The ABPI Code: What is it? Why does it matter?

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Managing Director
CompliMed
This presentation aims to address the following questions:

1. What is the ABPI Code?
2. Who does the Code apply to?
3. Where does the Code apply?
4. Where do other Codes apply?
5. How does this affect meetings?
6. Consequences of getting it wrong...
Key definitions: What is the ABPI Code?

- The **Code** is used by the UK Pharmaceutical Industry to **self-regulate activities**.
- It is enforced through a **complaints** system.
- It is administered by the **PMCPA** (Prescription Medicines Code of Practice Authority), **at arm's length** from the **ABPI** (Association of the British Pharmaceutical Industry).
- The **MHRA** (Medicines and Healthcare Products Regulatory Agency) is a government body that **regulates medicines**.
- The **SFO** (Serious Fraud Office) is a government body that **administers the UK Bribery Act**.
Regulation of UK Pharmaceutical Industry

Pharmaceutical Companies

Government regulation

- MHRA
- BLUE GUIDE
- BRIBERY ACT

Failing to comply with regulations can result in the MHRA imposing criminal sanctions (as well as civil) e.g. Fine and/or imprisonment.

Criminal law relies on proving a breach “beyond reasonable doubt”.
Regulation of UK Pharmaceutical Industry

Pharmaceutical Companies

Self regulation

Self-regulation is conducted through the industry’s own representative body. The PMCPA enforce the Code and have an arm’s length relationship with the ABPI. Self-regulation operates according to civil law i.e. demonstrating “balance of probabilities”.

ABPI

Bringing medicines to life

PMCPA

Prescription Medicines Code of Practice Authority

CompliMed Ltd.
Regulation of UK Pharmaceutical Industry

Pharmaceutical Companies

Self regulation

Government regulation

abpi

MHRA

SFO

BLUE GUIDE

BRIBERY ACT

PMCPA

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Who adheres to the Code?

- ABPI members **must** abide by the letter and spirit of the Code.
- ABPI non-members may give formal agreement to abide by the Code and accept the jurisdiction of PMCPA.
- The Code encompasses requirements of UK, International and European regulations and codes.
There are three EFPIA Codes

- **Existing** EFPIA Code on the Promotion of POMs to, and Interactions with, HCPs.
- **Existing** EFPIA Code on relationship between the pharmaceutical industry and patient organisations.
- **New** EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and HCP Organisations.
What is the ABPI Code?

 требуется
 New version will be enforced from 1 May 2014
What happens if a company breaches the Code?

- All breaches incur a financial penalty, usually per clause
- Most serious sanction is expulsion from the ABPI

If a company brings discredit upon and reduces confidence in the industry, this is published in the medical press and incurs a higher penalty - this can affect reputation and be picked up by consumer press.
Case Example: Case/AUTH/1682/2/05 & 1683/2/05
GP & Media/Director v AstraZeneca

“Well maintained @Loch Lomond”
Case Example: Case/AUTH/1682/2/05 & 1683/2/05
GP & Media/Director v AstraZeneca

PMCPA comments:

- Five hours of education could be held on one day without the need for overnight accommodation.
- ‘Well Maintained @ Loch Lomond’ compounded the impression of substantial hospitality.
- Hospitality offered was not secondary to the main purpose of the meeting.
- Delegates would be attracted by the prestigious spa venue and not the educational content.
“Drug giants court NHS nurses with luxury hotel breaks”

NHS nurses have been invited on luxury trips to four and five-star hotels by pharmaceutical firms..

The Sunday Times, 27 Feb 2005
Who does the Code apply to?
The Code applies to interactions with the following groups:

**Health professionals**, administrative staff, patients and the public.

Dr, dentist, pharmacist, nurse or anyone else who prescribes, supplies or administers, purchases or recommends medicines

Those prescribed a company product

Includes journalists

Examples include NHS business managers, procurement, finance and practice managers
Companies are responsible for third parties that act on their behalf...

This includes external agencies

* e.g. Advertising agencies, PR agencies, Print Buyers, Mailing Houses, Market Research Companies, Contract Clinical Research Organisations, Medical Education Providers, Contract Representatives, Events companies, Meeting Organisers...
Case Example: Case AUTH/2612/6/13
Anon v Gedeon Richter

- Two tweets were sent by an events company on behalf of Gedeon Richter for a forthcoming meeting.
- One of them promoted a prescription only medicine to members of the public.
- Gedeon Richter were ruled in breach of the Code.
Where does the Code apply?
Where Does the UK Code Apply?

