

CASE AUTH/2067/11/07

JOHNSON & JOHNSON CONSUMER SERVICES EAME v PFIZER

Smoking cessation campaign

Johnson & Johnson Consumer Services Eame alleged that Pfizer's 'Serious Quitters' smoking cessation campaign constituted the indirect promotion of Champix (varenicline), a prescription only medicine, to the public. The use of expressions such as 'new ways for you to quit' in conjunction with the suggestion to '... visit your local NHS stop smoking service or GP...' clearly told the patient that a new treatment for smoking cessation was available via a smoking cessation service or GP. Johnson & Johnson noted that television and radio advertisements placed an audible emphasis placed on the word 'new'. Champix, launched in December 2006, was the only treatment that could currently be considered as new. Johnson & Johnson added that by advising readers to seek advice from a smoking cessation clinic or GP was likely to bias treatment towards prescribed treatments such as Champix; patients were not told that there were treatments available over the counter.

The Panel noted Pfizer defined a serious quitter as a smoker who was motivated to quit despite having failed at least once before. Further the campaign aimed to *inter alia* highlight the important role of the health professional in helping smokers to quit.

The Panel considered that Pfizer's campaign in recommending visiting the local stop smoking service or GP practice to find new ways to quit might imply that there was some new approach to assist stopping smoking. In each press advertisement the word 'new' was used three times; it was not clear that the word related to previously untried ways for the individual as submitted by Pfizer. In any event the potential quitter would paraphrase the statement and ask about new ways to quit which might lead to health professionals and smoking cessation advisers to only consider new treatments. The most recent treatment was Champix, a prescription only medicine. Support, advice and NRT would be available from community pharmacists (including those who were not smoking cessation advisers) and these were not mentioned despite Pfizer's submission that the campaign aimed to highlight the role of the health professional.

The campaign encouraged smokers to discuss treatment options with certain health professionals only. The materials would encourage smokers to ask about new treatments. The health professional was likely to associate the word 'new' only with Champix and thus prescribe that product. The Panel considered that in effect the material encouraged patients to ask for a specific prescription only medicine to be prescribed. A breach of the Code was ruled.

The Panel did not consider that the emphasis in the campaign on the word 'new' meant that the campaign constituted advertising of a prescription only medicine to the public. No breach of the Code was ruled.

Johnson & Johnson Consumer Services Eame Limited complained about the 'Serious Quitters' smoking cessation campaign by Pfizer Limited.

COMPLAINT

Johnson & Johnson stated that it did not have issue with Pfizer's campaign per se but it had specific concerns about the use of the expressions 'new ways for you to quit/new ways to help you quit smoking and stay quit' eg:

Television campaign [Channel 5, 1 October 2007]: 'Whatever your reason for wanting to quit smoking, visit your local NHS stop smoking service or GP practice about new ways for you to quit. The moment you ask could be the moment you stop.'

Radio campaign [Kiss FM, 8 October 2007]: 'Whatever your reason for quitting, visit your local stop smoking service or GP practice to find out about new ways for you to quit, The moment you ask could be the moment you stop.'

Press campaign [Daily Express, 30 July 2007]: '... ask your healthcare professional about new ways to help you quit smoking and stay quit.' The items signed off with the statement 'Serious Quitters seek new ways to quit'.

Johnson & Johnson noted that Clause 20.2 of the Code stated that: 'Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine'. The supplementary information to Clause 20.2 Information to the Public stated: 'A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine'. Disease awareness campaigns (DACs) were also covered in detail in the 'Disease Awareness Campaign Guidance – Medicines and Healthcare products Regulatory Agency (MHRA) Guidance Note Number 26'. This document was published in 2003 and was referenced in the supplementary information to Clause 20.2. The MHRA disease awareness guidance stated 'Campaigns which aim to stimulate demand by the public for a specific medicine or specific medicines are likely to be

considered promotional, falling within the scope of Title VIII of Directive 2001/83/EC'. The document went on to state: 'A DAC may make reference to the availability of treatment options (which may include medicines as part of a range of possible management options) but should not be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option. The emphasis of the material should be on the condition and its recognition rather than on the treatment options'. In addition, the guidance stated that DACs should include information that was, *inter alia*, 'balanced and fair'. In particular, it stated that 'Management options should be presented in a balanced and fair manner that does not unduly emphasize particular options or the need to seek treatment'.

