

Advertising Complaint Case Report

J & J v GSK

NiQuitin Minis Mint 4mg Lozenges Professional Advertising Campaign

Case Summary:

J & J complained about health professional advertising for NiQuitin Minis Mint 4mg Lozenges which appeared in Scottish Pharmacist and in the Alliance Healthcare September Price List and Order Form. The complaint concerned five claims appearing in two advertisements and alleged breaches of the following provisions of the Code:

Rule 9: Potentially misleading advertising - Advertisers must hold evidence for claims
Rule 21: Comparative advertising - Comparisons shall be fair, balanced and supportable
Rule 25: Comparative advertising - Clinical superiority

Determination:

NiQuitin Minis Mint 4mg Lozenges are a new format of oral nicotine replacement therapy being promoted as particularly suitable for people who prefer a product which remains in the mouth for a shorter duration than gum or standard lozenges. PAGB considered that it was reasonable to expect that the intended audience (health professionals) would have a good level of knowledge about smoking cessation generally, individual products and the diversity of presentations available within NRT ranges. In determining the complaint PAGB considered SmPCs for the relevant products and evidence from studies submitted by the companies.

**Claim 1: Q. “Which oral format has been proven to tackle cravings in just 5 minutes?
A. NiQuitin 4mg Minis”**

PAGB determined that this statement is not a superiority claim, as suggested by J & J, but a statement of fact requiring substantiation in order to be used. The statement explicitly relates to oral products only and in so doing GSK has deliberately sought to exclude “non-oral” NRT presentations such as patches and nasal spray. The comparison is clearly restricted to oral formats only and would not be likely to mislead health professionals who should be familiar with the variety of NRT products available. GSK provided study data to substantiate the 5 minute claim.

Accordingly the claim is valid and the complaint is dismissed.

Claim 2: “New NiQuitin 4mg Minisdeliver higher blood nicotine levels than Inhalator or 4mg Gum”

J & J complained that the above claim was ambiguous and thus misleading and questioned the robustness of the supporting evidence. GSK submitted two studies in support of the claim. PAGB had a number of technical criticisms of one study which gave details of blood levels achieved using a range of different NRT products. As a result little weight could be attached to this paper. The results of the second study clearly showed that Minis gave a higher blood level than one brand of 4mg gum. However, PAGB concluded that the data was not sufficient to support the claim being made in the advertisement which relates to all brands of 4mg gum. In relation to the comparison to the Inhalator GSK sought to compare data from a single study with general information from the Summaries of Product Characteristics for NiQuitin Minis and Nicorette Inhalator. PAGB concluded that was not appropriate, and was not as valid as a true “head-to-head” comparative study.

Accordingly the claim was found to breach Rules 9 and 21 of the Professional Code and the complaint is upheld.

Claim 3: Make a clever choice with NiQuitin Minis as part of combination therapy

J & J complained that the claim is misleading. While it is a matter of subjective interpretation PAGB considers that health care professionals will be familiar with the phrase “combination therapy” in the context of smoking cessation and will not be misled by its use.

Accordingly the claim is valid and the complaint is dismissed.

**Claim 4: Q. NiQuitin Minis release their full dose of therapeutic nicotine how many times faster than Nicorette Gum?
A. 3 times faster.”**

J & J allege that the above claim is superiority claim requiring a head to head study to substantiate it. SmPCs for the products were provided together with evidence from dissolution studies for NiQuitin Minis. J & J was concerned that dissolution data is not relevant for gum where the rate of nicotine release is determined by the extent and duration of chewing and that therefore the claim does not compare like with like.

PAGB found the claim to be a comparison of the rates of nicotine release from two NRT products with different formats and not a superiority claim. Whilst PAGB agreed that dissolution data is not relevant for a chewing gum, there remains a point for each product at which the full dose is released. PAGB considered that the wording ‘release their full dose’ is an appropriate way of expressing the length of time taken for to release the nicotine from the respective formats. PAGB took account of the fact that some residual nicotine remains in Nicorette gum after it has been discarded but concluded that the gum could be considered to have released its full dose when taken out of the mouth after the requisite chewing time.

PAGB reviewed the SmPCs for all NRT Gums currently marketed in the UK; each states that the chewing routine should be continued for 30 minutes while the SmPC for NiQuitin Minis Mint Lozenges states that the product typically dissolves in 10 minutes. Although there will be variation between subjects, these timings have been accepted by MHRA for inclusion in the SmPCs, and hence PAGB regards them as a reliable benchmark.

Furthermore PAGB considered that the inclusion of an asterisked caveat to the claim “Speed of release in the mouth does not imply speed of craving relief” made it clear that the “three times faster” claim was based on the apparent speed of disappearance of nicotine from the mouth as indicated in the relevant SmPCs and did not imply that blood levels rise faster, or that cravings would be reduced more quickly.

Accordingly the claim is valid and the complaint is dismissed.

**Claim 5: “Deliver more therapeutic nicotine than:
Nicorette Gum
Nicorette Inhalator”**

J & J alleged that the claim is misleading and questioned the robustness of the supporting evidence. PAGB considered that the claim was similar to claim 2 discussed above; it was supported by the same study which PAGB did not consider to be sufficiently robust.

Accordingly the claim was found to breach Rules 9 and 21 of the Professional Code and the complaint is upheld.

Corrective action:

GSK has provided written undertakings that the offending claims have been amended or withdrawn and that no further items containing these claims will be printed or distributed.

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