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WHAT IS PROMOTION?

The Code defines promotion as:
"any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines"
This definition encompasses a wide range of materials produced and activities undertaken by a pharmaceutical company, all of which are subject to the requirements of the Code.

Whether or not something is promotion depends not just on the material or activity itself but also on

- the purpose - perceived and actual
- how it is used
- the consequences of use

Deciding whether or not something is promotional is often difficult and should be taken by someone with adequate experience of the Code. It is best to start from the position that it is promotional, and then try to find justification for it not being promotional, rather than the other way round.

Is it important to distinguish promotional and non-promotional activity?

Yes! The distinction between promotional activity and non-promotional activity is almost invariably a crucial one, but may often be a difficult distinction to make.

It is important because

- Medicines must not be promoted before licence – see p 20
- Medicines must not be promoted to the general public – see p 20
- There are certain specific requirements for promotional material, e.g. provision of Prescribing Information - see p69.
- Anything which is promotional must be clearly presented as promotional - see Disguised Promotion p66

What is not promotion?

Some activities are usually described as 'non-promotional' but **no activity can be regarded as inherently non-promotional**. Virtually every activity is at least potentially promotional.

It is therefore not correct to say that a particular activity is non-promotional, but that that particular activity **must be** non-promotional.

Each activity which **must be** non-promotional, must meet all relevant Code requirements before it can considered to **be** non-promotional. Requirements may relate to:

- The activity itself
- The purpose of the activity
- Materials associated with the activity
- Company staff involved in the activity

In many cases, failing to meet just one requirement will result in the activity becoming promotional. There is therefore a very fine line between being non-promotional and being promotional.

This area requires good judgement and considerable attention to detail.

What activities may be non-promotional?

The Code lists a number of activities which are considered not promotional, provided that certain conditions are met:

- Replies to individual enquiries - see p.218
- Letters to professional journals – same requirements as replies – see p200
- Factual statements with no product claims e.g. pack changes, price lists,
- Information supplied in relation to Health Technology Assessments, provided the information is factual, balanced and not misleading.
- SPCs
- PARs (UK and European)
- Labelling and package leaflets (provided that they are not promoting the product). These are covered by regulations
- Information on health and disease states if no specific product is mentioned - however, if the information relates to a disease area of interest to your company, it may be considered promotional and within the scope of the Code, even if no product is mentioned.

What activities MUST be non-promotional?

Information made available to patients or the general public – see p169
Relationships with Patient Organisations – see p 178
Public Relations activity – see p 182
The provision of medical and educational goods and services – see p 127
Clinical Research, including Non-interventional studies – see p 215
Market Research – see p 214
Activity during the pre-licence period.- see p 204

This list is not exhaustive.

ADVERSE EVENT REPORTING INFORMATION

All promotional material must include the following statement about adverse event reporting:

> 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company].

If the address of the wedsite for reporting is changed by MHRA, the new address should be used in materials as soon as possible. All materials must include the new address within one year of the change.

An appropriate company telephone number or email address may be included.

The statement is required on all promotional items including those which do not need to carry P.I. i.e. abbreviated advertisements, exhibition panels.

The statement should be prominent. This will usually mean that it should be in a larger typeface than the P.I. Clearly separating it from other text e.g by being enclosed in a box, will also increase the prominence.

Patient information

Any product information which is intended for patients taking that medicine must include the following or similar:

> 'Reporting of side effects'
> If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possibe side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www. mhra.gov.uk/yellowcard.
>
> By reporting side effects you can help provide more information on the safety of this medicine

LOOSE INSERT

Refer to 'Checklist for Promotional Material'.

Content

Consider all points on checklist.

Essential information

All apply.

- A loose insert is considered as a stand alone piece. It must therefore:
  - Include a date, even if distributed solely with a journal
  - Contain P.I.
- A loose insert CANNOT be, or include, an abbreviated advertisement.

Distribution

Distribution must be appropriate. Check that the usual readership of the journal is an appropriate audience for the insert e.g.

- a paediatric journal would not be appropriate for a product which is for adults only
- a journal for administrative staff would not be appropriate for an insert which was purely clinical.

Specific issues/requirements

- Advertisement on a loose insert in a journal:
  - Must consist of:
  - no more than a single sheet
  - on a page size no larger than journal page size
  - May be printed on one or both sides. If printed on both sides, this counts as 2 pages
  - Counts towards total advertising for a journal which is limited to 2 pages bearing advertising per product per issue.

- The Code states that any inserts or supplements which are promotional, but not advertisements as such, are not limited to two pages.

The distinction is not at all clear. One possible interpretation is:

- A report of a congress which is promotional only on the basis that it mentions a product, would not be considered an advertisement and would not be limited to two pages
- A report of a congress which 'actively' promotes a product e.g. where a company has had editorial input or control, would be considered an advertisement and would be limited to two pages.

Until this area is further clarified, careful judgement is required.

- The insert should be clearly distinguishable from editorial material. It should be clearly and obviously distinguishable from the rest of the journal, in both appearance and layout.

LINKED WEBSITE

Does the Code cover a linked site?

Whether or not a linked site is covered depends on

- The nature of the website
- The selection of the website
- The content of the website
- The purpose of the link
- The link itself

When is a linked site unlikely to be covered?

A linked site is unlikely to be covered by the Code, and a company is unlikely to be held responsible for that site if:

- the company has no input to or control over the linked site i.e. it is totally independent e.g. the website of a professional body or of a recognised patient group.
- the linked site is selected on the basis of quality, reputation et al
- The website contains no information about company products, or information only within an appropriate, general context .
- the link is provided as a resource to the reader
- the link is to the homepage of the website

When is a linked site likely to be covered?

A linked site is likely to be covered by the Code, and a company is likely to be held responsible for that site if:

- the company has some input to or control over the linked site
- the linked site is selected on the basis of relevance to the company or its products rather than on quality, reputation etc
- the website contains information about company products – particularly if the information forms a substantial part of the website or is very prominent on it
- the link is used as a means of adding weight to a company message
- the link is to a specific part of the website