In Johnson & Johnson's view, the reference to '... new ways for you to quit' in conjunction with the suggestion to '... visit your local NHS stop smoking service or GP practice...' clearly told the patient that a new treatment for smoking cessation was available via a smoking cessation service or GP. Johnson & Johnson also noted that there was an audible emphasis placed on the word 'new' on both the television and radio advertisements. The only treatment for smoking cessation that could currently be considered new was Pfizer's product Champix (varenicline) which was launched in December 2006.

Furthermore, the recommendation to seek advice on new treatment options from a smoking clinic or GP failed to cover the full range of established treatment options that were available widely through a number of types of retail outlets. In the case of nicotine replacement therapy (NRT), for instance, products were available as both GSL and pharmacy products. A recommendation to seek advice from a smoking cessation service or GP was likely to bias treatment towards prescribed treatments such as Champix.

In intercompany correspondence (provided), Pfizer had explained that its campaign was known as 'Serious Quitters'. It then defined a serious quitter as a smoker who was motivated to attempt to quit smoking but had failed in at least one previous attempt. Pfizer suggested that its campaign was targeted at these quitters in order to maintain their motivation and continue to encourage them to seek new ways to quit.

Johnson & Johnson argued that not only quitters who had already tried to stop smoking could be considered as serious quitters. Further, it was not clear in any of the components mentioned above that the campaign was targeted only at those smokers who had tried to quit before; the campaign would reach all smokers including those who had not previously tried to quit. Finally, even if this campaign communicated only to smokers who had previously tried to quit, this would not negate the overall impression that smokers were being asked to seek advice on a new form of treatment for nicotine addiction.

Pfizer argued that the phrase 'new ways for you to quit' sought to tell the reader that there were new ways

for them to quit because there would be methods that they had not tried. Johnson & Johnson did not accept that this was the overall impression given. If Pfizer had wished to provide an entirely balanced view of current therapy options it could have suggested in its campaign that smokers contact a health professional such as a GP, smoking cessation service or pharmacist for information.

Johnson & Johnson maintained that the overall impression of the Serious Quitters campaign was that there was a new option available from the smoker's GP or smoking cessation service. The only new option currently available was Pfizer's product Champix. Johnson & Johnson therefore believed that this campaign constituted the indirect promotion of a prescription only medicine to the general public in breach of Clauses 20.1 and 20.2.

RESPONSE

Pfizer stated that the campaign was developed in accordance to MHRA guidance on DACs and internal standard operating procedures and in consultation with an independent charity that aimed to help people stop smoking. The campaign was launched in collaboration with the charity.

Pfizer defined 'serious quitter' as a smoker who was motivated to attempt to quit but had failed in at least one previous attempt. There was of course no standard definition that accurately defined what made a 'serious quitter' and every company would have its own interpretation. Smoking was the leading preventable cause of death in the UK (over 114,000 deaths per year) and was a very difficult addiction to overcome. It was therefore important for those attempting to quit to maintain their motivation and to continue to seek new ways to do so. Most smokers tried to quit five to seven times before they finally succeeded and only 3-5% of unaided quitters remained smoke free after 6-12 months. This was why Pfizer's campaign aimed to reach all smokers in general and serious quitters in particular. Pfizer did not consider that its definition of 'serious quitters' nor the breadth of the campaign's reach breached the Code.

Pfizer did not believe that the wording implied or encouraged a prescription of Champix and it strongly believed that its campaign represented a fair and balanced view of all current treatments available to the serious and motivated quitter for the following reasons:

The phrase 'new ways for you to quit' sought to communicate that there were new ways for an individual smoker to quit because there would be methods that they had not yet tried. For example, a quitter might have used counselling support but not yet tried NRT. For that individual, NRT would be 'new'. New ways for a serious quitter could therefore mean counselling or behavioural therapy, or a variety of medicines including the many different forms of NRT, Zyban, Champix or other options. The majority of smokers tried to quit with no help at all, and this was the least effective method.

