CASE AUTH/2710/5/14

GENERAL PRACTITIONER v MEDA

Promotion of Dymista

A general practitioner alleged that an advertisement for Dymista (fluticasone/azelastine nasal spray), issued by Meda Pharmaceuticals and published in GP, 28 April 2014, was misleading.

The complainant noted that the advertisement featured the prominent claim that Dymista 'can be considered the drug of choice for the treatment of AR [allergic rhinitis]'. However, in the complainant's view, as Dymista was indicated for the relief of AR symptoms if monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient it was a second- or third-line treatment and not the drug of choice. The complainant alleged that the advertisement was unacceptable.

The detailed response from Meda is given below.

The Panel noted that the dark blue artwork and text of advertisement were prominent against a clear white background. The advertisement was headed with the Dymista product name and non-proprietary names. Below this was a depiction of the nasal spray being activated and this was followed by the claim that Dymista 'can be considered the drug of choice for the treatment of AR'; 'drug of choice' appeared in bolder and bigger font that the rest of the claim. The claim was referenced to Leung *et al* (2012) and was a quotation from that publication. The indication for Dymista was stated to the lower right of the claim in smaller black font. The prescribing information appeared along the lower edge of the advertisement.

The Panel noted Meda's submission that the claim was based on a published paper and that all the claims were based on material pre-vetted by the MHRA.

The Panel noted that Leung *et al* (2012) was in fact 'The Editors' Choice' of papers from a clinical journal. The editors had commented on Carr *et al* (2012) which was the source paper. In their review Leung *et al* stated that [Dymista] could be considered the drug of choice for the treatment of AR.

The Panel noted that although the claim at issue was an accurate quotation from Leung *et al*, (and Carr *et al*) the Code required that any quotation used in promotional material must comply with the Code. Further, the Code stated that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.

In the Panel's view, the claim that Dymista was 'the drug of choice' implied that no other medicine could, or should, be chosen as first-line therapy. Dymista was, however, a second-line therapy which should only be used when monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient. The Panel noted that although the indication for Dymista appeared in smaller print to the lower right of the claim, it did not negate the impression otherwise given by the claim. The Panel considered that the claim was all-embracing by virtue of the use of 'the'. A breach of the Code was ruled. The Panel considered that the claim gave a misleading impression regarding Dymista's place in the treatment of AR which could not be substantiated. Breaches of the Code were ruled.

A general practitioner, complained about a Dymista (fluticasone propionate/azelastine hydrochloride) advertisement (ref UK/DYM/13/0022(2)a) issued by Meda Pharmaceuticals Ltd and published in GP, 28 April 2014. Dymista was a nasal spray indicated for relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis (AR) if monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient.

COMPLAINT

The complainant noted that the advertisement featured the prominent claim that Dymista 'can be considered the drug of choice for the treatment of AR'. However, Dymista was indicated for the relief of symptoms of moderate to severe seasonal and perennial AR if monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient. In the complainant's view, Dymista was, therefore, a second- or third-line treatment and not the drug of choice and although the claim was in quotation marks it appeared to be designed to deliberately mislead. The complainant alleged that this was unacceptable advertising.

When writing to Meda, the Authority asked it to respond in relation to Clauses 7.2, 7.4, and 7.10 of the Code.

RESPONSE

Meda submitted that all Dymista promotional materials were pre-vetted by the Medicines and Healthcare Products Regulatory Agency (MHRA) at launch and Meda was required to include the full indication wherever the quotation was used in order to qualify its positioning and full indication. Meda disputed that the advertisement and specifically the quotation 'can be considered the drug of choice' was misleading or unsubstantiated in breach of Clauses 7.2, 7.4 and 7.10.

In response to a request from the case preparation manager for further comment, Meda submitted that the advertisement did not contravene Clause 7.2 as it clearly listed the Journal of Allergy and Clinical

Immunology, volume 129, number 5 as a reference and stated the full indication.

Meda submitted that the claims in the advertisement were substantiated; they were based on the results of the research referenced in the advertisement and Meda had prominently stated the full indication.

Meda disagreed that the advertisement was not in line with Clause 7.10; no exaggerated or all-embracing claims had been made. Meda submitted that all claims were based on MHRA pre-vetted material and the above mentioned reference was listed.

PANEL RULING

The Panel noted that the dark blue artwork and text of advertisement were prominent against a clear white background. The advertisement was headed with the Dymista product name and non-proprietary names. Below this was a depiction of the nasal spray being activated and this was followed by the claim that Dymista 'can be considered the drug of choice for the treatment of AR'; 'drug of choice' appeared in bolder and bigger font that the rest of the claim. The claim was referenced to Leung (2012) and was a quotation from that publication. The indication for Dymista was stated to the lower right of the claim in smaller black font. The prescribing information appeared along the lower edge of the advertisement.

The Panel noted Meda's submission that the claim was based on a published paper and that all the claims were based on material pre-vetted by the MHRA.

The Panel noted that Leung *et al* (2012) was in fact 'The Editors' Choice' of papers from the May 2012 edition of the Journal of Allergy and Clinical Immunology. The editors had commented on Carr *et al* (2012) which was the source paper. In their review Leung *et al* stated that [Dymista] could be considered the drug of choice for the treatment of AR. The source paper ie Carr *et al* compared the efficacy of Dymista with two first-line therapies ie intranasal fluticasone propionate and intranasal azelastine in 3,398 patients with moderate to severe seasonal AR in three multicentre, randomized, double-blind, placebo- and active-controlled, 14-day, parallel-group trials. Carr *et al* reported that Dymista was significantly more effective than intranasal fluticasone or azelastine and that their results showed that it could be considered the drug of choice for the treatment of AR.

The Panel noted that although the claim at issue was an accurate quotation from Leung *et al*, (and Carr *et al*) Clause 10.2 of Code required that any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. Further, the supplementary information to Clause 7 stated that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.

In the Panel's view, the claim that Dymista was 'the drug of choice' implied that no other medicine could, or should, be chosen as first-line therapy. Dymista was, however, a second-line therapy which should only be used when monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient. The Panel noted that although the indication for Dymista appeared in smaller print to the lower right of the claim, it did not negate the impression otherwise given by the claim. The Panel considered that the claim was all-embracing by virtue of the use of 'the'. A breach of Clause 7.10 was ruled. The Panel considered that the claim gave a misleading impression regarding Dymista's place in the treatment of AR which could not be substantiated. Breaches of Clauses 7.2 and 7.4 were ruled.

Complaint received **1 May 2014**

Case completed **30 June 2014**