CASE AUTH/2430/8/11

GLAXOSMITHKLINE CONSUMER HEALTHCARE v JOHNSON & JOHNSON

Promotion of Nicorette QuickMist

GlaxoSmithKline Consumer Healthcare complained about a mailing for Nicorette QuickMist (nicotine mouthspray) distributed to prescribers by Johnson & Johnson. Nicorette QuickMist was indicated for the relief and/or prevention of craving and nicotine withdrawal symptoms associated with tobacco dependence.

The detailed responses from Johnson & Johnson are given below.

The claim '60 second craving relief' was followed by 'Breakthrough cravings can jeopardise a quit attempt'. GlaxoSmithKline Consumer Healthcare explained that cravings were categorised as withdrawal, background cravings or acute, breakthrough cravings. GlaxoSmithKline Consumer Healthcare alleged that juxtaposing the two claims implied that Nicorette QuickMist would relieve breakthrough cravings in 60 seconds. Although Nicorette QuickMist was licensed to relieve cravings, to presumably include breakthrough cravings, the claim that it would do so in 60 seconds was misleading as the supporting study measured the effect on background cravings, not breakthrough cravings.

The Panel noted that the headline claim for 60 second craving relief was repeated in the first bullet point. The second bullet point read 'Breakthrough cravings can jeopardise a quit attempt'. In the Panel's view prescribers were likely to link the two claims and assume that the cravings relieved in 60 seconds in the first bullet point were breakthrough cravings as referred to in the second.

The Panel noted Johnson & Johnson's submission that there was no universal terminology to describe nicotine cravings. The mailing at issue was distributed to prescribers who, in the Panel's view, might have different understandings of the terms 'breakthrough', 'background', 'provoked', 'cue-induced' and 'situational' when used to describe nicotine cravings. The Panel further noted Johnson & Johnson's submission that breakthrough cravings were not directly linked to the 60 second claim. Given the juxtaposing of the two claims, however, and the lack of a common understanding of terms to describe cravings, the Panel considered that the mailing was misleading as alleged. A breach of the Code was ruled.

GlaxoSmithKline Consumer Healthcare alleged that the claim 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette' was in breach of the Code. The main message of the mailing was of 60 second craving relief based on a study that used a dose of 2 sprays. The cost claim was clearly based on a dose of 1 spray per cigarette, but as the main thrust of the mailing was about 60 second craving relief which was based on a dose of 2 sprays, GlaxoSmithKline Consumer Healthcare alleged that the cost claim was misleading. Further, the footnote declared that the cost was based on the duo pack, yet the large visual on the mailing was of the single pack.

The Panel noted that the '60 second craving relief' claim was based upon the results of a study in which patients had used two sprays of Nicorette QuickMist instead of smoking a cigarette. The two spray dosing regimen for this study was not made clear in the mailing. The cost claim at issue, however, was based on the use of one spray in place of a cigarette. Further, the mailing featured a photograph of a one dispenser pack (£11.48) but, according to a footnote, the cost claim was based on the duo dispenser pack (£9.25 per dispenser). The Panel thus considered that the claim 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette' was misleading as alleged. A breach of the Code was ruled.

GlaxoSmithKline Consumer Healthcare complained about a mailing (ref 06458) for Nicorette QuickMist (nicotine mouthspray) distributed to prescribers by Johnson & Johnson Limited. Nicorette QuickMist was indicated for the relief and/or prevention of craving and nicotine withdrawal symptoms associated with tobacco dependence.

1 Claims '60 second craving relief' followed by 'Breakthrough cravings can jeopardise a quit attempt'

The 60 second claim was referenced to 'Data on file 002' and the claim about breakthrough cravings was referenced to Shiffman *et al* (1996).

COMPLAINT

GlaxoSmithKline Consumer Healthcare explained that cravings to smoke were categorised as withdrawal, background cravings or acute, breakthrough cravings. The latter were also referred

to as situational, cue-induced or provoked cravings. Background cravings were thought to result from the physical withdrawal of nicotine from the body and the latter resulted from provocation by cues associated with smoking. Johnson & Johnson knew about these differences and highlighted them in an advertisement (ref 06841, March 2011) which stated 'Background nicotine cravings plus situational cravings are significant factors …'. Johnson & Johnson also recognised in the advertisement that it was these intense, cue-induced cravings that could lead to immediate lapse.

