

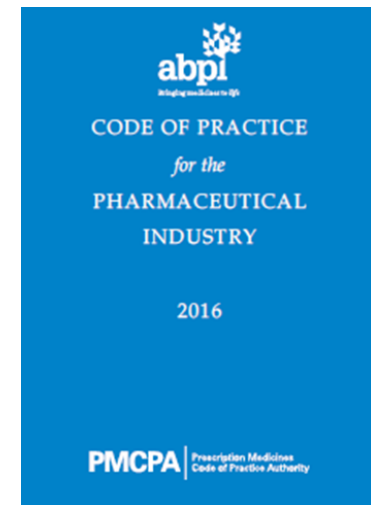


The ABPI Code of Practice – common pitfalls for medical writers

Jayne Packham

MedComms Networking Event 1 March 2017
www.MedCommsNetworking.com

Jayne Packham Consultancy
www.jaynepackham.co.uk

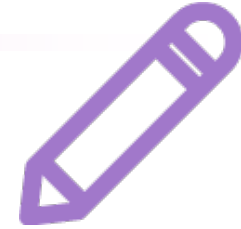


In this session ...

- 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 ...



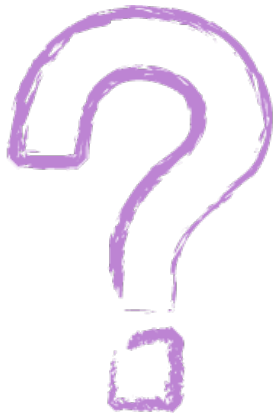
- What are you writing?
 - Manuscript
 - Patient materials
 - Training materials

- 3 things to consider ...



1. Is it promotional?

- Fully Code compliant
- Certified by the pharmaceutical company

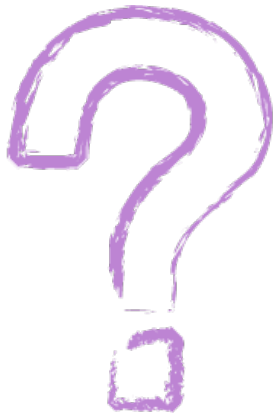


- Sales training materials
- Launch letter for a new medicine
- Promotional materials for Sales



