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

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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
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

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

So much more than Cl. 28!
Clause 28 – in summary
(refer to full-text)

28.1

• 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)

28.4
• 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

- 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 OR arms length
- Staff activities = Company activities
  - Including third party agencies

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Social Media Activities

- Listening, broadcasting or engaging in social media carries responsibilities:
  - Compliant to Code e.g. 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)

- Grünenthal - 2921/12/16 – Voluntary admission
  - 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
  - 1 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!

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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
To explore further...

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