The headline of the mailing at issue referred to 60 second craving relief and that the product 'acts fast'. The first bullet point reiterated this and claimed that 'Nicorette QuickMist, in an open label study, was clinically proven to relieve cravings in just 60 seconds'. The second bullet point stated that 'Breakthrough cravings can jeopardise a quit attempt'. Although this claim was true, juxtaposing the two claims implied that Nicorette QuickMist would relieve these breakthrough cravings in just 60 seconds. Although Nicorette QuickMist was licensed to relieve cravings, to presumably include breakthrough cravings, it was the claim that it would do so in 60 seconds that was in dispute as the study used to support this claim measured the effect on background cravings, not breakthrough cravings. The methods reported to evaluate the effect of Nicorette QuickMist on cravings showed that subjects were deprived of nicotine for 5 hours (after self-reported overnight abstinence) and were not given any cues to trigger a breakthrough craving before they were given the study medicine. Thus the study measured the effect of the interventions on background craving, not of breakthrough/cue-provoked craving. In inter-company correspondence, Johnson & Johnson claimed that the study was similar to Durcan *et al* (2004) which specifically looked at cue-provoked craving but this was not so. Participants in Durcan *et al* had to be abstinent for a number of hours and were then asked to unwrap a pack of their usual cigarettes; remove, light and hold the cigarette (without placing it in the mouth) for one minute. After extinguishing the cigarette, post-provocation craving was assessed and then the treatments were administered and the effects on this craving measured. It was this cue-provoked craving that was then relieved by using NiQuitin 4mg lozenge. This was substantially different from the methodology used in the Nicorette QuickMist study which only involved abstinence from smoking for a number of hours, and did not involve any further triggering of a cue-provoked/breakthrough craving.

The direct implication of juxtaposing the claims that Nicorette QuickMist relieved cravings in just 60 seconds and that breakthrough cravings could jeopardise a quit attempt was that Nicorette QuickMist had been shown to relieve breakthrough cravings in 60 seconds. This was not so. GlaxoSmithKline alleged that the mailing was thus misleading in breach of Clause 7.2.

RESPONSE

Johnson & Johnson noted that the mailing included a headline to show the fast-acting nature of Nicorette QuickMist; this was followed by a number of bullet points which outlined the benefits and attributes of the medicine itself. The bullet point at issue, 'Breakthrough cravings can jeopardise a quit attempt' was one of a number of bullet points in the mailing.

Johnson & Johnson noted the complainant's concern regarding the differentiation between background and breakthrough cravings and that juxtaposing the two claims 'Nicorette QuickMist, in an open label study, was clinically proven to relieve cravings in just 60 seconds' and 'Breakthrough cravings can jeopardise a quit attempt' implied that Nicorette QuickMist had been shown to relieve breakthrough cravings in 60 seconds.

Johnson & Johnson noted that GlaxoSmithKline Consumer Healthcare categorised cravings into two types; background and breakthrough. However, Johnson & Johnson submitted that the situation was more complex than that and there was no universal or standard terminology to describe nicotine cravings. All cravings were part of the nicotine withdrawal syndrome and could be referred to in terms of how they were induced, their severity, duration and whether they occurred despite a background level of nicotine.

Johnson & Johnson submitted that 'breakthrough cravings' was often used to describe cravings which occurred despite a level of background nicotine already being present. GlaxoSmithKline Consumer Healthcare used this term itself at recent symposia. It was not necessarily the case however, that breakthrough cravings were the same as cue-induced or situational cravings, as it might not be a cue, situation or provocation which resulted in the craving.

The Nicorette QuickMist summary of product characteristics (SPC) stated that the product was indicated to relieve and/or prevent cravings and nicotine withdrawal symptoms associated with tobacco dependence. As such, the SPC did not specify or categorise the types of cravings that Nicorette QuickMist should be used to relieve. Therefore, it was entirely reasonable to suggest that Nicorette QuickMist could be used to relieve any type of cravings that a smoker might experience.

The Nicorette QuickMist craving study (Hansson *et al* 2011) was a well designed study which used a well established model to provoke cravings in the study group. The study involved provoking cravings after 5 hours of witnessed abstinence.

Johnson & Johnson submitted that the concept of using provocation as a model for cravings was widely used and there were a number of approaches to provoking cravings in a study of this type. Both the Nicorette QuickMist craving study

and Durcan *et al* used a model of provoked cravings. Johnson & Johnson submitted that regardless of how provocation was accomplished, provoking cravings and the concept of using provoked cravings in a clinical study as a model for cravings was widely accepted.

The advertisement referred to by GlaxoSmithKline Consumer Healthcare (ref 06841), was an advertorial which separated out cravings. However, the term 'breakthrough cravings' had not been used. Any type of nicotine craving could lead to lapse or indeed relapse, regardless of the cause of the craving.

In summary, Johnson & Johnson stated that the claim 'Breakthrough cravings can jeopardise a quit attempt' was one bullet point within the mailing and was not directly linked to the '60 second craving relief' claim which appeared in the headline. The company believed that the use of 'breakthrough cravings' in the context of this mailing was justified and was not misleading, and disagreed with GlaxoSmithKline Consumer Healthcare that the term 'breakthrough cravings' only referred to 'acute, cue-provoked cravings'. Johnson & Johnson denied a breach of Clause 7.2.

In response to a request for further information, Johnson & Johnson submitted that Hansson *et al* was the published outcome of 'Data on file 002' which was cited in the mailing itself. Although the company was aware of the study and the key outcomes, it did not see the final Hansson *et al* publication until after it was published on 16 February 2011 ie a week after the mailing was certified.

