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## Pharma Websites and the ABPI Code

Sarah Dunnett BPharm MRPharmS DipClinPharm FPIPA(Hons)  
Managing Director | Medical Operations Partner

# + 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

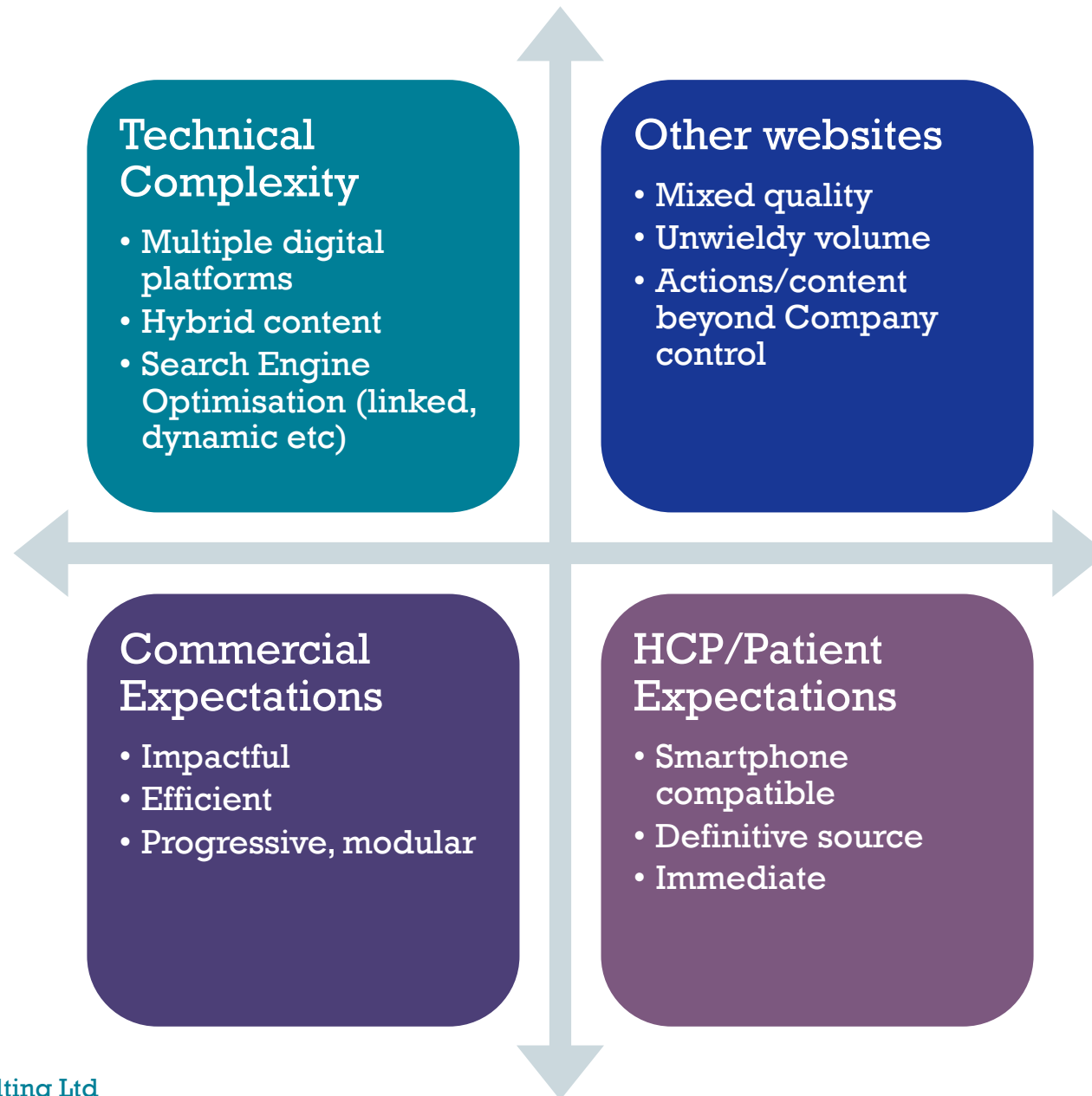
Many learnings for Medical Communications

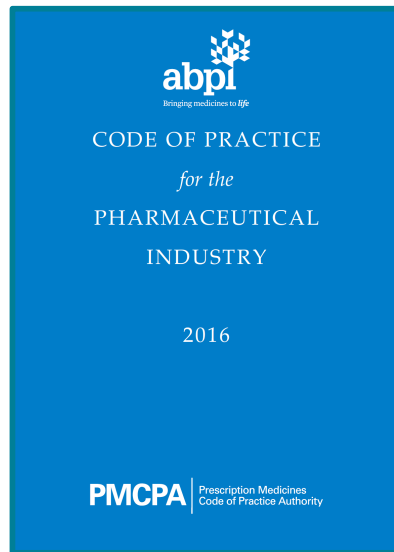
-  
Improve awareness, confidence  
and competency

