

Principles of Promotion Summary

1 Basics of Promotion



Timing – no product can be promoted in a country before the marketing authorization is granted in that country.

Marketing Authorization – promotional information and claims must be in line with the terms of the marketing authorization (i.e. information in the summary of product characteristics (SmPC) or US PI).

AUTHORIZED

2 Requirements for Promotional Information and Claims

CLAIMS

- Claims must be accurate, fair and balanced
- Claims must not mislead
- Claims must be up to date
- Claims must not be inconsistent with the details of the marketing authorization

Don't 'cherry pick' (e.g. show only the favourable data)
Only products or services intended for the same purpose should be compared
Don't state that a product is 'safe' or has 'proven safety'
Beware of exaggerated descriptions - 'best', 'strongest'
'All embracing' claims are difficult to substantiate



Claims may be misleading by distortion, omission, exaggeration, implication, and through artwork.

3 Substantiation

Consider the quality of evidence that is supporting a claim. Take care with

- exploratory endpoints
- real world evidence claims



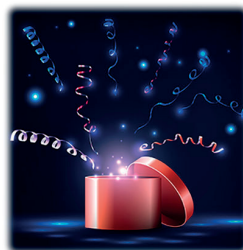
5 High Standards

This means looking at general suitability, avoiding causing offence, and making sure that promotion is in 'good taste'.

4 Use of artwork and illustrations

It is important to consider whether any artwork used might mislead in any way. 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. For example images of children should not be used for products not authorized in children. Think about the positioning of statements and artwork – placing items together can suggest that they are linked in some way.



Think about

- Imagery and format- could it cause offence or annoyance?
- Could statements be seen as disparaging a competitor or the medical professions?