



European Codes of Practice

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DIA Workshop

- Regulation and self-regulation of marketing and sales activities
- 16 and 17 May – Vienna, Austria
- Chair persons:
 - Richard Bergstrom, LIF, Sweden
 - Richard Laing, WHO, Switzerland
 - Paul Wood, AstraZeneca, UK



Regulation and self-regulation

- Control of marketing and sales activities
 - One of most important and topical compliance areas
 - Companies under intense scrutiny
 - Compliance in this area receiving large amounts of resource and investment
 - In companies and regulatory agencies



Glossary

- WHO: World Health Organisation
- IFPMA: International Federation of Pharmaceutical Manufacturers and Associations'
- EFPIA: European Federation of Pharmaceutical Industries and Associations'



EFPIA

- 2005 – EFPIA Code revised
- All 29 European national codes were revised
- Changed provision relating to hospitality



. . . future

- Proposals being developed relating to public communications by 2007
- Regulators' activities are being examined and expanded
- European companies and regulators also have to keep up with developments outside Europe including those in developed world and the USA



IFPMA

- IFPMA Code undergoing review
- Internet brings particular challenges



DIA – participants/speakers

- WHO
- IFPMA
- EFPIA
- European Commission
- European Patient Forum
- National regulators / Code bodies
- Pharma companies
- Lawyers



Speakers

- WHO, IFPMA, EFPIA
- European Commission
- Regulators
- National Codes
- Pharma companies
- Lawyers
- Patient group



Introduction

- 1st DIA meeting on subject
- 2 partners: industry and prescribers
- Prescribers have been ignored
- Need to look at ethical interaction with prescribers
- Delicate balance between regulation and self-regulation



1989

- Codes came from anti trust laws
- Marketing practice big issue at WHO
- Too many drugs
- No promotion in developing countries
- AIDS changed things – no drugs available
- No longer promotion, but access is issue



2006

- Many ethical issues
- Promoting better access among disadvantaged
- Pricing issues
- Public clinical trial registration
- Licensing of patents
- Enforcement of patents
- Corporate public responsibility



Evolving issues

- Keeping prescribing up to date
- New technologies
- Greater transparency
- Globalisation of pharma industry
- Indian and China emerging as large generic players



Evolving issues - 2

- Marketing codes don't apply to large segment of pharma industry
- IFPMA regulates RoW
 - Not those countries/areas where well developed Codes are already in existence



IFPMA

- Code revisions recent
- Need for universal standards of promotion
- New IFPMA Code due January 2007



Sanctions

- Primary sanction is publicity
- IFPMA not able to enforce
- Enforcement via local Code, if available
- If no local Code or not up to IFPMA standard then IFPMA Code leads
- IFPMA will be having discussions with HCPs – need ethical standard for pharma industry – need for level playing field



IFPMA

- Pharma industry has bad name
- New Code – 1 January, 2007
- Relates to Associations and Companies



IFPMA Code

- No self-standing social activities
 - Global ban!
- No foreign travel unless truly international meeting
- Venues – not only meetings we sponsor/organise
 - Also those we sponsor HCPs to attend!



IFPMA Code - 2

- IFPMA website will clearly state which markets are governed by their own Codes and which by IFPMA
 - EFPIA website gives national Codes
- Challenge: getting smaller markets to comply
- Need to raise standards everywhere



EFPIA

- Founded 1978
- 28 National Association members
- 44 direct company members
- 10 association member companies
- 2 sub-groups
 - Vaccines
 - Emerging biotech



EFPIA Code

- New Code implemented – 1 January, 2006
- No direct applicability
 - via Associations, ie PMCPA in UK
- New Code – more legal in style
- Strictiest Code always applies



HQs must keep local offices
informed and abide by their
Code !

European Commission

- Directive 2001/83/EC
- Member states have responsibility for ensuring Directive is enforced
- No DTC advertising
- Need for compliance with SmPC
- Recognise single licence = 25 markets = 25 national systems



A lawyer's view

- Enforcement of law is national issue
- Individual countries have their own marketing laws
- Internet still too difficult
- Law and regulation becomes academic unless enforcement happens



Country specific

UK – MHRA – Pre-vetting

- Unlikely to be more than 50 per year
- Staff increased from 15 to 30
- New active substances
- Niche/busy markets, ie contraceptives
- New population/indications, ie children
- Safety concerns
- Not intended to delay launch
- Not there to test boundaries



UK - PMCPA

- Non member companies usually abide by the Code
- Companies have their own Codes too
- New Code
 - Lots of calls re meetings
 - More patient centred



Sweden

- Self regulation since 1969
- No advertising of POMs until 1 May, 2006



Germany

- Competition proceedings lead to law suits, which lead to civil court proceedings
- Quick decisions – 24 hours
- 15,000 to 20,000 cases per year



Spain

- Code also available in English
- Spanish pharma industry cannot promote in Spain even if MA in another country
- Surveillance Unit actively monitors Code
- Up to 360,000 Euros for sanctions
- Meetings
 - Suitability of venue
 - Scientific content



Austria

- No support for congresses outside Austria
- Accompanying persons not welcome
- No gifts
- No documentation – no payment
- Sanctions
 - Include informing company's HQ
 - Fines 20,000 to 100,000 Euros



Example



Example

- Swedish company wanting meeting in Spain
 - No licence in Spain – no promotion!
- Both Swedish and Spanish codes apply
- Local subsidiary must be notified
 - Swedish affiliate must inform Spanish affiliate!



- If no local office
 - Check with Spanish national association
- Strictest Code always applies



Strictest Code

- Big issue
- Check with local affiliate
- Look at strictest Code
 - Usually UK!



Check list

- Local Company SOP
- Global Company SOP
- National Code
- EFPIA Code
- IFPMA Code
- WHO Ethical Criteria