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Pharma Websites and the ABPI Code

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Website Compliance



- ABPI Prescription Medicines Code of Practice Authority (PMCPA) Code in association with:
 - MHRA Blue Guide
 - PMCPA Guidance on Digital Communications
 - ABPI Pharmacovigilance Expert Network Guidance
 - PMCPA Code cases

Many learnings for Medical Communications

Improve awareness, confidence and competency

Facilitate innovation





Many challenges going online...

Technical Complexity

- Multiple digital platforms
- Hybrid content
- Search Engine
 Optimisation (linked, dynamic etc)

Other websites

- Mixed quality
- Unwieldy volume
- Actions/content beyond Company control

Commercial Expectations

- Impactful
- Efficient
- Progressive, modular

HCP/Patient Expectations

- Smartphone compatible
- Definitive source
- Immediate



CODE OF PRACTICE

for the
PHARMACEUTICAL
INDUSTRY

2016

PMCPA Prescription Medicines Code of Practice Authority

Macro approach

- 1 Scope, definitions
- 2 Professional
- 9 High standards, sponsorship
- 12 Disguised promotion
- 14 Certification
- 15 Representatives
- 16 Training
- 25 Scientific services
- 29 Undertakings

Content

- 4 PI / Obligatory info
- 5 Abbreviated ads
- 6 Journal ads
- 7 Info claims comparisons
- 8 Disparaging refs
- 10 Reprints, quotes

So much more than Cl. 28!

Scope

- 3 Marketing authorisation
- 11 Distribution
- 13 Clinical studies
- 17 Samples
- 28 Internet

Relationships

- 18 Giving
- 19 MEGS
- 20 Joint Working
- 21 Organisations
- 22 Meetings, sponsorship
- 23 Consultants
- 24 Transfer of Value
- 26 Public/media relations
- 27 Patient organisations



Clause 28 – in summary

(refer to full-text)

Short, high impact Clause Cross-ref to MHRA Blue Guide Few website Cases breaches Cl. 28



- Comply with all relevant clauses
- · Label with intended audience
- If access not limited to HCPs, must also have content for the public

28.2

• Scope if UK company or affiliate involved (publish, initiate, authorise) and refers to UK use or availability

28.3

• Cl 26.2 public information must be factual, balanced, not leading



Clause 28 – in summary

(refer to full-text)



- Independent journals may include adverts and be accessible to the public
- Prescribed medicines: label every page intended for HCPs

28.5

- SmPC, leaflets, public assessment reports, approved refs: non-promo style
- Sufficient information for the public
- Cl 13.1 clinical trial disclosure required

28.6

- Websites ownership, sponsorship to be clear
- Linked sites not necessarily in scope



MHRA Blue Guide



The Blue Guide

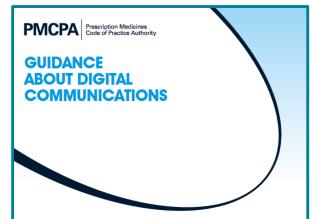
ADVERTISING AND PROMOTION OF MEDICINES IN THE UK

Third Edition
First revision - September 2014

- Sept 2014
- 5.10 / 6.3 / 7.5 + all relevant sections
 - Content must not contravene Regulations
 - No promotion of POM to public
 - Clearly labelled / separated area for HCPs vs patients vs public
 - Adequate non-promo content for public
 - Disease information
 - Selected documents
 - Press releases
 - Safety reporting

+ PMCPA Digital Guidance

- 2012, updated 2016
 - Intended audience must be clear
 - Any promotion must comply with the Code (restrict public access or label and provide alternative)
 - Social media / discussion forums OK if
 - exchanges are moderated
 - safety issues are reported
- If Pharma sponsors a site
 - Ensure full control <u>OR</u> arms length
- Staff activities = Company activities
 - Including third party agencies



INTRODUCTION

In the UK, the promotion of prescription medicines to health professionals is carried out within a robust regulatory framework to support high quality patient care. The ABPI Code of Practice for the Pharmaceutical Industry, administered by the Prescription Medicines Code of Practice Authority (PMCPA), is the self-regulatory code which applies, *inter alia*, to the promotion of prescription medicines to health professionals and to the provision of information about prescription only medicines to the public. The Code reflects and extends beyond UK law. This guidance reflects the requirements of the 2016 Code.

The pharmaceutical industry is highly regulated. In stark contrast, digital communication such as social networking sites, including Twitter, Facebook, Instagram, Wikipedia, Pinterest and WhatsApp, blogs and discussion forums, and other user generated content is largely unregulated. Indeed, for many other industries this can be part of the attraction for engaging in this way. The challenge is how these tools can be used by the pharmaceutical industry.