The options available to help a smoker quit were reinforced on the Serious Quitters website (www.seriousquitters.co.uk) which discussed the different types of medicines available (without naming specific products) as well as behavioural therapy in the 'know your options' section.

Pfizer had deliberately used the phrase 'new ways for you to quit' in the plural so that it pointed towards different options that were available to the serious quitter who was looking for ways that were new to him or her. This could be any psychological or pharmacological treatment that they had not tried before. Pfizer did not believe that this implied Champix.

The campaign aimed to: demonstrate the health benefits of quitting; highlight the important role of the health professional in helping smokers quit successfully and provide further support to smokers who were serious about quitting for good. The campaign had been prepared fully in accordance with MHRA guidance and therefore fell outside the scope of the prohibitions set out in Title VIII of Directive 2001/83/EC.

The relevant requirements set out in the guidance were:

- The Serious Quitters campaign focussed on promoting awareness and educating the public about health, disease and its management, as highlighted in Point 2 of the guidance.
- Point 3 of the guidance stated that DACs should highlight to the public where they could find appropriate sources of advice. The Serious Quitters campaign did this clearly by advising smokers to visit their NHS Stop Smoking Service or GP practice. This would normally result in discussions with pharmacists, nurses, stop smoking advisers or GPs, depending on the service.
- Point 4 of the guidance stated that campaigns which aimed to stimulate the public to demand a specific medicine or specific medicines were likely to be considered promotional. Serious Quitters was a public health awareness campaign which aimed to demonstrate the benefits of quitting, highlighted the important role of the health professional in helping smokers to quit successfully and provided further support for smokers who were serious about quitting for good. It did not promote any prescription or non-prescription medicines.
- Point 5 of the guidance stated that a DAC might refer to the availability of treatment options (which might include medicines as part of a range of possible management options) but not in such a way as to encourage an individual to ask a prescriber to prescribe a particular medicine. Serious Quitters communicated to the smoker that if they had not found a way to quit that worked for them, they should visit their NHS Stop Smoking Service or GP practice. Visiting NHS Stop Smoking Services might involve assessment by

specialist stop smoking advisers, pharmacists providing a smoking cessation service, nurse advisers or GPs. They played a key role in helping serious quitters to stop smoking, as well as helping them find psychological or pharmacological therapies (prescription or non-prescription) that they had not tried before.

- Point 6 of the guidance stated that DACs for diseases or conditions where there was only one, one leading, or few medicines, could potentially draw attention to the medicine (albeit indirectly), regardless of whether it was referred to or not. DACs in these circumstances required particular care. There were a wide range of treatment options (not one, one leading, or a few) available to the smoker who had tried before to quit but failed, such as various forms of NRT, behavioural modification therapies and prescription treatments. Therefore, the DAC did not draw attention to one particular treatment.
- Point 7 of the guidance stated that DACs should include information that was:

i) Accurate: The information provided by the Serious Quitters campaign regarding the health benefits of quitting was accurate and was not misleading. It was widely accepted that quitting smoking was one of the best ways to improve health.

ii) Up-to-date: The Serious Quitters campaign was launched in collaboration with a charity. Callers to Serious Quitters had the option of being transferred to a charity counsellor. The information obtained by the smoker from the charity counsellor would be the most up-to-date information available. Charity counsellors were experts in their field and provided accurate independent information to smokers who were trying to quit.

iii) Substantiable: Good advice from a health professional, together with support strategies and treatments, were crucial factors in helping smokers beat nicotine addiction. Studies showed that even brief advice from health professionals increased the likelihood of a smoker staying off cigarettes by up to 30%. This was why serious quitters were recommended to seek help from health professionals; without their advice and support, the chances of quitting were considerably lower.