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

Nature Reviews Clinical Oncology (2015) | doi:10.1038/nrclinonc.2015.48

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



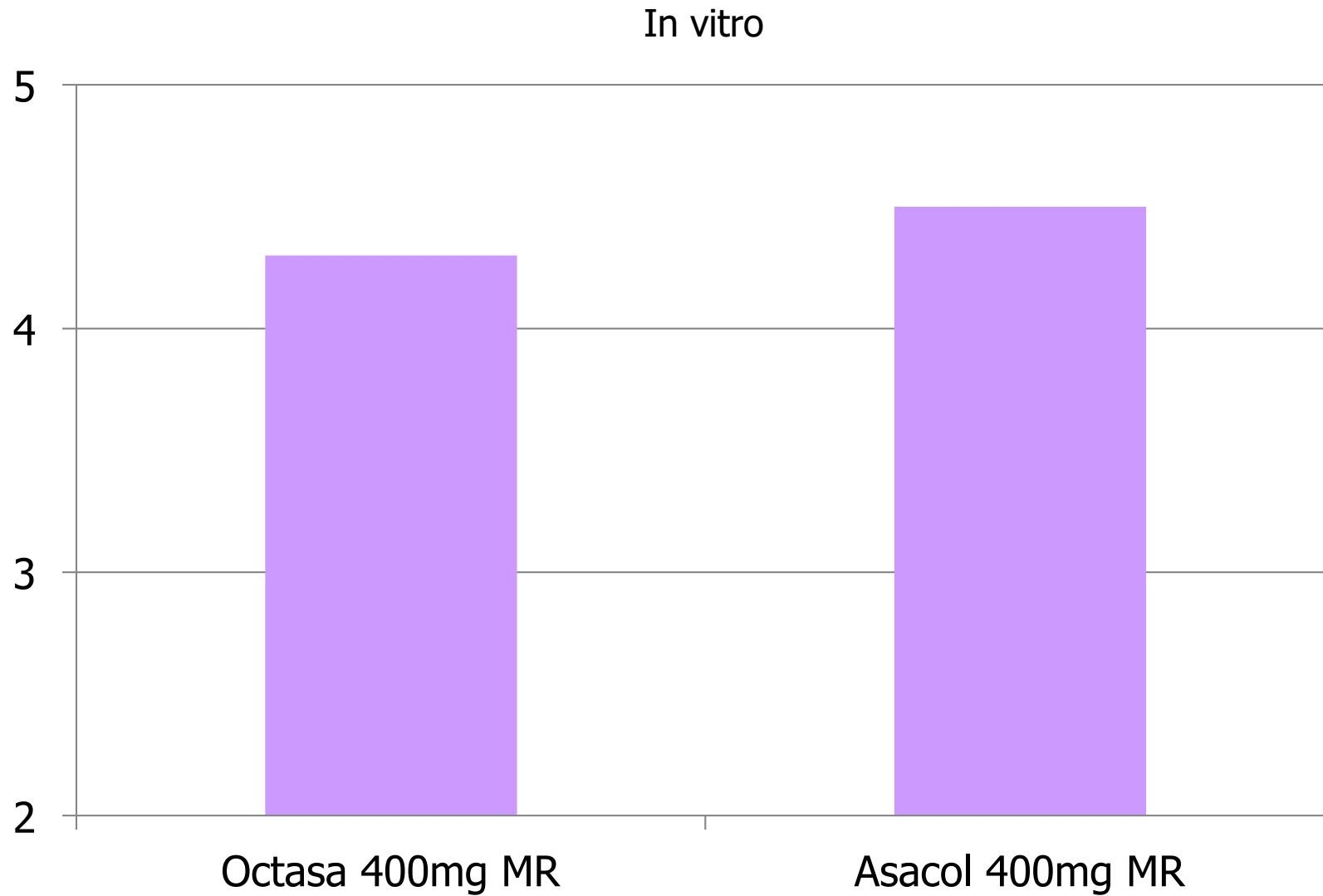
Look and feel

Could the reader be misled by:

- Layout
- Font size
- Bold text



Dissolution profiles



There are no direct clinical comparisons of Octasa 400mg MR and Asacol 400mg MR UK formulation

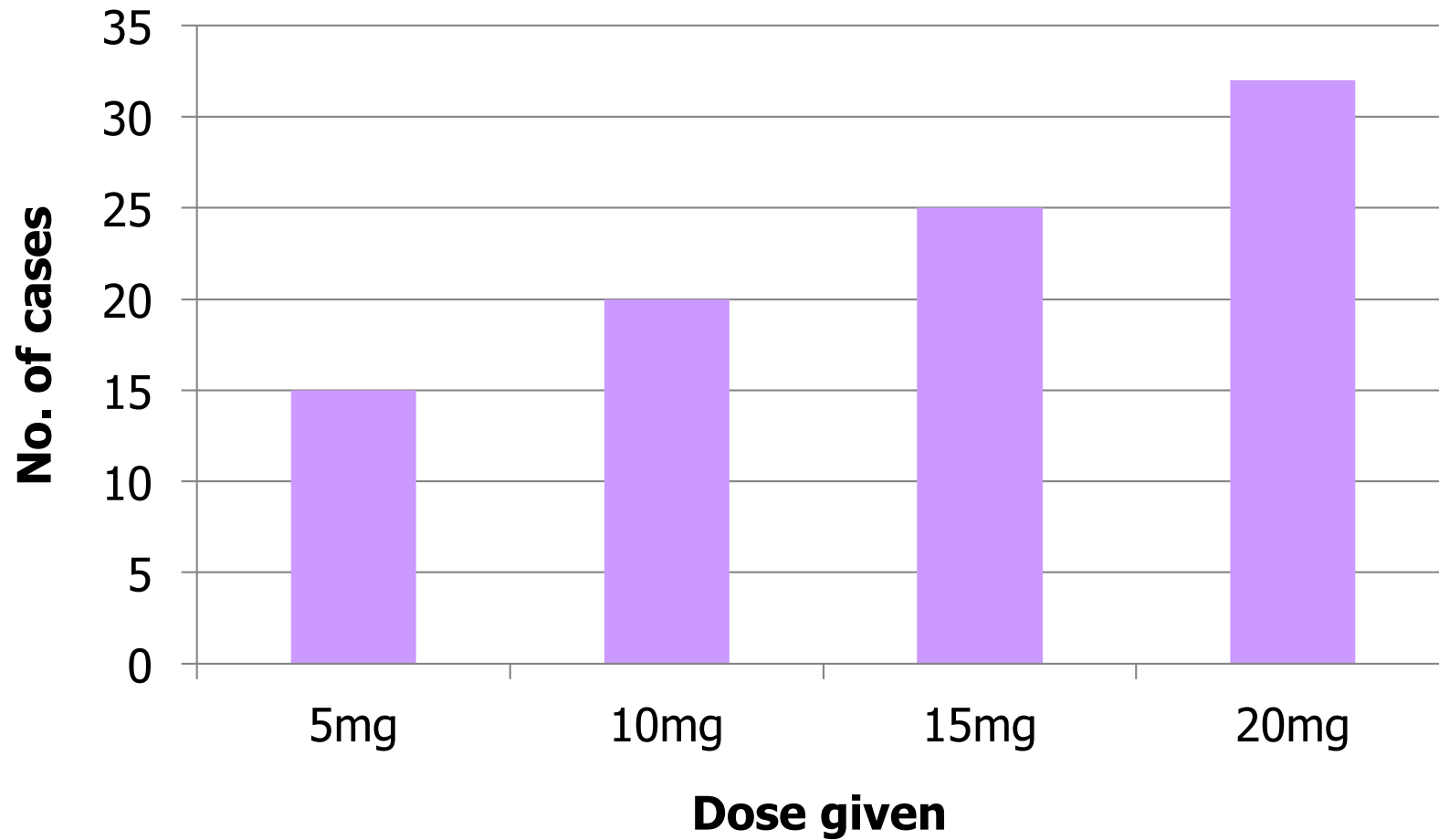
Graphs

- 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



Get in touch

- Bespoke in-house training
- Open 1 and 2 day courses
- Code up to date webinars

www.jaynepackham.co.uk

jayne@jaynepackham.co.uk

