



Advertising Standards Authority
Mid City Place 71 High Holborn London WC1V 6QT
Telephone 020 7492 2222 Fax 020 7242 3696
Textphone 020 7242 8159 E-mail enquiries@asa.org.uk
Online www.asa.org.uk

Stephen Fawbert

By e-mail
Stephen.Fawbert@mhra.gsi.gov.uk

14 August 2009

Dear Mr Fawbert

**CONSULTATION RESPONSE ON EUROPEAN COMMISSION PROPOSALS
ON INFORMATION TO PATIENTS FOR PRESCRIPTION MEDICINES (MLX
358)**

1. Introduction

- 1.1 The Advertising Standards Authority (ASA) is grateful for the opportunity to provide information to MHRA consultation (MLX 358). The ASA is happy for this letter to be published.
- 1.2 The ASA is the UK self-regulatory body for ensuring that all advertisements, wherever they appear, are legal, decent, honest and truthful. The ASA is here to protect consumers and maintain a level playing field for business.
- 1.3 The ASA is the independent body that administers the Advertising Codes. The Codes are owned and updated by two industry bodies: the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP).¹
- 1.4 The self-regulatory system is based on a concordat between advertisers, agencies and the media that each will act in support of the highest standards in advertising. Compliance with the Codes and ASA adjudications is binding on all advertisers. It is not a voluntary system.
- 1.5 The system is both self-regulatory (for non-broadcast advertising e.g. press, poster, cinema, online) and co-regulatory (for TV and radio advertising). The Codes do sit within a legal framework, which means

¹ The Committee members represent the three main parts of the advertising industry: advertising agencies, media owners (e.g. poster site owners, newspapers, broadcasters) and the advertisers themselves. Details of the members of CAP and BCAP can be found at:
<http://www.bcap.org.uk/cap/links/CAP+Members/>

that, where appropriate, they reflect the standards required in law, e.g. misleading advertising and medicines advertising.

- 1.6 More detailed information about the ASA, CAP/BCAP and the Advertising Codes can be found at: www.asa.org.uk and www.cap.org.uk.

2. ASA response to MHRA consultation questions

- 2.1 The ASA has no view on the fundamental principles of the proposal. It is a decision for Government to decide whether it is safe or appropriate for such information to be provided to consumers. If that information appears in UK media space, then it would fall within our remit, be subject to the Advertising Codes and the ASA would have a role in ensuring that the ads are not misleading and are responsible. The ASA notes that MHRA considers that TV and radio would not be appropriate media to carry such information.
- 2.2 The ASA agrees with the key elements of the European Commission's proposal as being the best way to protect the consumer, outlined in paragraph 13 of the MHRA consultation paper.
- 2.3 The ASA agrees with the UK Government position set out in paragraphs 16-18 of the MHRA consultation paper. The ASA supports effective self-regulation and believes that national bodies are best placed to decide what is and is not advertising, based on national guidance and enforcement arrangements.
- 2.4 Although we do not have any specific comments at this stage about the MHRA's policy position, should the Commission's proposals become law, the ASA and CAP would have a strong interest in the implementation process.
- 2.5 For example, we would need to liaise very closely with the MHRA about where the line is to be drawn between advertising a prescription-only medicine (POM) and providing non-promotional information. The ASA currently has a strict line on the direct or indirect advertising of POMs within advertising space. (See the AMI Clinic ruling, which indirectly advertised an unlicensed medicine with the statement "NASAL DELIVERY TECHNOLOGY CALL THE DOCTORS AT ADVANCED

MEDICAL INSTITUTE”.² This ruling would have been the same if the product were a POM.) The Commission’s proposals may well lead to a change in our policy.

- 2.6 The ASA and CAP are also concerned that if the proposals are not clear enough, they might be implemented in a way that adversely affects our ability to manoeuvre as a self-regulatory body (e.g. they might cause the system to fall foul of - or directly interpret - the law.) It is important that we work closely together to ensure that the Ad Code and ASA processes can effectively deal with the content of such ads.
- 2.7 The ASA is not in a position to assess the impact of the proposals as it is unlikely that they will particularly affect the ASA while the advertising to consumers of prescription-only medicines remains illegal.
- 2.8 The ASA is not in a position to propose any additional measures.
- 2.9 The ASA is not in a position to assess whether these measures will adversely impact on public health.

