The ABPI Code of Practice – common pitfalls for medical writers

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In this session ...

- Assume that you are familiar with the ABPI Code of Practice

- What are the common pitfalls?
  - Words
  - Layout

- This session gives a flavour and is not comprehensive training!
Before you start writing ...

- What are you writing?
  - Manuscript
  - Patient materials
  - Training materials

- 3 things to consider ...
1. Is it promotional?

- Fully Code compliant
- Certified by the pharmaceutical company
- Sales training materials
- Launch letter for a new medicine
- Promotional materials for Sales
2. Is it non-promotional?

- The pharmaceutical company will still want to check it is non-promotional

- Patient materials
- Materials for a non-promotional advisory board meeting
- Manuscript
3. How is it going to be used?

- Manuscript for journal
- Later given out pro-actively by Sales staff
- Non-promotional
- Promotional
Information, claims and comparisons
Information, claims, comparisons

- Information, claims and comparisons must be:
  - Accurate
  - Balanced
  - Fair
  - Objective
  - Unambiguous
  - Based on an up to date evaluation of all evidence
  - Reflect that evidence clearly
  - Materials must be sufficiently complete to allow recipient to form their own opinion

- Must not mislead
  - By implication
  - By distortion
  - By exaggeration
  - Undue emphasis
New male contraceptive Pill with no side effects

Wonder drug 'could cure breast cancer'

Viagra without the wait: Anti-impotence lotion that offers instant results and no side-effects

In tests, performed on rats, the new delivery method has proven successful in nine out of ten cases.
Banned words ... safe

- Cannot say:
  - No adverse reactions
  - No toxic hazards
  - No risks of addiction or dependency
  - Avoids a side effect .. or does not cause..
  - Avoid the words ‘safe’, ‘proven safety’, ‘demonstrated safety’, ‘placebo-like’

- Consider: generally well tolerated
A published paper

- Could Sales proactively give out this paper?

*NATURE REVIEWS CLINICAL ONCOLOGY* | RESEARCH HIGHLIGHT | IN BRIEF

LUNG CANCER

Nivolumab is a safe and effective treatment of NSCLC

Published online 10 March 2015
Watch out for

- Unique
- New
- Approved by the MHRA
- Our drug is better
- Hope for thousands
Watch out for

- Define your endpoints
  - Primary
  - Secondary
  - Composite
  - Exploratory

- Put secondary endpoint data in the context of the primary endpoints
Look and feel

Could the reader be misled by:

- Layout
- Font size
- Bold text
There are no direct clinical comparisons of Octasa 400mg MR and Asacol 400mg MR UK formulation
Graphs

- Ensure graphs don’t mislead and distort
  - Incompleteness
  - Suppressed zeros
  - Unusual scales
  - Clear labelling
  - Faithfully reproduced
  - Include patient numbers, not just %
  - p values, NS
  - Footnotes are not adequate – claim should stand alone

- Graphs can be modified to comply with SPC and Code
  - State they have been modified

- If a graph in a paper is misleading, it should not be used
Licensed for 5-15mg

Cases of renal toxicity

No. of cases

Dose given

0 5 10 15 20 25 30 35

5mg 10mg 15mg 20mg
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