the voice of New Zealand advertisers

anza association of New Zealand advertisers

TAPS therapeutic advertising pre-vetting service

GUIDELINE 8 **Medicines**	**Comparative Advertising for Healthcare Professionals**
Last Updated	August 2016
What kind of product is this guideline for?	Medicines
What is the purpose of this guideline?	To provide guidance on advertisements that contain comparative claims between medicines or classes of medicines. Please Note: Guideline 9 in the Medicines Section of the TAPS Guidelines is specific for comparative advertising when directed to Consumers. Guideline 1 in the Cosmetic Section of the TAPS Guidelines is specific for comparative advertising between cosmetic products / devices / procedures and medicines / medical devices / methods of treatment.

BACKGROUND

Comparative advertising is covered in the ASA Code for Comparative Advertising, the ASA Therapeutic and Health Advertising Code, the Medicines New Zealand Code of Practice and the Self Medication Industry Code of Practice.

Whilst the healthcare professional is in a better position because of training to assess and discern more easily comparative claims for medicines, some care is still needed to ensure that the comparative claims are not misleading even in small issues including the design of the studies and points of omission. It is still particularly difficult for the healthcare professional (such as a busy GP or pharmacist) to spend time in fully assessing comparative claims for medicines where the evidence is likely to be in the form of a detailed clinical trial report that may be more difficult to interpret.

All codes recommend extreme caution in any form of comparative advertising because of the risk of misleading the healthcare professional albeit sometimes unintentionally.

GUIDELINES

The following points are relevant for comparative advertising to healthcare professionals.

1] **Peer Review Journals. Currency of publication.** Clinical Trials quoted should generally be current and have been published in a recognised peer review journal such as the BMJ, Lancet, New England Journal of Medicine, JAMA, or a well-recognised specialist medical journal. Currency of the publication is important and generally papers older than about 10-15 years may well have been superseded by more recent work with newer medicines. This poses more of a problem for OTC than prescription medicines but is still relevant.

2] **Clear Statement of Comparator.** Care should be exercised in ensuring that the comparator products are outlined clearly and that the claims do not imply or draw a conclusion about a comparison of the advertised product with the total market. Any claim implying a comparison with the total market of products in a similar therapeutic group is likely to be flawed and lack the scientific support. In addition the comparative doses of medicines used will also be very relevant i.e. make sure you are comparing 'apples with apples'.

3] **Comparison confined to medicines in the publication.** Most clinical trials are specific in comparing the product advertised against placebo or against one to three products of a similar classification. The comparative claim should therefore confine itself to a comparison with the medicines in the actual clinical trial. Head to head clinical trials with a comparator medicine are regarded as key for comparative claims.

4] **Key conclusions of publication important.** The comparison should be supported by the key conclusions in the clinical trial based on proper statistical significance.

5] **Gold Standard of prospective double blind clinical trial.** Most comparative claims should be supported by the standard of a prospective, double blind, randomised, controlled clinical trial which has sufficient power and which has sufficient patient numbers over a reasonably long period of time. Direct comparative double blind clinical trials provide the most robust scientific/medical support for a comparative claim. Comparing trials of different design/protocols and with different end points etc. will make the comparison less robust. Exclusions and end points should be clearly stated to evaluate the comparative claim.

6] **Intention to Treat.** The generally accepted medical standard is the "intention to treat" analysis which allows for drop outs etc. during the trial and includes these in the final statistical analysis. This adds credibility to the result.

7] **Statistical Significance.** For normal purposes a statistical significance of $p < 0.05$ is the accepted level at which a conclusion can be made that the result was due to the medicine and did not happen by chance. i.e. 5 chances in 100 or 1 chance in 20 that the result was not due to chance. Results of $p < 0.01$ or 0.001 would be regarded as statistically significant.

8] **Patient Numbers and length of treatment/trial time.** Patient numbers and length of trial time are pertinent points in assessing the significance of a result in a clinical trial. Clearly large patient numbers as in a multicentre trial e.g. 500 -2000 patients do carry more weight re the result. Trials conducted over the longer term period of greater than three months and from six months - 1 year plus are also likely to be more significant.

9] **Other Relevant Factors.** Other factors can also be relevant in assessing a comparative claim from a clinical trial such as a wash-out period in a cross over study and exclusion criteria for patients. Matching of patient populations, randomisation etc. are also all relevant factors.

10] **Other Types of study.** Other types of trial like the large open study, single blind study, retrospective study or the case control study whilst useful do not have the same robustness as the prospective double blind randomised controlled clinical trial. Open studies generally need a large number of patients enrolled in order to make any conclusions.

11] **Main body of medical opinion. Evidence-based medicine.** It is preferable to have at least one other study to reproduce the results of the study quoted in order to give greater weight to the conclusion or comparison. The general principle is that the comparison or conclusion must be supported by current medical opinion and the current clinical publications in recent journals to satisfy the major criterion of using "evidence-based medicine" on which to draw a conclusion and which forms the basis of sound prescribing or recommendation at the pharmacy.

The above points will be taken into account when assessing comparative advertising claims.