

# HEALTH PROFESSIONAL CONSULTANT TO A PHARMACEUTICAL COMPANY v JOHNSON & JOHNSON

## Promotion of Nicorette

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 principles set out above were applied to this complaint. 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.

The complaint concerned an online advertisement for Nicorette (nicotine) issued by Johnson & Johnson and was published in Pulse online. The advertisement was headed 'Nicorette Do Something Incredible' and referred to combination nicotine replacement therapy (NRT).

The complainant stated that there was no generic name on the advertisement nor any mention of where the prescribing information could be found (although if one clicked on the advertisement it was present). It appeared to be a 'teaser'.

The complainant explained that this style of advertisement might be acceptable for consumer advertising but not for healthcare professionals. The complainant was concerned that there were not adequate internal controls to ensure that it was not used in publications aimed at the wrong audience. The complainant stated that it was difficult to read the prescribing information as it had not been split into smaller columns and instead was in one large block.

The detailed response from Johnson & Johnson is given below.

As the non-proprietary name was included next to the brand name on the first banner the Panel ruled no breach of the Code.

The Panel noted that the first banner did not include a clear, prominent statement as to where the prescribing information could be found and therefore, ruled a breach of the Code.

The Panel did not consider the advertisement was a teaser. Information about Nicorette had been provided, including prescribing information, and thus the Panel ruled no breach of the Code.

The Panel considered that the advertisement was such that it was aimed at prescribers who would be the main audience of Pulse. The Panel therefore ruled no breach of the Code. It noted that the advertisement was for general sales list medicines and not prescription only medicines. The Code prohibited the promotion of prescription only medicines to the public. There could be no breach in that regard and the Panel ruled accordingly.

The Panel considered that although line length at around 140 characters was more than recommended this did not necessarily mean the prescribing information was not legible. The spacing between the lines and emboldening of the headings were helpful. The Panel decided that although on the limits of acceptability the prescribing information was legible and no breach of the Code was ruled.

A 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.

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) (ref UK/NI/16-7664) issued by Johnson & Johnson Limited and was published in Pulse online. The advertisement was headed 'Nicorette Do Something Incredible' and referred to combination nicotine replacement therapy (NRT).

## COMPLAINT

The complainant stated that there was no generic name on the advertisement nor any mention of where the prescribing information could be found (although if one clicked on the advertisement it was present).

The complainant further stated that the content of the advertisement itself gave no information and appeared to be a 'teaser'.

The complainant explained that this style of advertisement might be acceptable for consumer advertising but not to be directed towards healthcare professionals. The complainant was concerned that there were not adequate internal controls to ensure that it was not used in publications aimed at the wrong audience.

The complainant stated that it was difficult to read the prescribing information as it had not been split into smaller columns and instead was in one large block.

In writing to Johnson & Johnson attention was drawn to the requirements of Clauses 4.3, 4.4, 9.1, 11.1 and 26.1.

## RESPONSE

Johnson & Johnson explained that the advertisement at issue was a 'rolling banner' made up of four banners which flicked through automatically, one after the other over approximately 10 seconds and repeated constantly on a loop. Johnson & Johnson submitted that the reader would see each of the four rolling banners and the individual banners should not be considered in isolation.

### 1 Non-proprietary name

Johnson & Johnson submitted that the first banner in the advertisement clearly stated the non-proprietary name, 'nicotine', immediately adjacent to the brand name at its first appearance, fulfilling the requirements in Clause 4.3. The text on this was 'Nicorette nicotine Do something incredible'.

### 2 Prescribing information

Johnson & Johnson submitted that the link to the prescribing information was highlighted in bold writing at the bottom of both the second and third banners which included 'Click here for prescribing and adverse event reporting information and references'. The link took the reader directly to a copy of the prescribing information, as well as the required adverse event reporting statement and references for all the claims. The advertisement satisfied the requirements of Clause 4.4. The complainant confirmed that he/she could view the prescribing information by clicking on the advertisement.

