

Medicines Promotion Regulations for Marketing Personnel Summary

1 Requirements for promotional claims

CLAIMS



Claims must be accurate, fair and balanced. They 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 in all promotional activities. This means 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.



Remember: In the same way as for written claims, artwork can mislead by distortion, omission or exaggeration. In terms of artwork you need to consider the context of the piece and the impression created. Placing items together can suggest that they are linked in some way.

2 Digital Considerations

Approval must be 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)

4 Information for approval of assets



Signatories need to know the purpose of the asset, the target audience, and the mode of dissemination.

Some statements or claims may

be approvable in one context but not in another. Assets can only be used for the specific purpose for which they have been approved. Material should only be sent or distributed to people whose need for, or interest in it, can reasonably be assumed. Assets may only be distributed by the approved means.

3 Working with patients and the public

Material for the general public must be non promotional in content, appearance and tone as well as factual, accurate and balanced. Patients are a special subset of the general public.



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 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