❖ Material & activities directed towards a UK audience?

OR

❖ Material & activities which are undertaken by a UK company?

OR

❖ Material used and activities taking place in UK?
Which other Codes apply?

- Overseas Company activities/materials must comply with
  - national code of organising Company country AND
  - national code of the country in which the activity/materials used

- If EU country has no national code, then EFPIA is used.
Example

- If Company based in Switzerland, organises a meeting for international delegates in Spain the following Code apply:
  - Swiss
  - Spanish
  - Country Codes for each delegate
Case Example: Case AUTH/2469/12/11
Bayer Voluntary Admission

- Bayer Global symposium at international congress
- Their invitation promoting Levitra (vardenafil) had not been certified by the UK, did not require technical information, and had been sent in transparent envelopes to UK recipients, some of whom were not health professionals.
- Bayer UK were held in breach of the UK Code.
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<thead>
<tr>
<th>Country</th>
<th>Code Name</th>
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<tr>
<td>Impression</td>
<td>Appropriate</td>
<td>Appropriate</td>
<td>Professional</td>
<td>Appropriate balance between duration of educational content/hospitality provided</td>
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<tr>
<td>Purpose</td>
<td>Scientific/educational event</td>
<td>Job related/science orientated event</td>
<td>Scientific/educational</td>
<td>Educational. Directly related to HCP area of expertise.</td>
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<td>Accommodation</td>
<td>Reasonable, related and limited to scientific/objective of event</td>
<td>necessary accommodation</td>
<td>Only to faculty HCPs</td>
<td>Reasonable accommodation expenses, appropriate for time, duration of meeting &amp; origin of delegate.</td>
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<td>Venue</td>
<td>Reasonable, related and limited to scientific/objective of event. Not recreational, extravagant, eccentric</td>
<td>Not extravagant or known for entertainment value.</td>
<td>Appropriate as judged by conference/meeting organisers</td>
<td>Justified and support provision of education.</td>
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<td>Travel</td>
<td>Reasonable, related and limited to scientific/objective of event</td>
<td>Economy if in Europe, business class if intercontinental</td>
<td>Only to faculty HCPs</td>
<td>Economy or business travel.</td>
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<td>Subsistence</td>
<td>Reasonable, related and limited to scientific/objective of event Not exceed 60 Euros. No gala dinner or concerts.</td>
<td>Breakfast with accommodation. 60 Euros, if outside Germany refer to local limits</td>
<td>Modest meals as judged by local standards</td>
<td>Secondary to educational content. Meals &amp; beverages appropriate for educational content, duration of meeting &amp; not excessive</td>
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<td>Sponsorship</td>
<td>Preliminary programme available &amp; accessible at least 6 months and finalised a month before congress. Registration fee must be reasonable, related and limited to scientific/objective of event. No entertainment,</td>
<td>Participation fees. Only if link to company activities and expertise of event participant is provided. No entertainment. Truly international meeting</td>
<td>Payment only to conference’s sponsor to reduce overall registration fees. No payment for attendance. Must not include entertainment</td>
<td>Conducive to informational communication. No payment for attendance. Must not include entertainment</td>
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UK requirements: Which areas need to be considered for meetings?
<table>
<thead>
<tr>
<th>Meetings Checklist</th>
<th>Which areas need to be considered?</th>
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<tr>
<td></td>
<td>❑ Purpose</td>
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<td>❑ Organiser / partner / sponsor</td>
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<td>❑ Sponsored meetings</td>
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<td>❑ Invite / agenda</td>
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<td>❑ Other materials</td>
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<td>❑ Speakers / chair</td>
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<td>❑ Fee-for-service / written agreements</td>
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<td>❑ Payments</td>
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<td>❑ Audience</td>
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<td>❑ Topic</td>
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<td>❑ Educational content</td>
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<td>❑ Venue</td>
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<td>❑ Accommodation</td>
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<td>❑ Exhibition stands</td>
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<td>❑ Promotional aids</td>
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<td>❑ Travel</td>
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<td>❑ Subsistence</td>
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<td>❑ Declarations of involvement</td>
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<td>❑ Outside UK</td>
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<td>❑ Applicability of Codes</td>
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<td>❑ Promotion at International Meetings</td>
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<td>❑ Advisory Boards</td>
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<td>❑ Rep briefings</td>
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<td>❑ Local policies</td>
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<td>❑ Overall Impression</td>
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<td>❑ Certification / Examination</td>
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<td></td>
<td>❑ Disclosure</td>
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Thank you

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