The ASA is grateful for having been provided with the opportunity to have input into this consultation. If there are any questions arising from this response please do not hesitate to contact me.

Yours sincerely



Lynsay Taffe
Communications and Policy Manager

Encs

² See Annex

ANNEX

ASA ruling against AMI Clinic Ltd

AMI Clinic Ltd
1st Floor
Evergreen House
2-4 King Street
Twickenham TW1 3RZ

Date: 18 February 2009
Media: Poster
Sector: Health and beauty
Agency: First Choice Media

Number of complaints: 522

Background

The posters were withdrawn at the request of the ASA pending the outcome of the investigation.

Ad

A poster for AMI Clinic Ltd (AMI) stated in large, prominent lettering 'WANT LONGER LASTING SEX?' The word 'SEX' appeared in very large lettering. Smaller text stated 'NASAL DELIVERY TECHNOLOGY CALL THE DOCTORS AT ADVANCED MEDICAL INSTITUTE'.

Issue

1. 521 complainants believed the poster was offensive and, therefore, unsuitable for display in public locations, which included near schools and in areas with a high Jewish population, where it could be seen by children, and
2. The ASA challenged whether the poster advertised an unlicensed medicine.

Response

1. AMI explained that the marketing campaign sought to address serious men's health issues while removing the stigma and taboo associated with seeking help for them. Independent research confirmed that only 11% of men with a sexual dysfunction sought medical advice. AMI pointed out that, in addition, only a small number of those who did take the first step were willing to follow up and obtain treatment. They said research had shown that, in many cases, men were too embarrassed to talk to a doctor or visit a pharmacy despite widespread publicity of these conditions since the launch of Viagra. They believed sometimes bold, arresting statements were the only way of

successfully engaging men and promoting the availability of treatment and removing the perceived embarrassment or shame associated with seeking it. They said they never intended to cause offence, but given the nature of their business, it was inevitable that some people would be embarrassed or offended by the directness of AMI's campaign. They pointed out, however, that they had complied with the request of the ASA and withdrawn all posters, without prejudice, pending the outcome of the investigation.

AMI said, in their view, there was nothing irresponsible in talking about sexual problems in an open manner and pointed out that frank discussions of people's sexual problems had been present in the media for decades. They said it appeared, from the number of people who participated in open debates on the subject on the radio, for example, that there was a clear need for members of the public to address their sexual problems.

They pointed out that press advertising, which featured the text '... do you want longer lasting sex', had been approved by the Committee of Advertising Practice (CAP) Copy Advice team and that merely enlarging the word 'SEX' on a poster, which was appropriate for the different medium and wholly relevant to AMI's treatment of sexual problems, did not make them irresponsible towards consumers or wider society. They believed 21st Century Britain was more than able to cope with the content of the campaign without serious or widespread offence being caused. Although they recognised a number of complaints had been received, they believed in the wider context of reality TV programmes, 'lads mags', online content, the commonality of graphic simulated sex on prime-time TV and film and factual shows such as Channel 4's 'Embarrassing Illnesses/Bodies', we were living in a more liberal and tolerant age than, for example, ten years ago.

They pointed out that a recent high-profile poster campaign for the 2008 film 'Sex and the City' emblazoned the word 'SEX' in very large lettering all over the UK and posters for the film 'Sex Drive', used the imagery of a speed dial as a prone man's erect penis and included the text 'COMING SOON'. AMI said their poster highlighted a serious medical condition and was significantly less obtrusive in their opinion than other posters. They further believed the word 'sex', in itself, could and should not cause offence to any great degree.

AMI said, in their opinion, the number of complaints was relatively small in the context of the number of people who could have seen the poster. They believed any unintentional offence that had been caused was not serious or

widespread: the poster included no swearing, innuendo, inappropriate or suggestive imagery or nudity.