Although not asked to address Clause 4.1 and the legibility of prescribing information Johnson &

Johnson was happy to address the point. Johnson & Johnson submitted that the prescribing information fulfilled the requirements of Clause 4.1 as well as the recommendations given in supplementary information to Clause 4.1, that the prescribing information must be clear and legible. In this regard the prescribing information used type size such that a lower case 'x' was larger than 1mm on an A4 printed copy, with an easy to read font style and black lettering on a white background and had sufficient space between lines to assist with easy reading, with emboldened headings so prescriber could easily find the section they wish to read.

Although the prescribing information contained more than 100 characters per line, Johnson & Johnson noted that this was an online banner advertisement, and the prescribing information was provided as an electronic document. Thus, legibility was entirely dependent upon the size and quality of the screen that the reader was using. All devices were capable of 'zooming in' on documents, and it was assumed that the complainant was able to zoom in on the prescribing information in this instance.

Given that the requirement for legibility were fulfilled as the PDF version of the prescribing information was clearly legible, Johnson & Johnson submitted that the prescribing information was not in breach of the Code.

### 3 Content of advertisement

Johnson & Johnson noted the complainant's statement that the advertisement gave no information and appeared to be a teaser intended to elicit an interest in something which would be following or would be available at a later date, without providing any information about it. Johnson & Johnson stated that the advertisement in question scrolled through four different banners which posed the question to the healthcare professional, 'How do you empower them to quit for good?'

Healthcare professionals faced great challenges in helping patients to quit smoking, and large numbers of quit attempts failed. Patients might require support in terms of behavioural therapy and medicines might help them resist cravings to smoke and avoid some of the symptoms of nicotine withdrawal; healthcare professionals could therefore help empower patients to make a successful quit attempt. In this instance, the advertisement highlighted that prescribing combination nicotine replacement therapy (NRT) could be a more effective way to help patients quit smoking for good than prescribing nicotine patches alone. Nicorette was indicated to aid smokers wishing to quit and to relieve and/or prevent cravings and nicotine withdrawal symptoms associated with tobacco dependence. Johnson & Johnson therefore submitted that the advertisement was not a teaser and did not breach Clause 9.1.

### 4 Suitability of audience

Johnson & Johnson stated that the advertisement was aimed at healthcare professionals and had been

reviewed and certified as such under the ABPI Code. Pulse was widely read by general practitioners (GPs), and most would be interested in helping patients quit smoking, and might find it helpful to consider ways to support patients through a quit attempt. Thus the wording in the advertisement talked directly to the healthcare professional, asking, 'How do you empower them to quit for good?' where 'them' would be interpreted by healthcare professional's as meaning their patients who wished to quit smoking. A high proportion of Nicorette prescriptions came from general practice and hence displaying the Nicorette advertisement in Pulse was appropriate; it was the number 1 GP magazine in the UK. The media plan for Nicorette ABPI approved materials focused on GPs, nurses and pharmacists, with materials being adapted as appropriate to be suitable for the intended audience. Any Nicorette advertisements aimed at prescribers were reviewed and approved by Johnson & Johnson in accordance with the ABPI Code. The requirements for Clause 11.1 had been met as this advertisement, distributed via the Pulse website, would be of interest to and relevant for its audience.

## 5 Advertising to the public

Johnson & Johnson pointed out that Nicorette held a legal category of general sales list (GSL) and therefore any advertising aimed at consumers was subject to the Proprietary Association of Great Britain (PAGB) Code of Practice for Advertising Over-The-Counter medicines and was fully reviewed and approved by both Johnson and Johnson and the PAGB. Nicorette digital advertising for consumers targeted online spaces used by consumers. As described above, the media plan for ABPI materials targeted healthcare professional journals and websites. Johnson & Johnson submitted it had no reason to believe that the advertisement in question on the Pulse website had been seen by members of public. Therefore, Johnson & Johnson denied a breach of Clause 26.1.

In response to a request for further information Johnson & Johnson provided an electronic copy of the rolling banner advertisement.

