

Medicines Promotion Regulations for Medical Personnel

Summary



1 Requirements for statements made in medical materials

Statements must be accurate, fair and balanced. They must be up to date and must not mislead (directly or by implication).



If you are working in a promotional setting statements must not be inconsistent with the details of the marketing authorisation.

2 Substantiation

The standard of evidence required to support a particular statement will depend on the nature of the statement and the therapy area.

Materials based upon 'real world' evidence should include a statement making it clear that the information is based on real world evidence and is therefore subject to potential bias.

3 Activities Prior to the Granting of a Marketing Authorisation



The provision of off-label information about products is allowed under certain circumstances, and these activities are usually carried out by medical personnel to avoid them being perceived as promotional.

The circumstances where sharing of off-label information is allowable are:

- When there is a legitimate business need
- In response to an external request
- When there is an established expectation e.g. business press releases, scientific publications



Remember: Always remember that off label promotion is illegal. Therefore it is vital that the activities and materials that you undertake or utilize in relation to these circumstances cannot be perceived by others as promotional in any way. If you have any doubts seek the advice of a senior colleague. The sanctions for off label promotion can be very severe.

4 Scientific Exchange



There is no official definition of 'scientific exchange', but the term has been used by regulatory authorities to acknowledge that exchange of information during the development of a product needs to

be allowed for certain 'legitimate' reasons. In addition the term 'exchange' implies a two way process in terms of sharing information. In scientific exchange there is a sharing of knowledge without a 'training' or 'teaching' element.

Congresses



It is generally expected at congresses for learned societies that 'cutting edge' science will be discussed during the sessions and symposia. This may

include research developments in terms of pipeline products. When symposia that are not part of the formal proceedings of a learned society congress, they should be treated as company 'stand alone' meetings and should not be used for scientific exchange.

Advisory Boards

- There must be a clear and documented business need for the advice
- The number of advisors invited and the duration of the advisory board must not exceed what is reasonably necessary to achieve the objectives
- They must not be attended by sales representatives or their first line managers
- There must be a clear, documented rationale for the choice of advisors which should stand up to scrutiny
- The agenda must allow enough time for active discussion and input from all of the advisors. Their input must constitute the majority of the agenda
- Information provided to the advisors must not exceed what is reasonably necessary to achieve the objectives of the advisory board and must be presented in a non promotional way
- Appropriate contracts and agreements must be in place with advisors

5 External requests

The enquiry must be unsolicited, and the response must not go beyond the scope of the enquiry. The response must not be promotional in any way.

