

Revision Module 2

Non- Promotional Activities

1 Activities Prior to Marketing Authorization

The sharing of off-label information is allowable:



- 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: off label promotion is illegal. Therefore it is vital that the activities and materials that you review in relation to these circumstances cannot be perceived by others as promotional in any way. The sanctions for off label promotion can be very severe.

Scientific Exchange

The term 'scientific exchange' 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.

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



2 Working with patients and the public

Material must be non promotional in content, appearance and tone as well as factual, accurate and balanced. They must not cause undue alarm or raise unfounded hopes.



Disease Awareness Campaigns: The primary purpose must be to increase awareness and knowledge of a disease - not a particular treatment.

Patient Support: Generally patient support programmes provide information, services or items. These should be to help patients better manage their disease or their treatment of it.

Patient Organisations: Pharmaceutical companies may interact with patient organisations but must always respect their independence. Work should be covered by suitable contracts/agreements.

5 Value transfer

Support must not, in any way, be offered, promised or made as an incentive or reward for any past, present or future willingness to prescribe, administer, approve, supply or use products or services sold or provided by AstraZeneca, or to obtain or retain business, or to gain any other business advantage for AstraZeneca.



3 Working with the Media

Material must be factual, accurate, and balanced. The content, style and presentation must be non promotional. The subject matter and information given must be 'newsworthy' to the intended audience.



4 Market Research and NI Studies

A non-interventional study is observational in nature. The product is prescribed in the usual manner, in accordance with the terms of the MA, without any additional investigations, monitoring or interventions. The decision to treat is taken separately from the decision to include the patient in the study. Collected data should undergo formal analysis.



For market research there must be a genuine business need. It must never be, or appear to be, promotional in nature. Ask yourself whether it be considered disguised promotion. Consider also whether the research should be blinded. The rights of respondents must be respected (confidentiality, privacy, consent etc.)