Changes to the ABPI Code of Practice -

from a Medical Education & PR perspective

For Network Pharma members

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Working in partnership with

NetworkPharma

Background

- European (EFPIA) Code updated in 2007
- ABPI had to conform by 1st July
- Plus UK-specific changes
- Emphasis on changes in line with EFPIA Code:
  - *Promotion to* HCPs
  - Becomes *Interaction with* HCPs
- Key words for 2008:
  - Contracting
  - Transparency

Headlines for PR & Med Ed

- "Written Agreements" (Contracts) for all HCP service providers
  - Speakers
  - Media Spokespeople
  - Individuals & institutions
- Declarations of grants & service fees
- Publication of *details* of Patient Group support
  - Companies must *ensure* PG sponsorship declarations
- Public disclosure of all types of clinical research
- New client processes

Contracts

- All HCPs providing services to Pharma need a contract:
  - Advisory Boards
  - Speakers
  - Media spokespeople
  - Trainers
  - Market Research
  - Authors
  - Consultants
  - HCP organisations

Contracts: A single exemption

- Only one exemption allowed:
  - One-off remote market research with small honorarium
  - E.g. telephone-based interview / (e)mailed questionnaire

Contract details

- Contract must specify:
  - Service being provided
  - Basis for the Fee
- Companies are *"strongly encouraged"* to include in contracts:
  - Clause requiring the service provider to make appropriate declarations of interest

- (HCPs employed part-time by Pharma
  - Recommendation to tell NHS employers)

Services must be legitimate

- Services must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- A legitimate need for the service must be clearly identified
  - Chairpersons?
- Selection of service provider must be directly related to the need
- Service provider must be selected by the relevant company expert
- Number of service providers must be appropriate to the identified need
- Written contract signed before service commences

Records

- Must keep records about services provided

Fair Market Value (FMV)

- All payments at FMV
- Similar service = similar payment

Business Class Flights

- 'Hospitality offered to Service Providers must also comply with the "relevant provisions" of Clause 19'
  - E.g. Level of hospitality
  - Business class air travel is still allowed for Speakers & other service providers

Contracts with institutions

- Pharma can only engage the services of an institution for the purposes of:
  - Enhancing patient care
  - Benefiting the NHS whilst maintaining patient care
  - To conduct **research**
- Everything must be contracted & must comply with 18.4

Grants to institutions

- Donations, grants and benefits in kind to institutions:
  - Must comply with 18.4 or are for conducting research
  - Must therefore be Certified
  - Must be documented & kept on record
  - Must not be an inducement to prescribe, buy, sell, etc
- Companies are ‘encouraged’ to declare support publicly
- Companies are ‘encouraged’ to ask the institution to publicly declare the donation / service.
- Declarations on material should indicate the ***nature*** of support

Meetings: “out”

- Meetings must not be held at luxurious, *extravagant* or deluxe venues
- Sponsorship of entertainment is unacceptable

Meetings: “in”

- Quizzes, but only if:
  - Non-promotional
  - Test the learning gained at the meeting
  - No prizes
- Sponsorship statements must declare the ***nature*** of the support
- All Meetings connected with Planning, training & investigator meetings for both clinical trials & non-interventional studies
- Training courses
- Sponsorship of delegate places & travel grants
- Visits to research & manufacturing facilities

International events

Outside UK:

- State where each product is licensed
- State that licences vary from country to country
  - Except promotional aids

Inside UK:

- As for outside UK, *plus:*
- Promoted products must be licensed in major developed country
- A significant proportion of delegates must be from a country where the product is licensed.

Scope

- Now formally allowed:
  - Disease awareness
  - Market expansion
  - Joint working with healthcare institutions
- International journals:
  - home country is: where it is compiled, edited, typeset, printed and bound
  - not where the head office is located.

