Turbohaler or Accuhaler. The main goal of the study was to answer two questions: How likely health professionals and patients were to use and even switch to the Spiromax and which benefits/features of Spiromax should be communicated to maximize its potential in the market?

The study was in two parts which appeared to be wholly separate. One part of the study involved interviews with 181 health professionals experienced in the treatment of asthma and COPD across 9 European countries (France, Germany, Italy, Spain, UK, Netherlands, Belgium, Denmark and Sweden). The other part of the study involved 261 interviews with 80 asthma/COPD patients from the same countries except for Denmark where there were no patients. The patients must not have used Easi-Breathe before and must use a Turbohaler or an Accuhaler. It was not explained in the study when or why the patients were interviewed on more than one occasion. The Panel queried whether 261 was the sum total of interviews with 80 patients and 181 health professionals. The study stated that respondents (health professionals and patients) evaluated the DuoResp Spiromax after they had seen a demonstration video, tried an empty device and in the case of health professionals had additionally read the product profile. In that regard the Panel disagreed with Teva's submission that the study clearly supported the intuitive nature of the Spiromax device and the ability to handle the device without any instruction. Further the Panel noted that the study concluded that training could not be completely eliminated '…but the easy training use of the inhaler is a step in the right direction in the treatment of patients with asthma and COPD'.

The study reported that the new device was considered to be user friendly by 80% of patients; 75% considered the device to be intuitive or very intuitive mainly due to ease of use. The study also reported that 76% of patients handled the new device correctly without receiving any instruction. 80% of patients found Spiromax to be more intuitive than their currently used device. Plusa *et al* stated that the majority of health professionals (78%) regarded the new device as user friendly and that it was considered to be intuitive or very intuitive by 87%; 87% also handled it correctly without receiving any instruction. Comparison with the currently used device showed that 89% of health professionals found the new device to be more intuitive than the currently used device and 78% considered it to be easier to teach to their patients than the currently used device.

The Panel noted the authors' findings above and queried statements such as '76% of patients handled [Spiromax] correctly without receiving any instruction' given that they had all seen a demonstration video. The Panel considered that some important detail was missing from the published report as in its absence readers could not fully understand the study methodology nor the importance of its outcomes. Nonetheless, the Panel noted that whilst the majority of patients and health professionals were positive about Spiromax, there were still 25% of patients and 13% of health professionals who did not find it intuitive or very intuitive.

The Panel noted that the advertisement portrayed a patient's perspective of Spiromax and that Plusa *et al* had interviewed only 80 patients vs 181 health professionals. The Panel considered that readers would assume from the advertisement that all patients would immediately know how to use DuoResp Spiromax from the moment it was dispensed to them and that patients would not need to be counselled in the correct use of the device. This was not so and in that regard the Panel was very concerned about the possible risk that some asthma or COPD patients would lose control of their symptoms for want of adequate training. The advertisement stated in small, grey font, below the prescribing information, that instructions for use should be followed as per the patient information leaflet. In the Panel's view this statement was easily missed. The Panel noted that Teva acknowledged that some patients had difficulty in using inhalers and it recommended that health professionals refer patients to the patient information leaflet. The Panel considered that a statement referring readers to the patient information leaflet for instructions on how to use the Spiromax device contradicted the headline claim 'The moment I picked it up I knew how to use it'. Further, that patients were required to follow instructions as per the patient information leaflet meant that the device was not unequivocally intuitive as implied. The Panel considered that in the circumstances, the claims 'The moment I picked it up I knew how to use it' and 'Intuitive design' in the advertisement were misleading as to the ease of use of Spiromax and ruled a breach of Clause 7.2. The Panel considered that high standards had not been maintained and ruled a breach of Clause 9.1.

Complaint received **17 December 2015**

Case completed **3 February 2016**