

#### (Including additional guidance on the use of titles)

#### Who we are

We are the <u>Committee of Advertising Practice</u> (CAP). We write the advertising rules, which are enforced by the Advertising Standards Authority (ASA), the UK's independent regulator. You can read about the UK advertising regulatory system <u>on the ASA website</u>. For free and confidential advice about specific non-broadcast ads, please contact the <u>CAP Copy Advice team</u>.

#### Why are we contacting you?

It has come to our attention that there are a significant number of websites advertising braces and dental devices. Some of these websites have claimed that their brace systems are less painful and have a faster effect than traditional braces. We consider such claims would need to be substantiated with robust documentary evidence in the form of high-quality human clinical trials, which we are yet to see in relation to pain and speed of treatment claims.

In the absence of sufficient substantiation, claims such as *"less painful"* and *"faster treatment"* should not be used. We are communicating this guidance to the dental and orthodontic industry to ensure a level playing field and compliance with the CAP Code.

#### Case study #1

The <u>ASA investigated</u> a website advertising braces claiming they would provide "...greater pain reduction, less root resorption and fast safe and affordable solution". The advertiser stated that their braces differentiated from traditional brace systems as they had less root resorption and moved the roots of the teeth towards their final position from the start of treatment, which occurred in one stage, sometimes occurring in weeks. It was noted by the ASA that consumers may require the tooth realignment for a variety of reasons such as cosmetic and clinical reasons. A consumer was likely to look at the length of time for treatment as an influence for their decision, so evidence should've been provided to this effect.

The advertiser provided a list of publications, summaries of papers and articles. They also provided two case studies and an orthodontic reclassification for misaligned teeth. Full articles weren't provided in relation to the comparison between the advertised product and traditional braces and they did not take into consideration the pain and speed of treatment issues raised.

The ASA considered the papers were not adequate substantiation for the claims made and the complaint was subsequently upheld.

#### Case study #2

The <u>ASA investigated</u> a website advertising braces which stated the braces "move teeth faster, freely, quickly and comfortably" when compared with traditional braces. The evidence provided in support of the claims consisted of unpublished Masters Theses and commercial surveys, both of which were not peer-reviewed. The studies were also conducted on models of the mouth rather than human subjects. The ASA found this evidence was not sufficient to support the claims being made for the performance of braces in humans. The ASA also looked at the clinical trials provided. Many of the studies measured surrogate markers, such as microbial count or frictional forces, rather than measuring pain or rate of tooth movement. This was problematic as the claims made in the ad referred to quicker and less painful treatment. The ASA found that the studies reported faster and reduced pain and they all exhibited methodological issues: none of the trials were blinded, while single-blinding would've been appropriate in this instance.

The ASA considered the evidence was not adequate to demonstrate that the braces provided faster and less painful treatment than traditional braces. Therefore the ASA found the claims had not been substantiated and were misleading, thus upholding this complaint.



#### Case study #3

The <u>ASA investigated</u> a website promoting an orthodontic device which was advertised as "clinically proven to move teeth up, hopefully to 50% faster... also clinically proven to reduce the pain and discomfort associated with braces and aligners by up to 71%." The ASA understood the advertiser took various methods to measure the speed rate and discomfort levels of the braces.

#### Speed testing

"Faster claims" - the advertiser provided two randomised, controlled, double-blind, parallel group clinical trials in support of this claim. First trial - an analysis of the measurement error relating to tooth movement was carried out on a model of the oral cavity (a typodont) and not on the actual patients. The study did not provide any further details regarding how the measurement error was carried out and why it was considered to be robust.

Second trial - here the subgroups would vary based on the different number and type of extractions performed on them. Also the study's design could have varied for each individual participant. Specifically that there may have been discrepancies in the period of time each participant had their assessment carried out along with the necessary brace adjustments. The study did not refer to a measurement of error when determining how accurate the investigator was at measuring extraction spaces. We concluded that such action would have made the data reliable in order to establish the validity of the study's objective. Furthermore, the study was initially designed to remove any participants who were found to have loose devices during the course of the study. However, that no longer became the case and such patients could continue to participate in the study.

#### Pain testing

"Less painful claims" - a clinical trial took place involving 70 patients, a mixture of adults and children. Patients were assigned to comparison groups using a block allocation sequence and randomisation. Patients recorded their pain using visual analogue scales. Those in the group not testing the device were not given a placebo. As such, the trial wasn't placebo controlled, which the ASA considered a fundamental variable for assessing pain, and concluded adequate evidence wasn't provided to support the pain relief claim.