AMI believed the poster could not have caused serious offence or harm through placement near a school or in an area with a high Jewish population. Although it could prompt children to ask questions, they believed most children learnt about sex through sources other than a poster, for example, magazines. They pointed out that it was a publicised Government plan that children as young as five-years-of-age would be given sex education. In addition, they believed there was nothing in the poster that was likely to offend the Jewish community in particular. Jewish Law permitted sex within the context of marriage and nothing in the poster campaign suggested, promoted, encouraged or implied anything against that view. AMI also pointed out that they were understanding of religious sensitivities but that sexual problems were not excluded from any specific religion and there was no reason why any part of the community should be ignored or treated differently for reasons of ethnicity or religion.

2. AMI said the generally accepted definition of a medicine was 'any drug or remedy that treats or prevents or alleviates the symptoms of disease, illness or pain'. They believed they had not promoted or advertised a medicine or referred to any medication, attributes or functions of any medicines, but rather had advertised a delivery system relating to treatment. They said the poster clearly stated that AMI owned nasal delivery technology and added that the CAP Code did not state that the advertising (or indirect advertising) of a delivery method for a medicine was prohibited.

Furthermore, AMI said they provided a medical service offering treatment programs to the public. They said the phrase 'Want longer lasting sex?' did not relate to a medicine but the treatment programmes provided. They said any medicine the treatment incorporated was prescribed by UK-registered doctors and provided by a pharmacy as part of the programme. They explained that they did not hold a marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) for any medicines because none was needed for their particular treatments; they were not advertising medicines.

AMI believed there was an important and vital difference between medical service advertising and advertising medicines. They said in some cases, the treatment of male sexual problems involved only counselling, or counselling could be provided free to patients for whom medicine was also necessary. A fully-qualified Managing Health and Social Care (MHSC) Psychosexual

Therapist & Counsellor who specialised in sexual dysfunction was a member of AMI's full-time staff.

Assessment

1. Upheld

The ASA noted AMI's argument that the poster delivered their message in a blunt and direct manner, which included the word 'SEX' in large lettering, but incorporated no swearing, suggestive imagery or nudity. We also noted, however, a number of people who had seen the posters had felt that the language used was offensive and inappropriate for general public display.

We understood that many people also considered the posters' bright colours and very large text, including the word 'SEX' to attract attention, was unsubtle and crass. We also understood that the word 'SEX', in itself, had caused concern in many cases and, in the context of 'WANT LONGER LASTING SEX?', which related directly to sexual intercourse, had also caused embarrassment amongst some parents or guardians who had been quizzed about its meaning by children. A number of complainants pointed out to us that the sheer size and prominence of the message made it impossible to avoid, which they found very uncomfortable.

We recognised that the sensitive nature of the message AMI wanted to deliver about their product and the treatment programmes they offered could be intrusive to some readers under any circumstances. We also noted the poster contained nothing explicit, and considered that the word 'sex' was not necessarily problematic in itself. We considered, however, that the style and tone of this ad, with direct reference to sexual intercourse through the phrase 'Want longer lasting sex?', was presented in too stark and prominent a manner, and as a result were concerned that it had caused both serious and widespread offence.

In view of this, we concluded that the poster was unsuitable for public display.

On this point, the poster breached CAP Code clauses 2.2 (Responsible advertising) and 5.1 (Decency).

2. Upheld

We noted AMI's argument that the poster did not promote or advertise a medicine, but instead advertised the way in which the medicine would be administered to patients: through nasal delivery technology.

We noted their argument that the phrase 'WANT LONGER LASTING SEX?' related to their treatment programmes and, whilst we recognised that AMI also offered counselling services, we considered that by including that phrase and making reference to nasal delivery, AMI had indirectly advertised the medicine itself.

We noted that the medicine was available by prescription only and that AMI did not hold a marketing authorisation for any medicines prescribed as part of their treatment programmes. We therefore concluded that the poster had indirectly advertised an unlicensed medicine, which was available only on prescription, to the public.

On this point, the poster breached CAP Code clause 50.11 (Medicines).

Action

The poster must not appear again in its current form. References to 'nasal delivery' must be removed. Other phrases which could be interpreted as referring to medicines must not be used.

Adjudication of the ASA Council (Non-broadcast)