-  
Facilitate innovation



# + Many challenges going online...





## 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 – MECS
- 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

## 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

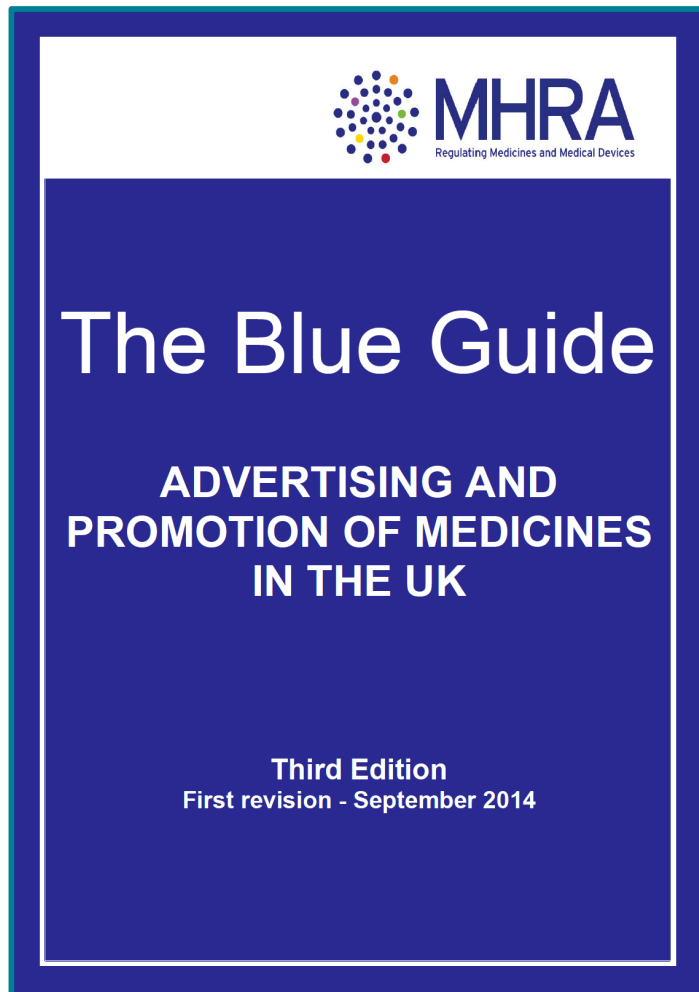
## 28.5

- 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

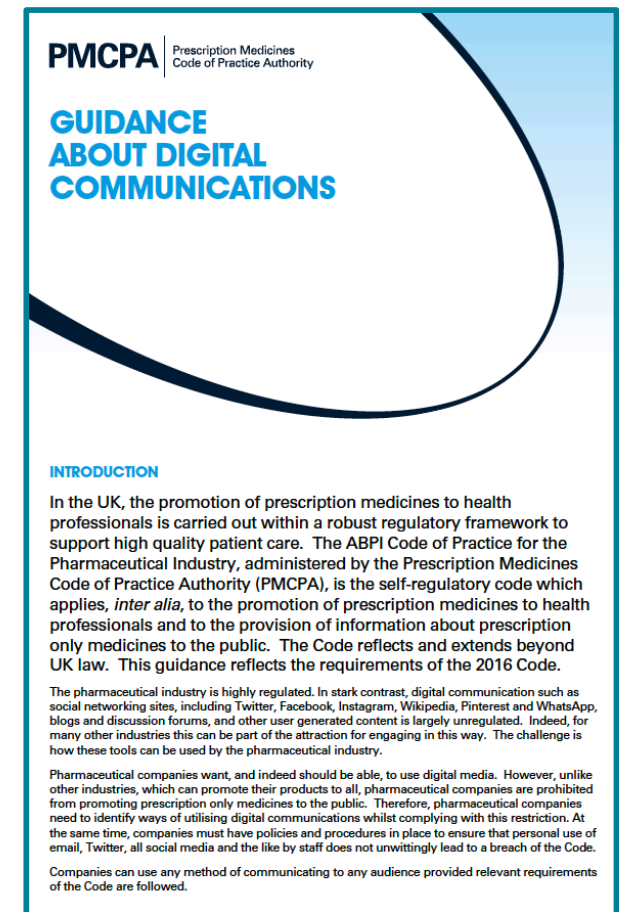
# + MHRA Blue Guide



- 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

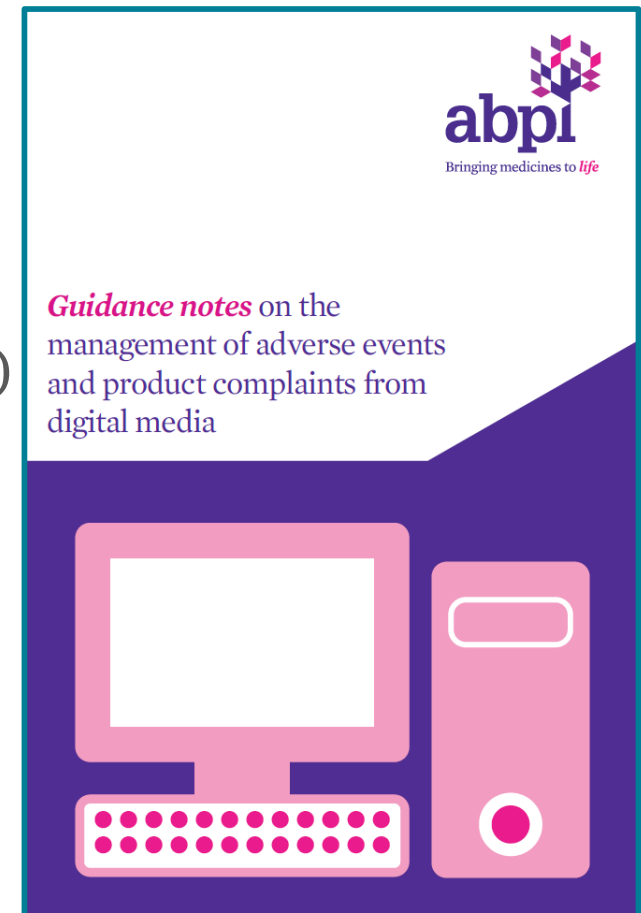
- 2012, updated 2016
  - Intended audience must be clear
  - Any promotion must comply with the Code (restrict public access or label and provide alternative)
  - Social media / discussion forums OK if
    - exchanges are moderated
    - safety issues are reported
- If Pharma sponsors a site