The ASA concluded adequate evidence was not provided to support the claim for their device being "50% faster". Similarly the ASA were not satisfied with the methodologies used for evidencing their claims for "reducing pain and discomfort". On both points the ASA subsequently upheld this complaint.

#### What makes a good clinical trial for "faster treatment" and "less painful" claims?

- New objective claims should be backed up by evidence in the form of at least one experimental human study (ideally double blind and placebo-controlled)
- Use human subjects for the assessment of faster treatment and less painful claims
- Remember a body of evidence focuses on the quality of data and studies being peer-reviewed by an independent expert or through peer-reviewed journals will generally hold more weight
- Fair trials, where each patient and the treatment they receive can be compared fairly ie: the same amount of extractions performed within the same time frame



## Advice

Please take immediate action to ensure your advertising complies, including online.

### Do's:

- Focus on promoting the exclusive features of the braces and dental devices and how these differentiate from traditional braces.
  - **How they look** For example "clear brackets make them more aesthetically pleasing because they are virtually invisible"
  - **How they make the wearer look** "Avoid the metal-mouth look and minimise the visibility of braces even further"
  - Easier to clean (if you can show this) "Fewer places for plaque and bacteria to accumulate with the clear braces more visible to see"
  - o Discreet "Resistant to staining so your brace will remain discreet"
  - How they work "Braces fix in place and work 24 hours a day, seven days a week"
  - Who can wear them "Suitable for all ages including teenagers and adults"
  - Materials used "Strong materials used"

### Don'ts:

- **Don't use claims** such as "faster and less painful treatment" for braces/devices which aren't backed up by evidence.
- Avoid using typodont models for clinical trials
- Avoid reliance on "parts of articles" and non-peer reviewed studies, without the involvement of an independent expert or reputable publication



"Easier to spot plaque and bacteria with the clear braces"





#### Advice in relation to using the title "Dr"

The ASA continues to receive complaints about this issue, so to help with that, please find below some helpful guidance and consider the advice available on <u>our website</u>.

#### If you are a dentist or a dental care professional make sure you take care when considering the "Dr" title

Please take care when using the title "Dr" so that people do not get confused that you are a medical doctor. When used in certain contexts, for example clearly juxtaposed with general health claims, this might imply that you hold a general medical qualification which can lead to confusion amongst consumers.

- The General Dental Council (GDC) permits its members to use the title "Dr", however when the context is around general health claims the need for clarity is paramount and in this context we would recommend the following conditions:
  - o It should be made clear when using the title "Dr" in this context that this is a courtesy title only.
  - This should be clear and prominently close to the practitioner's title and qualifications.
  - And if not clear from the context, it should also be made clear that the practitioner does not hold a general medical qualification.

#### **Example scenarios:**

# I have recently become a dentist and obtained a Bachelor of Dental Surgery (BDS) qualification, can I use the title "Dr" on our website?

- In order to prevent confusion for consumers, we would recommend that you also make immediately clear that this is a courtesy title only and that you do not hold a general medical qualification. Then this would be sufficient to use the title "Dr".
  - For example: Dr Jane Smith (courtesy title I do not hold a general medical qualification)
  - Or, you could opt for. Jane Smith BDS

# I am a dentist with a Bachelor of Dental Surgery (BDS). I also have a Doctor of Philosophy (PhD) in health care innovation. I would like to use the title "Dr" on my website would this be allowed?

- As above, provided that the context does not lead to confusion that it is a general medical qualification, then this would likely be fine.
  - *For example:* Dr John Doe BDS Phd (Health Care Innovation I do not hold a general medical qualification)



#### **Appendix: Code rules**

#### Relevant CAP Code rules:

#### 3.1

Marketing communications must not materially mislead or be likely to do so.

#### 3.7

Before distributing or submitting a marketing communication for publication, marketers must hold documentary evidence to prove claims that consumers are likely to regard as objective and that are capable of objective substantiation. The ASA may regard claims as misleading in the absence of adequate substantiation.

#### 3.33

Marketing communications that include a comparison with an identifiable competitor must not mislead, or be likely to mislead, the consumer about either the advertised product or the competing product.

#### 12.1

Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. Substantiation will be assessed on the basis of the available scientific knowledge.

Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA, VMD or under the auspices of the EMA, or for a CE-marked medical device. A medicinal claim is a claim that a product or its constituent(s) can be used with a view to making a medical diagnosis or can treat or prevent disease, including an injury, ailment or adverse condition, whether of body or mind, in human beings.

Secondary medicinal claims made for cosmetic products as defined in the appropriate European legislation must be backed by evidence. These are limited to any preventative action of the product and may not include claims to treat disease.

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