

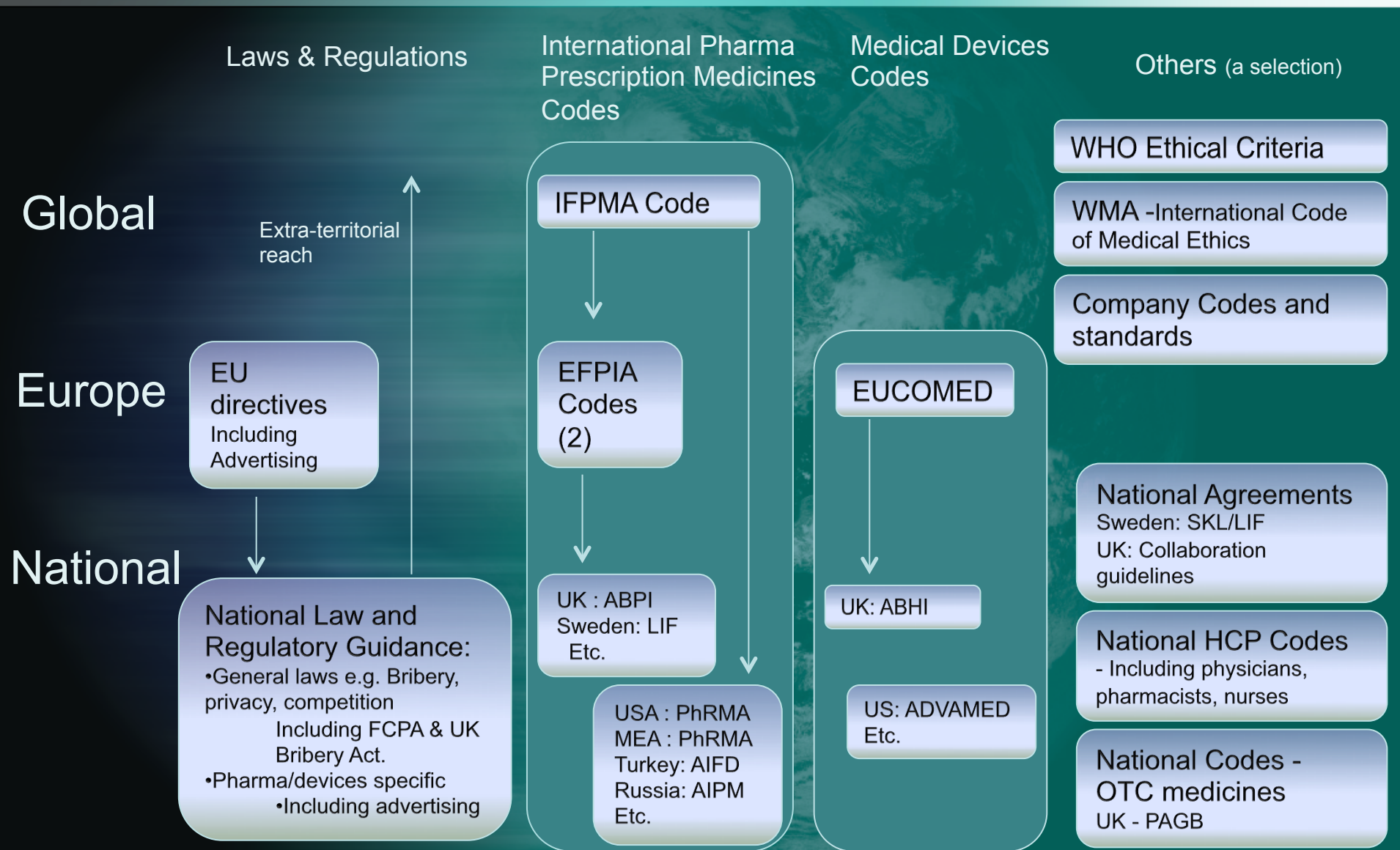
What's new in compliance? What's coming soon?

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Overview

- IFPMA Code
- ABPI Code
- ABPI /PMCPA Initiatives
- USA & Europe
- What might be coming in the future?