iv) Comprehensive: The health aspects of smoking were well known to the public and the benefits of stopping smoking were highlighted in the campaign through statements such as 'your lungs will love you for it' and 'your tongue will love you for it'. The many health benefits from stopping smoking were reinforced on the Serious Quitters website in the 'know the reasons why' section.

v) Balanced and fair: It was well accepted that smoking was unhealthy and the campaign sought to communicate the health benefits to be gained from quitting. The campaign also communicated specifically with those smokers who had tried to quit before and

failed. Therefore it recommended that they visit their NHS stop smoking service or GP practice for support and advice on new ways for them to quit. It did not however promote any particular treatment.

vi) Readable and accessible: The language, design and formatting of the campaign materials had all been prepared so as to be clearly understood by the intended audience ie smokers who were serious about quitting.

vii) Source identified: There were no medical claims in the campaign materials that required supporting references to be displayed. The key principles which the campaign sought to communicate were supportable by clinical literature as outlined above. The provision of the campaign by Pfizer in collaboration with the charity was clearly documented.

- Point 8 of the guidance stated that the campaign must meet the DAC guidance on structure set out in the 'Advice for the patient' section. The campaign highlighted to the serious quitter that if they had tried to quit before and failed, they should visit their local NHS Stop Smoking Service or GP practice to find out about new ways for them to quit. Further support and advice was available via the website together with a freephone telephone number so that the serious quitter could call an expert smoking cessation counsellor from the charity.

It was for the reasons above that Pfizer believed that it had fully met the criteria set out in the MHRA guidance for DACs by highlighting the importance of stopping smoking and the availability of treatment options for the serious quitter. Pfizer believed that the Serious Quitters campaign complied in all respects with Title VIII of Directive 2001/83/EC (the 'Advertising Directive') as implemented in the UK by the Medicines (Advertising) Regulations 1994 and with the Code. Accordingly, Pfizer denied a breach of Clauses 20.1 and 20.2. In Pfizer's view its campaign provided high quality, non-promotional information and did not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

PANEL RULING

The Panel noted that it had to rule with regard to the Code and not whether or not the materials were in line with the MHRA guidance.

The Panel noted that in accordance with Clause 20.2 of the Code companies could make information about prescription only medicines available to the public either directly or indirectly. Such information must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Further, statements must not be made for the purpose

of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The supplementary information to Clause 20.2 stated that in relation to DACs that particular care must be taken where the company's product, although not named, was the only medicine relevant to the disease or symptoms in question. DACs or public health campaigns could be conducted with the purpose of encouraging the public to seek treatment while in no way promoting the use of a specific medicine.

The Panel noted Pfizer defined a serious quitter as a smoker who was motivated to attempt to quit but had failed in at least one previous attempt. Further the campaign aimed to *inter alia* highlight the important role of the health professional in helping smokers to quit.

The Panel considered that Pfizer's campaign in recommending readers to visit the local stop smoking service or GP practice to find new ways to quit might imply that there was some new approach to assist stopping smoking. In each press advertisement the word 'new' was used three times; it was not clear that the word related to previously untried ways for the individual as submitted by Pfizer. In any event the potential quitter would paraphrase the statement and ask about new ways to quit which might lead to health professionals and smoking cessation advisers to only consider new treatments. The most recent treatment was Pfizer's product Champix which was a prescription only medicine. Support, advice and NRT would be available from community pharmacists (including those who were not smoking cessation advisers) and these were not mentioned despite Pfizer's submission that the campaign aimed to highlight the role of the health professional.

The campaign encouraged smokers to discuss treatment options with certain health professionals only. The nature of the materials would encourage smokers to ask about new treatments. The health professional was likely to associate the word 'new' only with Champix and thus prescribe that product. Thus the Panel considered that in effect the material encouraged patients to ask for a specific prescription only medicine to be prescribed. A breach of Clause 20.2 was ruled.

The Panel did not consider that the emphasis in the campaign on the word 'new' meant that the campaign constituted advertising of a prescription only medicine to the public. No breach of Clause 20.1 was ruled.

Complaint received	21 November 2007
Case completed	31 January 2008