Changes to the ABPI Code of Practice -
from a Medical Education & PR perspective

For Network Pharma members
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 from 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

<table>
<thead>
<tr>
<th>Subject</th>
<th>2006 clause no.</th>
<th>2008 Clause no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reprints</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Material Distribution</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Disguised promotion</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Non-interventional studies</td>
<td>NEW</td>
<td>13</td>
</tr>
<tr>
<td><strong>Use of consultants</strong></td>
<td><strong>NEW</strong></td>
<td>20</td>
</tr>
<tr>
<td>Scientific Service</td>
<td>13</td>
<td>21</td>
</tr>
<tr>
<td>Patients</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>Patient Groups</td>
<td><strong>NEW</strong></td>
<td>23</td>
</tr>
<tr>
<td>Internet</td>
<td>21</td>
<td>24</td>
</tr>
<tr>
<td>Breach of undertaking</td>
<td>22</td>
<td>25</td>
</tr>
</tbody>
</table>
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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