International advisory boards

- No change
  - Each country's rules apply for their own HCPs
  - Plus the country of the ad board itself
  - Plus the country of the organising Pharma team
  - But all based on EFPIA Code

Promotional Aids

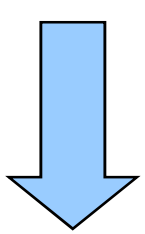
- Limit still £6
  - perceived value
  - Still has to be relevant to medicine
- Brand names in text books are ok

Mailings & announcements

- Same 8 per year limit:
  - Limit now excludes safety statements **and price changes**
    - As long as no promotional claims

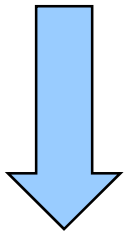
- Promotional E-mails not included
  - recipient gives permission to receive

Websites for HCPs



Password protection

OR



Separate section for patients

Only websites *intended* for the public need to comply with rules for patients (now clause 22)

Patient Groups (1)

- Now a stand-alone clause
- Guidance on content of written agreements:
  - Activity name
  - Names & roles of everyone involved (including suppliers)
  - Timeframe of project
  - Amount of funding / description of non-financial support
  - A statement that all sponsorship must be declared form the beginning
  - Reference to relevant Codes
  - Signatories
  - Dates of signing
- **Individual** Agreements should be Certified

Patient Groups (2)

- Hospitality must comply with Clause 19
- Can't *request* sole sponsorship
- Written permission to use Patient Group logos
- Must declare an annual list of PGs PLUS a **summary of the support** provided (>£500 value)
  - By 31 March 2009
  - At national or European level
- Companies must *ensure*:
  - sponsorship is declared
  - wording reflects the nature of the involvement.

PMCPA Guidance on patient statements (case studies)

- Patient case studies ok
- Everything said by company or patient about disease or treatment subject to the Code.
- Must choose ‘typical’ patients
  - I.e. Not those at the severe end of the disease spectrum or with an outstanding response to treatment.
- Patients can be paid if they have given up their own time to provide case study material to a company. Such payment should fairly reflect the time and effort involved.

Studies - public disclosure

- Companies must publicly disclose clinical trials.
  - All completed trials for products licensed for use in at least one country
  - Ongoing clinical trials
    - within 21 days of the first patient enrollment
- The public statements must not be promotional.
- NIS Study results must be analysed & reports made available ‘within a reasonable time’ to the company scientific service & sent to all HCPs who participate
- Publication of NIS involving marketed medicines is encouraged and ideally in a similar manner as for clinical trials.
- More information at http://clinicaltrials.ifpma.org

NIS rules

- Mandatory for proactive NIS
- Are ‘encouraged’ for all other types of NIS,
  - Registries
  - Epidemiological
  - Retrospective NIS
  - etc
- Apply to all studies completed after 1st July
  - (and ideally should be applied immediately).

Disguised promotion

- Disguised Promotion includes:
  - post-marketing experience programmes
  - all post-authorisation studies
    - Prospective or retrospective.
- In addition to existing list:
  - market research
  - clinical assessments, etc
- Sponsorship statements must declare the **nature** of support

Adverse event reporting

- “Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to (company name) on xxxxxxxx.”
- A telephone number or email address can be included.
- Text should be prominent and ideally be larger than that in the PI itself.
- Black triangles are now mandatory

Clause Re-reordering

Subject	2006 clause no.	2008 Clause no.
Reprints	11	10
Material Distribution	12	11
Disguised promotion	10	12
Non-interventional studies	NEW	13
Use of consultants	NEW	20
Scientific Service	13	21
Patients	20	22
Patient Groups	NEW	23
Internet	21	24
Breach of undertaking	22	25

Implementation Dates

- Code effective from 1st July 2008
- New material must comply from 1st July
- Existing materials must comply by 1st November
- New AE statement:
  - New materials must have new AE statement by 1st November
  - Existing materials must be updated to new AE statement by 1st July 2009
- New Patient Group reporting by 1st March 2009

Other implications for your clients

- Companies must take ‘reasonable steps’ to ensure that licensees and partners in joint ventures, etc, comply with the Code

- UK should remind Global teams that the UK Code applies to UK HCPs

Other implications for your clients

- Electronic certification
- Samples
- Therapy Reviews
- Representative call rates

Other implications for your clients

- Changes to constitution such that:
  - PMCPA do not *Investigate*
  - Companies must submit ‘complete response’
  - Anonymous complaints may not proceed
  - Media coverage will!
  - Interim publication of lengthy cases
  - Public reprimands in Nursing press

Thank you for listening - any questions?

www.stevengrayconsulting.co.uk

Compliance support for the pharmaceutical industry
(Including training, training material, audits & template policies)

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