CASE AUTH/2936/2/17 NO BREACH OF THE CODE

HEALTH PROFESSIONAL CONSULTANT TO A PHARMACEUTICAL COMPANY v JOHNSON & JOHNSON

Online Nicorette advertisement

A complaint was received in a private capacity from a health professional who stated that he/ she worked as a consultant to a pharmaceutical company.

The complaint concerned an online advertisement for Nicorette (nicotine) issued by Johnson & Johnson and was published in Pulse magazine February.

The advertisement was headed 'How do you empower them to quit for good?' followed by the claims 'Combination NRT [nicotine replacement therapy] is 43% more effective than patch alone. This was followed by a photograph of one Nicorette patch pack with a Nicorette Quick mist mouth spray. Under which was the claim 'nothing beats Nicorette dual support'. The advertisement included a photograph of a man on the beach throwing and catching a young child in the air.

The complainant alleged that the child in the advertisement was an inappropriate age. The complainant was also concerned that the claim '...43% more effective than patch alone' gave no absolute data. Given there was no absolute values, the heading 'how do you empower them to quit for good' could be taken to mean this always worked which was highly unlikely.

The detailed response from Johnson & Johnson is given below.

The Panel considered that the claim 'combination NRT is 43% more effective than patch alone' was a comparison of efficacy of the two. There was no mention of relative risk as such. The odds ratio was provided in small type above the details of reference 1 in the bottom left hand part of the advertisement.

The Panel did not accept that the heading 'How do you empower them to quit for good?' and the content of the advertisement including the claim 'Nothing beats Nicorette dual support' implied that Nicorette dual support always worked as alleged. The Panel considered that the difficulty smokers had in quitting would be well understood by the audience and that success would be likely to be due to a number of factors. The Panel did not consider that the advertisement was misleading and ruled no breach of the Code.

The Panel did not consider that the inclusion of a photograph of an infant in the advertisement for NRT was such that health professionals would consider that the product should be prescribed for that infant. The Panel noted that the photograph also included an adult for whom the product could be used. It was not unreasonable to use the

photograph, particularly given the impact an adult's smoking could have on children. The health of children appeared to be a reason for adults to try to stop smoking. The Panel thus ruled no breach of the Code in this regard.

The complainant stated at the time of submitting the complaint that he/she was a health professional who worked as a consultant to Novartis. It had previously been decided, following consideration by the then Code of Practice Committee and the ABPI Board of Management, that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for intercompany complaints, the employing company would be named in the report. The complainant would be advised that this would happen and be given an opportunity to withdraw the complaint.

This issue came to the fore many years ago when an employee of a pharmaceutical research company complained in a private capacity about a journal advertisement issued by GlaxoSmithKline UK Ltd (Case AUTH/1498/7/03). In Case AUTH/1498/7/03 it was decided that the pharmaceutical research company would be named in the case report whilst making it clear that the complaint was made in a private capacity.

The case preparation manager decided that the principles set out above would apply to consultants. Consultancy status should not be used to circumvent the normal rules for inter-company complaints.

The complainant was advised that if he/she wished to proceed with the complaint in a private capacity Novartis would be named in the case report; and the respondent company would be informed of his/her professional status and the connection with pharmaceutical companies. The complainant so agreed.

Novartis stated that it had no knowledge of, or involvement in, the complaint and did not know the complainant's identity.

The complaint concerned an online advertisement for Nicorette (nicotine) issued by Johnson & Johnson Limited and was published in Pulse magazine February (ref UK/NI/16-7093(1).

The advertisement was headed 'How do you empower them to quit for good?' followed by the claims 'Combination NRT [nicotine replacement therapy] is 43% more effective than patch alone (referenced to Cahill *et al* Cochrane summaries 2013). This was followed by a photograph of one Nicorette patch pack with a Nicorette Quick mist mouth spray.

Under which was the claim 'nothing beats Nicorette dual support' which was also referenced to Cahill et al. The advertisement included a photograph of a man on the beach throwing and catching a young child in the air.

COMPLAINT

The complainant alleged that the child in the advertisement was an inappropriate age. The complainant was also concerned that the claim '...43% more effective than patch alone' gave no absolute data. Given there was no absolute values, the heading 'how do you empower them to quit for good' could be taken to mean this always worked which was highly unlikely.

In writing to Johnson & Johnson attention was drawn to the requirements of Clauses 7.2 and 9.1.