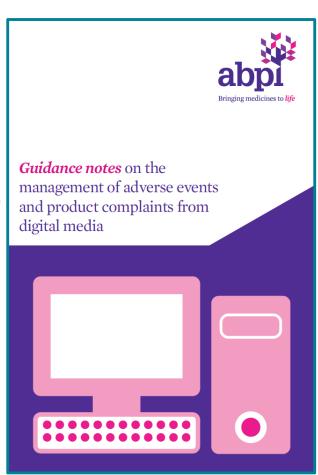
Pharmaceutical companies want, and indeed should be able, to use digital media. However, unlike other industries, which can promote their products to all, pharmaceutical companies are prohibited from promoting prescription only medicines to the public. Therefore, pharmaceutical companies need to identify ways of utilising digital communications whilst complying with this restriction. At the same time, companies must have policies and procedures in place to ensure that personal use of email, Twitter, all social media and the like by staff does not unwittingly lead to a breach of the Code.

Companies can use any method of communicating to any audience provided relevant requirements of the Code are followed.

+

Social Media Activities

- Listening, broadcasting or engaging in social media carries responsibilities:
 - Compliant to Code
 eg non-promotional, transparency, data privacy
 - Safety signals must be managed
- 2013: Pharmacovigilance Expert Network (PEN)
 - Responsible to screen own Company sites (daily)
 - Team training
 - Ensure timely processing of individual case safety reports
 - Observations on third party sites must report
 - Project with exit strategy



+ Illustrative Code Cases (1)

- Lincoln Medical 2924/12/16
 - UK distributor
 - Two UK Prescription Only Medicines named on website, with indication
 - No content for patients/public and no HCP-only access
 - Promotion to the public Breach 9.1, 26.1, 28.1

Care: Sufficient content for public or separation required

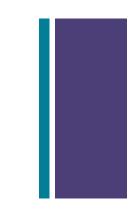
+ Illustrative Code Cases (2)



- Internal video certified final part of an internal communication package
- Advertising agency and third party production company actions
- Production company supplied shortened version to actor who posted to YouTube Breach 9.1, 26.1, 26.2
- Astellas 2912/12/16 Voluntary admission
 - 2 videos posted to Vimeo by ex-employee of agency Breach 9.1, 26.1, 26.2
 - l video to secure area of YouTube by agency no breach

Care: Promotion to the public
Pharma accountable for Agency actions
Reputation management: Trust? Future relationship?

+ Illustrative Code Cases (3)



- Roche 2927/1/17
 - Emotive coverage of progressive MS management
 - Media website far beyond Roche's acceptable press release No breach
- Allergan 2455/11/11
 - Employee Tweet referred to potential new use of prescription only medicine following press release
 - Breach 22.1 (= new 26.1), 9.1

Care: Follow-up of press releases
Accountability of Pharma assessed during Case ruling



Illustrative Code Cases (4)



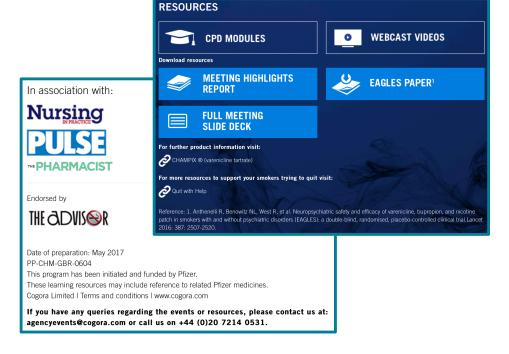
- Novo Nordisk 2890/11/16
 - Video exaggerated impact of medicine in patient area of website Breach 26.2
 - Lack of clarity of company involvement in booklet Breach 9.10
 - Delayed recertification of video Breach 14.5
- Stirling Anglian 2926/1/17
 - Content not maintained 'new' product > 2 years post launch Breach 7.11

Care: Transparency / clarity

Maintenance of content







- Pfizer 2931/1/17
- The Ultimate Stop Smoking Roadshow 2017 Breach 9.2, otherwise OK ['Ultimate' did not recognise the special nature of medicines and the professional standing of the audience]

Example of what can be achieved!



Application by Medical Communications

Many published cases → Enhance our knowledge

- Macro impression, balance
- Detail certification, choice of words
- Robust processes / contracts / publication controls are critical

With care, creative web initiatives are achievable

- Press releases even pre-license
- Disease awareness and vaccine promotion
- Medical Information services
- Modular interactive webtools



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