Codes and Regulations – a jigsaw puzzle



N.B. This overview identifies some major standards but does not aim to be comprehensive

New IFPMA Code of Practice



- Global implementation: 1st September 2012
- Title change and expanded scope to cover all interactions with HCPs, medical institutions and patient organizations
 - Fees for Services: Consultancy, market research, advisory boards, etc.
 - CME: New general statement supporting continuing medical education which must be educational in nature, fair and balanced
 - Interactions with Patient Organizations: Including scope, definition, declaration of involvement and restrictions on events
- Prohibition of secondary entertainment
- Samples may only be provided to HCPs authorized to prescribe that product
- Transparency - Companies will disclose clinical trial information
- New high-level guiding Principles that speak to the 'spirit' of the Code

IFPMA Code - Guiding Principles Values (and rules)

- 1** The healthcare and well-being of patients are the first priority for pharmaceutical companies.
- 2** Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
- 3** Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
- 4** Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
- 5** Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
- 6** Pharmaceutical companies will respect the privacy and personal information of patients.
- 7** All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
- 8** Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.



New ABPI code

- Second 2012 code
 - into effect 1 July
 - transitional period until 1 November 2012
- As a result of
 - Consolidation of the UK regulations (The Human Medicines Regulations 2012 due to become law on 2 July)
 - Changes to the IFPMA Code

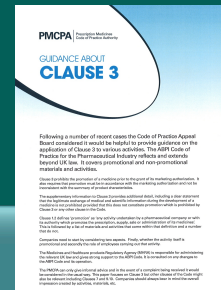
New ABPI code: Changes worth noting

- Most changes are of no great significance
- Definition of 'promotion' changed:
 - Was: “ ... promotes the prescription, supply, sale or administration ...
 - Now: “.. Promotes the administration, consumption, purchase, prescription, recommendation, sale, supply or use ...”
- Definition of HCP broadened to include:
 - “ ..purchase or recommend” a medicine
- Changed URL for ADR reporting
- Changed abbreviated ad statement
 - Information now on a website
- Starter packs now banned
- Patient organisation support
 - Cannot require to be sole sponsor of ANY (previously any major) programme

Other ABPI/PMCPA initiatives

- Clause 3 Guidance
- Ethical Standards in Health and Sciences Group
- Digital Communications Guidance
- Memorandum of understanding – ABPI / SFO

ABPI Code Clause 3 Guidance



- No Promotion before receiving the Marketing Authorisation;
- Promotion must be in accordance with the MA and not inconsistent with the SmPC
- The legitimate exchange of scientific information during the development of a medicine is not prohibited

- Consider the activity itself AND the role of employees (especially Medical Liaison roles)
- The proactive provision of information on unauthorised uses is likely to be classed as promotion
 - Includes invitations to ask on exhibition stands
 - But not 'on-subject' responses to a unsolicited, specific enquiries from HCPs - including letters in medical journals

ABPI Code Clause 3 - Advance Notification

Limited proactive activities before a MA grant to assist the NHS with financial planning

- Relates to NHS needs 2-3 years before launch
 - For changes that may significantly affect their expenditure (+ or -)
 - Likely cost/budget implications must be indicated
- Product must be novel
- Information directed at policy makers on budgets
- Information must be factual and limited

Ethical standards in Health & Life Sciences group

- “Guidance on collaboration between HCPs and Pharmaceutical Industry”
- Core Principles
 - Collaboration benefits patients
 - Relationships can be managed without compromising clinical decisions
 - Robust Law and self regulations ensure high ethical standards
- Facts: 10 things you should know
- Dos and Don'ts for HCPs and for pharma



Digital Communications Guidance

- PMCPA Digital Media guidance (April 2011)
- Draft FDA guidance on off-label responses (Dec 2011)
- Digital working group
- Cases reinforce message:
 - Compliance requirements for digital same as other communication channels

ABPI – SFO memorandum of understanding

- UK Bribery Act - Headlines

- Offences

- Offering, promising or giving of an advantage,
 - Requesting, agreeing to receive or accepting an advantage
 - Discrete offence of bribery of a foreign public official
 - New offence of failure by a commercial organisation to prevent a bribe being paid for or on its behalf.
 - a defence if the organisation has adequate procedures to prevent bribery

- Important Question: How does this affect currently acceptable practices relating to HCP support and contracting?