RESPONSE

6 Combination NRT claim

Johnson & Johnson submitted that the odds ratio related to the claim 'Combination NRT is 43% more effective than patch alone' ('Odds ratio 1.43 (95%Cl 1.08 to 1.91)') was contained within the advertisement, above the reference list. As the claim was not referring to relative risk there was no requirement to provide the absolute risk and the 2013 Cochrane review reference contained no information regarding absolute risk. Johnson & Johnson disagreed with the complainant that the call out 'How do you empower them to quit for good?' could be interpreted as a guarantee of effect or that using odds ratio without absolute values breached Clauses 7.2 or 9.1. However, it acknowledged that it could be difficult to communicate odds ratio values such that a healthcare professional could interpret the clinical impact. Johnson & Johnson was, therefore, reviewing how best to address this issue in order to increase clarity, and consequently would amend this claim in future materials.

7 Imagery of child

Johnson & Johnson submitted that the picture of a man with his child on the beach was a lifestyle image and reflected the motivations of some people who might ask health professional's for help in quitting smoking. It showed the lifestyle benefits of quitting for good and being smoke free, ie the freedom and health to lead a happy and active family life.

The Office for National Statistics report on smoking related behaviour and attitudes 2008/9 reported that 22% of smokers who wanted to quit said they wanted to give up because of the effect of smoking on children, and 16% said it was because of family pressure. Children were especially vulnerable to second hand smoke, resulting in 300,000 GP visits and 9,500 hospital admissions every year. A healthcare professional would be likely to see adult smokers in their day-to-day practice who were citing their children as a reason for wanting to quit smoking. Healthcare professionals might also use the impact of smoking on children's health as

a motivational tool to initiate a discussion around quitting smoking with parents. Therefore, Johnson & Johnson submitted that the imagery of a parent with a child was appropriate in this context. The use of the word "them" in this context would be interpreted by a prescribing healthcare professional as meaning their patients who were smokers, and would not be interpreted as referring to the man and the infant pictured.

Johnson & Johnson did not accept that any healthcare professional reading the advertisement would think that the imagery implied that Nicorette was suitable for infants. Smoking was not prevalent amongst toddlers, and it was highly unlikely that a GP would be helping a child of this age to make a successful guit attempt or would consider the advertisement in the context of a child of this age. Consequently, it did not believe that any healthcare professional would interpret the advertisement as implying that Nicorette could be used in this age group or that the advertisement breached Clauses 7.2 or 9.1. Nicorette was indicated to aid adult or adolescent smokers from the age of 12 wishing to quit and should any healthcare professional wish to confirm the licensed age indication, this was clear on the prescribing information which was positioned immediately below the image. This advertisement was not in breach of the Code in this regard.

PANEL RULING

The Panel examined the advertisement and considered that it used the example of combination NRT as one of a number of ways of empowering smokers to quit. The photograph of an adult and child was, in the Panel's view, another example of something that might empower smokers to quit for good.

The Panel noted that the supplementary information to Clause 7.2 stated that referring only to relative risk, especially with regard to risk reduction could make a medicine appear more effective than it actually was. In order to assess the clinical impact of an outcome, the reader also needed to know the absolute risk involved. In that regard relative risk should never be referred to without also referring to the absolute risk. Absolute risk could be referred to in isolation. The claim 'combination NRT is 43% more effective than patch alone' was a comparison of efficacy of the two. There was no mention of relative risk as such. The odds ratio was provided in small type above the details of reference 1 in the bottom left hand part of the advertisement.

The Panel did not accept that the heading 'How do you empower them to quit for good?' and the content of the advertisement including the claim 'Nothing beats Nicorette dual support' implied that Nicorette dual support always worked as alleged. The Panel considered that the difficulty smokers had in quitting would be well understood by the audience and that success would be likely to be due to a number of factors. The Panel did not consider that the advertisement was misleading and ruled no breach of Clause 7.2.

The Panel noted that the supplementary information to Clause 7.8 of the Code stated that care must be taken to ensure that artwork did not mislead as to the nature of a medicine or any claim or comparison. Depictions of children should not be used in relation to products not authorized for use in children in any way which might encourage such use.

The Panel did not consider that the inclusion of a photograph of an infant in the advertisement for NRT was such that health professionals would consider that the product should be prescribed for that infant. The Panel noted that the photograph also included

an adult for whom the product could be used. It was not unreasonable to use the photograph, particularly given the impact an adult's smoking could have on children. The health of children appeared to be a reason for adults to try to stop smoking. The Panel thus ruled no breach of Clauses 7.2 and 9.1 of the Code in this regard.

Complaint received 15 February 2017

Case completed 27 April 2017