

TAPS | therapeutic advertising pre-vetting service

GUIDELINE 7 Medicines	Use of Patient Story Information in Promotional Material for Consumers (For use by patients, caregivers or patient support groups)
Last Updated	August 2016
What kind of product is this guideline for?	Medicines
What is the purpose of this guideline?	To provide guidance on the compliance aspects of using patient stories or information from patient stories in promotional material (e.g. print, books, DVDs, online video) without breaching the Medicines Act 1981 Section 58 (1) (c) (iii).

BACKGROUND

Use of Patient Story/Testimony Information in Promotional Material [Print, Books or DVD] for use by Patients, Caregivers or Patient Support Group

The use of patient stories/testimonies is one form of promotion for medicines. These are developed for a number of reasons and are often intended to make the patient aware of the experience of having a disease state and its subsequent treatment. In many cases these promotional pieces are designed to indicate to the patient that his/her experience with both the condition and the treatment is common to a number of patients and that the patient is not alone.

TAPS has also produced a guideline re the "Use of Patient Videos" [c.f. TAPS Guideline 5 in the Medicines Section of the TAPS Guideline Page] re the administration of medicines, generally by injection or infusion, in conditions where self-administration is used. This guideline was written following the use of a number of patient videos re the administration of the medicine. Following consultation with Medsafe it was agreed that this was possible within the current Medicines Act as 1] the decision for the sale had been made & 2] there was a major emphasis on the administration of the medicine re appropriate use for compliance. In this case there was no direct promotion of the medicine per se or its benefits. Whilst some mention was made of the condition and the treatment and whilst patients were used in these videos, it was the view of Medsafe that the material was not specifically an advertisement but more instructional and similar to the patient CMI. Even this is a grey area open to interpretation.

This guideline does not cover the above situation with the use of videos/DVDs re administration of the medicine. It is concerned with patient stories and testimonies regarding their experience with the disease / condition and also the treatment. In this case there is no real emphasis or mention of

the administration of the medicine and thus this guideline has been developed to cover this general situation. The medicines are often given by mouth.

Material produced for patients, care givers, family members and patient support groups would be regarded as consumer advertising under the Medicines Act as there is specific mention under section 2 [Interpretation] of healthcare professionals like medical practitioners, dentists or pharmacists. Because of this, care will be needed not to breach section 58 of the Medicines Act regarding both healthcare professional endorsement and patient testimonial. The relevant part of section 58 is:-

58 Further restrictions on advertisements

(1) Subject to [section 60](#) of this Act, no person shall publish, or cause or permit to be published, any medical advertisement that-

c) Directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised-

(ii) Is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

(iii) Has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement;

Because the wording is so broad it would be difficult for a court not to rule against the advertiser in the event of any implied healthcare professional endorsement or patient testimonial. At present there is no court precedent that TAPS is aware of regarding this section of the Medicines Act and hence the need for caution. This is also the approach adopted by Medsafe.

GUIDELINES

The following guidelines will therefore be relevant for any such patient material.

1] Brand names should not be used as the Medsafe interpretation of the use of brand names in promotional/patient support material is that it is advertising. It is also likely that the material could be used for patients/carers for whom a prescribing/sale decision has not been made.

2] Use of the generic name for a medicine still under patent would be regarded in the same way as the direct use of the brand name and hence would be likely to breach the Medicines Act. As there is no generic equivalent of the medicine then there can only be the one brand intended.

3] It is therefore preferable to use expressions like "these new medicines" or "new treatment" or "class of treatment or medicine" or "the generic class of the medicine" such as "ACE inhibitor", "atypical antipsychotic" in order to avoid mention of either brand or generic name. This is the preferred option following consultation with Medsafe.

4] Often such patient stories mention only the positive benefits of the medicine without some reference to difficulties with adverse effects or cautions particularly in the initial stages of starting a new medicine. This would be regarded as lacking the appropriate balance and the Advertising Standards Complaints Board [ASCB] decision on a patient booklet "Lives Moving Forward" focussed on this point in particular. The use of mandatories for the medicine does not get round this issue as the mandatories would then mention the brand name and this would be regarded as advertising the brand in combination with a patient story or testimonial thus leading to a likely breach of section 58 of the Medicines Act.

5] Use of healthcare professionals should be done with particular care to avoid any implication of endorsement. Any mention of the brand or generic name by the healthcare professional would almost certainly imply an endorsement and thus be likely to breach section 58 of the Medicines Act. The preferred option is to mention only the "class of medicine".

6] Care should be exercised in the production of DVDs or videos re the specific pack shots of medicines with the brand names clearly visible as this is likely to mean an advertisement for the medicine and thus breach section 58.

7] Production of such patient material should be carefully thought through from the outset and there should be discussion with TAPS and also Medsafe where there is likely to be any uncertainty regarding a breach of section 58 of the Medicines Act.