PANEL RULING

The Panel noted that the headline claim for 60 second craving relief was repeated in the first bullet point, 'Nicorette QuickMist, in an open label study, was clinically proven to relieve cravings in just 60 seconds'. The headline claim and first bullet point were referenced to 'Data on file 002', a study in which smokers were given two sprays of Nicorette QuickMist, a 2mg NiQuitin Lozenge or a 4mg NiQuitin Lozenge after 5 hours of witnessed abstinence. Urges to smoke were scored on a 100mm visual analogue scale in the first minute post-administration. The mean differences between mouth spray and either strength of the lozenges were statistically significant ($p<0.001$).

The Panel noted that the '60 second' bullet point was followed by the second bullet point which read 'Breakthrough cravings can jeopardise a quit attempt'. In the Panel's view prescribers were likely to link the two claims and assume that the cravings relieved in 60 seconds in the first bullet point were breakthrough cravings as referred to in the second.

The Panel noted Johnson & Johnson's submission that there was no universal or standard terminology to describe nicotine cravings. The mailing at issue was distributed to prescribers who, in the Panel's view, might have different understandings of the terms 'breakthrough', 'background', 'provoked', 'cue-induced' and 'situational' when used to describe nicotine cravings. The Panel further noted Johnson & Johnson's submission that breakthrough cravings were not directly linked to the '60 second craving relief claim'. Given the juxtaposing of the two claims, however, and the lack of a common understanding of terms to describe cravings, the Panel considered that the mailing was misleading as alleged. A breach of Clause 7.2 was ruled.

2 Claim 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette**

****Based on the NHS cost of the duo pack'**

COMPLAINT

GlaxoSmithKline Consumer Healthcare stated that the main message of the mailing was the 60 second craving relief claim. It appeared as the headline, the first bullet point and as one of the key take-home points. The study that generated the 60 second relief claim used a dose of 2 sprays, but this was not stated in the mailing. The cost claim was clearly based on a dosing of 1 spray per cigarette, but as the main thrust of the mailer was about 60 second craving relief and this was based on a dose of 2 sprays, GlaxoSmithKline Consumer Healthcare alleged that this was misleading. Similarly, the footnote declared the cost was based on using the duo pack, yet the large visual on the mailer was of a single pack.

In inter-company correspondence Johnson & Johnson stated that it had been careful to include all relevant information in the bullet point 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette**', '**Based on the NHS cost of the duo pack'.

GlaxoSmithKline Consumer Healthcare stated that Johnson & Johnson's defence of the cost claim could not be seen in isolation from the 60 second claim as it was part of the same mailing, with the 60 second claim being the most prominent message. Readers would assume that the cost was thus based on the same dosing schedule unless stated otherwise. GlaxoSmithKline Consumer Healthcare therefore alleged that the claim was misleading in breach of Clause 7.2.

RESPONSE

Johnson & Johnson stated that it deliberately sought to ensure that the claim included all relevant information, both to avoid confusion and ensure that this was made absolutely clear to prescribers. The claim 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette**' included some

additional information, '**Based on the NHS cost of the duo pack' to provide prescribers with all the relevant information, to allow them to make a fully informed decision about the product.

Johnson & Johnson noted that an additional bullet had also been included within the mailer to highlight the dosing schedule of Nicorette QuickMist. The bullet 'Flexible dosing regimen: 1 or 2 sprays to be used when cigarettes would have normally been smoked or if cravings emerge' made it clear to the reader that the dosing could be one or two sprays. Furthermore, the dosing of the product and the prices for both the 1 and 2 dispenser packs were included within the prescribing information.

Johnson & Johnson considered that it was clear within the body of the claim that the cost was based on an average 20 per day smoker, using one spray in place of their normal cigarette. The wording could not have been clearer and Johnson & Johnson failed to understand how the claim could mislead. The company denied a breach of Clause 7.2.

PANEL RULING

The Panel noted that the claim for '60 second craving relief' which featured in the headlines on the front and back of the mailing and in the first bullet point on the front page, was based upon the results of a study in which patients had used two sprays of Nicorette QuickMist instead of smoking a cigarette. The two spray dosing regimen for this study was not made clear in the mailing. The cost claim at issue, however, was based on the use of one spray in place of smoking a cigarette.

The mailing featured the photograph of a one dispenser pack which had an NHS cost of £11.48; the cost claim at issue was based on the cost of the duo dispenser pack which had an NHS cost of £18.50 ie £9.25 per dispenser.

The Panel noted that if the cost claim had been based on the use of a two spray dose to replace each cigarette, from a one dispenser pack, the daily cost of treatment would be £3.06.

The Panel thus considered that the claim 'Cost of treatment: £1.23 per day for an average 20 per day smoker, using one spray in place of their normal cigarette' was misleading. Although a footnote read 'Based on the NHS cost of the duo pack' the Panel noted that claims must be capable of standing alone and in general should not be qualified by the use of footnotes. In the Panel's view, readers would assume that the daily cost of Nicorette QuickMist treatment was based upon the use of the one dispenser pack illustrated.

Given the clinical claims in the mailing and the photograph of the one dispenser pack, the Panel considered that the claim at issue was misleading as alleged. A breach of Clause 7.2 was ruled.

Complaint received **8 August 2011**

Case completed **15 September 2011**