

TAPS | therapeutic advertising pre-vetting service

GUIDELINE 5 Medicines	Prescription Medicines and Patient / Consumer DVDs
Last Updated	August 2016
What kind of product is this guideline for?	Prescription Medicines
What is the purpose of this guideline?	To provide background and guidance on the use of Patient / Consumer DVDs in relation to the issue of healthcare professional endorsement and patient testimonial. This is relevant to section 58 of the Medicines Act, which essentially prohibits both healthcare professional endorsement and patient / consumer testimonials in advertisements for medicines.

- 1. Introduction:** Normally the use of healthcare professional endorsement or patient testimonial in advertisements to consumers for medicines would breach section 58 of the Medicines Act. However there are occasions where advertisers will want to use patient DVDs as a service to clinics or specialists.
- 2. Definition of Advertisement:** The definition of an advertisement and medical advertisement in section 56 of the Medicines Act would probably capture patient / consumer DVDs. In addition the Advertising Standards Authority [ASA] interpretation of an advertisement in section 5 of the Advertising Codes of Practice would also capture these DVDs as advertisements. This has been reinforced by an ASCB decision [02/107. AWAP 02/06 May 10 2002 Pharmac's letter on generic beclomethasone] where a letter to prescribers was deemed by the Advertising Standards Complaints Board [ASCB] to be an advertisement.

However it is unlikely that the Medicines Act at the time it was written (1981) envisaged the use of patient DVDs for specialized products generally requiring infusion or injection administration and a good understanding by the patient of the place of the medication in the overall treatment. It would be regarded as very specialized promotion generally after the prescription for the product had been written and would generally be used more for instructional purposes to "improve health outcomes". This matter has arisen in a number of patient / consumer DVDs for specialized products in cancer treatment, post transplant, Hepatitis C etc. for products that are normally given by injection and often by self-administration.

3. Section 58 of the Medicines Act: The original intention of section 58 of the Medicines Act was probably the following. The use of healthcare professionals, people in white coats etc. was likely to give undue authority to the non-discerning consumer regarding the promotion of a product. Similarly patient testimonials tend to put more weight on simple anecdote rather than scientific or evidence based claims. For this reason the use of either healthcare professional endorsement or patient testimonial is regarded as a breach of the Medicines Act. Dispensation was given in section 60 of the Medicines Act regarding the use of either healthcare professional endorsement or patient testimonial where the advertising was strictly targeted to healthcare professionals i.e. those people qualified to give therapeutic treatment in the course of a profession or occupation, as this group would have the skills for discernment.

It is clear the use of healthcare professionals and patients in such DVDs does often help with credibility for the patient. They can provide some reassurance on the background of the condition and help to signal to the patient that they are not alone in areas such as administration. New patients can benefit from previous patient experience.

4. TAPS Approach: TAPS would normally review such DVDs on a case by case basis. However some guidelines are useful in helping advertisers with compliance. This is where either healthcare professionals or patients are used in the DVD.

The key objective is that these patient DVDs should be targeted to improving health outcomes. Through these DVDs patients should be better informed on the background of the condition and on practical aspects of administration of the medicine.

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- i. Generally the prescription for the medicine will have been written and there is no actual prescribing decision yet to be made.
- ii. The DVD will be important for "improving health outcomes" on matters of disease background and medicine administration, storage requirements and handling, for products given by injection/infusion and particularly where self-administration is required and pre-instruction will be necessary.
- iii. The DVD will clearly be seen to be instructional in nature on the background to the condition and administration of the medicine rather than promotion of the medicine per se.
- iv. Within reason the use of the brand name should be kept to a minimum and the DVD should assist the healthcare professional with individual treatment to improve health outcomes. Clearly some generic names are long and difficult to include and therefore use of brand names will likely be acceptable in this case.
- v. The DVD should include a statement that the patient should be referred to their healthcare professional for further comment or details in the event of problems with administration or with side effects.

- vi. Healthcare professionals should only describe the background of the condition and the general treatment with a note on the place of the medicine in the overall treatment scheme. They can also demonstrate administration of the medicine. However they should not be seen to be promoting the medicine as such.
- vii. Where patients are used they should confine their comments to the practical issues of administration and use of the product. They can talk about their condition. They should not refer to taking the medicine themselves and benefiting from it as this would be a patient testimonial.
- viii. The information provided in the DVD should comply with the datasheet and CMI and should not be seen to extend the use of the medicine in any way.
- ix. Generally DVDs that include HCPs and patients for more oral forms will be unlikely to add too much to improving patient outcomes and care should be exercised prior to making such DVDs. There may be occasions where there are different dosage forms such as extended release formulations where timing of dosage and transfer to the new formulation may need further patient explanation although this is probably rare, and may be able to be adequately covered with printed instructions. In these cases the DVD should generally be made without the use of healthcare professionals and patients.
- x. These guidelines should support the spirit of the Medicines NZ Code of Practice and the ASA Therapeutic and Health Advertising Code. The advertiser must "observe a high standard of social responsibility" in the preparation and production of the advertisement.
- xi. DVDs are often part of a patient kit so it is important that the kit also follows similar guidelines with having instructional information on the administration of the medicine. This is based on the point that the kit will normally be handed out to patients where the prescription has been written and the decision on the product has already been made. Any advertising material in the patient kit will need to comply with the requirements of the Legislation, ASA Codes and the Medicines NZ Code of Practice regarding the provision of mandatory product information. Such advertisements should obtain final TAPS Approval.
- xii. These guidelines do not claim to be definitive or exhaustive. They should be useful for advertisers and TAPS / DA Adjudicators in assessing the compliance of patient / consumer DVDs. In the event of any grey areas then it is likely that TAPS will consult further with Medsafe and the ASA.