  - Ensure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





# + 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)



- 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

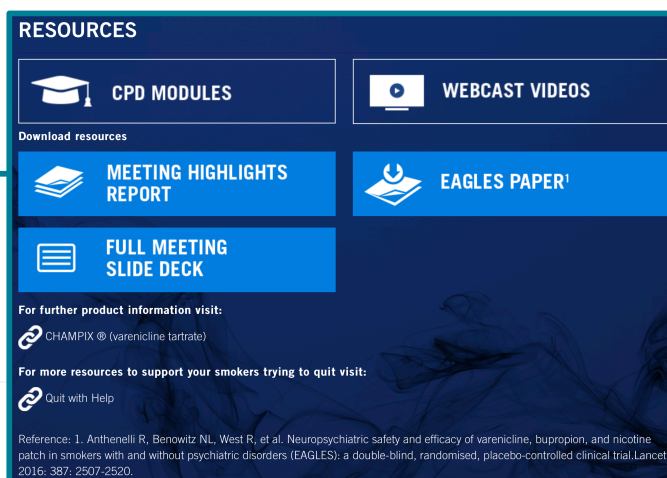
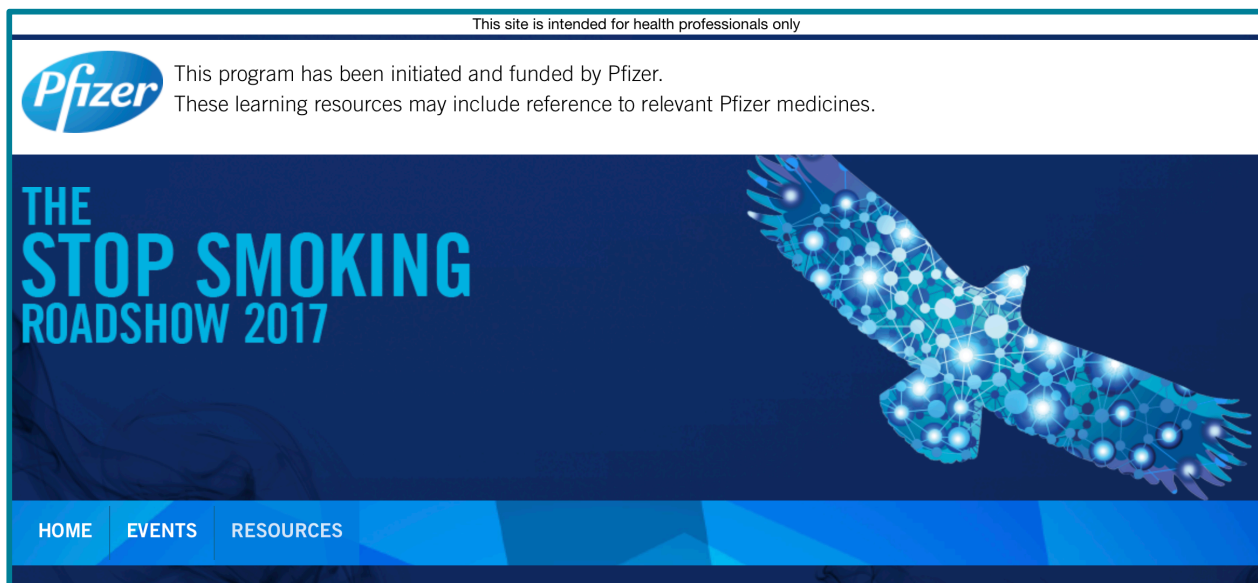
Care: Follow-up of press releases  
Accountability of Pharma assessed during Case ruling

## + 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 > 2years 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]

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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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[enquiries@sarahdunnett.co.uk](mailto:enquiries@sarahdunnett.co.uk)

[www.sarahdunnett.co.uk](http://www.sarahdunnett.co.uk)

linkedin: /sarahdunnett