NOMINATED SIGNATORY

Revision Module 1
Promotional Activities

1 Requirements for promotional claims

Claims must be accurate, fair and balanced. The must be up to date and must not mislead (directly or by implication). They must not be inconsistent with the details of the marketing authorisation.

Keep in mind the need for high standards - looking at general suitability, avoiding causing offence, and making sure that promotion is in 'good taste'. In addition promotion must not be disparaging to the medical profession or to competitor products. All promotional claims must be supportable by some kind of evidence.

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.

Remember the importance of establishing what exactly you are reviewing, how the material will be used, its purpose, the target audience and the mode of distribution. Do not make assumptions.

3 Digital Material

Assets must be approved in complete and final form - interactivity, downloads, links, metadata etc all need to be checked for compliance with regulations.

When considering target audience, treat anyone who is not a health professional as a member of the general public. Note that 'filters' on social media are not considered adequate for targeting health professionals. Digital media must conform to regulations covering data privacy, security and confidentiality.

Any required permission needs to be formally documented. In addition, there must be an opportunity to withdraw permission at any time (e.g. unsubscribe option on promotional emails).

Company employees posting on social media may be considered to be representing the company (even if they are expressing personal views).

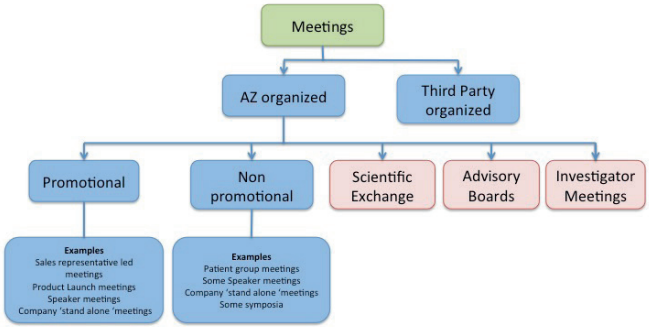
Note the FDA stance: use of the 'like' button in Facebook will constitute endorsement of that content by a company.

4 Meetings and Hospitality

All meetings designed to update HCPs on areas of medicine, science or our products should have a clear educational content. It should enhance medical knowledge, enhance the proper use of medicines or enhance patient care.

Key questions:

- What is the type of meeting and purpose?
- Is there clear educational content where required?
- Are the hospitality arrangements acceptable?
- Is the impression of the meeting acceptable?



Other considerations:

- Is the documentation adequate?
- Are the costs acceptable?
- Are the content and arrangements appropriate for the target audience?
- Has the involvement of AstraZeneca been made clear?

5 Obligatory Information

Requirements in terms of obligatory information vary between countries. Consider the following:

- Prescribing Information
- Unique identifying number for each asset
- Date of preparation and expiry
- Adverse event reporting
- Declaration of AZ involvement