### PANEL RULING

The Panel noted that the advertisement, published in Pulse today online continuously revolved through four banners, one after the other, over 10 seconds. The Panel noted that the supplementary information to Clause 4.1, Electronic Journals, stated the first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information could be found. This should be in the form of a direct link. The first part was often linked to other parts and in such circumstances the linked parts would be considered as one advertisement. If the first part mentioned the product name then this was the most prominent display of the brand name and the non-proprietary name of the medicine or a list of the active ingredients using approved names where

such existed must appear immediately adjacent to the most prominent display of the brand name. The Panel noted that the purpose of this supplementary information was to ensure that the prescribing information and other obligatory information were an integral part of the advertisement thus satisfying Clause 4.1 in that regard.

The Panel considered that there were differences between a static banner on which one proactively clicked to link to other material including the prescribing information, and a series of continuously revolving banners. The length of time that each banner was displayed within a revolving series would vary, could not be influenced by the reader and might be longer or shorter than those in the material at issue in this case where each banner was displayed for 2.5 seconds. The Panel considered that such cases should be considered individually in relation to the requirements of the Code.

The Panel noted that Clause 4.3 required the non-proprietary name or the list of active ingredients using approved names where such existed to appear immediately adjacent to the most prominent display of the brand name. As the non-proprietary name was included next to the brand name on the first banner the Panel ruled no breach of Clause 4.3.

The Panel noted that the first banner did not include a clear, prominent statement as to where the prescribing information could be found. The Panel noted the complainant's submission that although there was no mention of where the prescribing information could be found, if one clicked on the advertisement it was present. The Panel noted that the case preparation manager had not raised Clause 4.6 with Johnson & Johnson. Clause 4.6 required the statement as to where the prescribing information was found in the case of promotional material included on the internet which, as stated in the supplementary information to Clause 4.1 and noted above, should appear on the first banner rather than on the second or third. The Panel was thus unable to make a ruling in that regard. The Panel noted that Clause 4.4 was raised which required that in the case of digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 4.1 might be provided either by inclusion in the digital material itself, or by way of a clear and prominent direct single click link. Although the prescribing information was provided, if the reader clicked on the advertisement, the link was not clear and prominent on the first banner and the Panel, therefore, ruled a breach of Clause 4.4.

The Panel did not consider the advertisement was a teaser as set out in the supplementary information to Clause 9.1. Information about Nicorette had been provided, including prescribing information, and thus the Panel ruled no breach of Clause 9.1.

Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated

that promotional material should be tailored to the audience to whom it was directed.

The Panel considered whether the content of the advertisement was suitable for the readership of the journal. The Panel noted Johnson & Johnson's submission that Pulse was widely read by GPs and that a high proportion of Nicorette prescriptions came from GPs. The Panel further noted Johnson & Johnson's submission that materials were adapted to be suitable for the intended audience. The Panel considered that the advertisement was such that it was aimed at prescribers who would be the main audience of Pulse. The Panel therefore ruled no breach of Clause 11.1. It noted that the advertisement was for general sales list medicines and not prescription only medicines. Clause 26.1 prohibited the promotion of prescription only medicines to the public. There could be no breach of Clause 26.1 and the Panel ruled accordingly.

The Panel noted that Johnson & Johnson had not been asked to comment on the legibility of the prescribing information and Clause 4.1 by the

case preparation manager. However, this was the relevant clause in relation to the allegation that it was difficult to read the prescribing information. Johnson & Johnson had responded to the allegation. In these unusual circumstances, the Panel decided to consider the matter. The Panel noted the line length used in the prescribing information was longer than 100 characters. The supplementary information to Clause 4.1, Legibility of Prescribing Information gave recommendations to assist legibility. The Panel considered that although line length at around 140 characters was more than recommended this did not necessarily mean the prescribing information was not legible. The spacing between the lines and boldening of the headings were helpful. The Panel decided that although on the limits of acceptability the prescribing information was legible and no breach of Clause 4.1 was ruled.

**Complaint received**                      **8 February 2017**

**Case completed**                              **10 May 2017**