ABPI – SFO memorandum of understanding

**MEMORANDUM OF UNDERSTANDING BETWEEN
THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY,
THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY AND
THE SERIOUS FRAUD OFFICE**

Introduction

The Association of the British Pharmaceutical Industry (ABPI) and the Prescription Medicines Code of Practice Authority (PMCPA) are committed to ensuring that patients and the public benefit from appropriate use of medicines as part of the provision of high quality healthcare. The promotion of medicines for prescribing to health professionals and other interactions that the pharmaceutical industry undertakes that lead to, or are related to, the use of medicines are carried out within a robust regulatory framework to maintain patient safety and public health.

The arrangements in the United Kingdom for the regulation of the promotion of medicines for prescribing and interactions with health professionals are subject to two complementary systems of control, self regulation by the pharmaceutical industry by means of the ABPI Code of Practice for the Pharmaceutical Industry, administered by the PMCPA, and UK law. The advertising law is administered by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the UK Health Ministers. The control of medicines advertising in the UK is thus based on the long established system of self regulation supported by the statutory role of the MHRA. The relationship between the MHRA, ABPI and PMCPA is set out in a memorandum of understanding.

- “The SFO values self regulation by the pharmaceutical industry. This self regulation has worked well to date and is supported both by legislation and the memorandum of understanding with the MHRA.”
- “The SFO will be consulted in future over prospective changes to the ABPI Code.”



WHAT IS HAPPENING IN THE USA & EUROPE?

Transparency in the USA

Physician Payment sunshine Act

- Law 2010 - Aim is transparency in financial relationships between industry and physicians
- It requires yearly reporting to HHS of all physician and teaching hospital payments over \$10 or cumulative value of \$100 dollars
- CMS delayed the implementation until 2013

Transparency Laws in Europe

French Sunshine Act – draft Dec 2011

- Broader scope & different disclosure process than USA
- Privacy issues

Rest of Europe – an evolving picture

- Country by country
- E.g. NL proposals

EFPIA – Transparency requirements

- Companies are encouraged to make available publicly information about donations, grants or benefits in kind
- Companies are encouraged to include in contracts with HCPs obliging them to declare that they are consultant to the company whenever he/she writes or speaks in public
- Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support

Other change in France

- Result of the “Servier –Mediator case”
- AFSSAPS reorganised to ANSM
- Change to mandatory prior authorisation of advertising to HCPs
 - 4 submission dates in the year
 - Currently unclear if it applies to International congresses (IC)
 - Many companies decided not to submit if materials for IC in English

Two European Conference vetting schemes

Pharmaceuticals

- E4Ethics (www.efpia-e4ethics.eu/)
 - Operational
 - Also site visits

Devices

- Eucomed
 - Pilot phase
 - Will be mandatory

Recent European Court of Justice conclusions (in my own words)

Damgaard (February 2010)

- Dissemination of information by independent third parties not excluded from the EU definition of advertising.
- So - Information from journalists (and patients associations etc.) could be considered as advertising prescription medicines

ABPI v MHRA (April 2010)

- Personal incentives to prescribers to prescribe certain medicines are not a breach of the advertising regulations if they come from health authorities
- Incentives from companies remain illegal

MSD: SmPC on websites (May 2011)

- Unadulterated SmPC is not advertising
- Intent, content and practical impact are important in deciding what is and is not advertising
- Just because it comes from a company doesn't mean it is advertising.
- 'Push' is different from 'pull'; passive websites do not push.



WHAT MIGHT BE COMING IN THE FUTURE?

European Commission Corporate Responsibility initiative What will this mean for Pharma?

balanced
multistakeholder
approach

address company
transparency

consider self- and co-
regulation schemes -
acknowledge the role of
complementary regulation

promote market
reward for responsible
business conduct



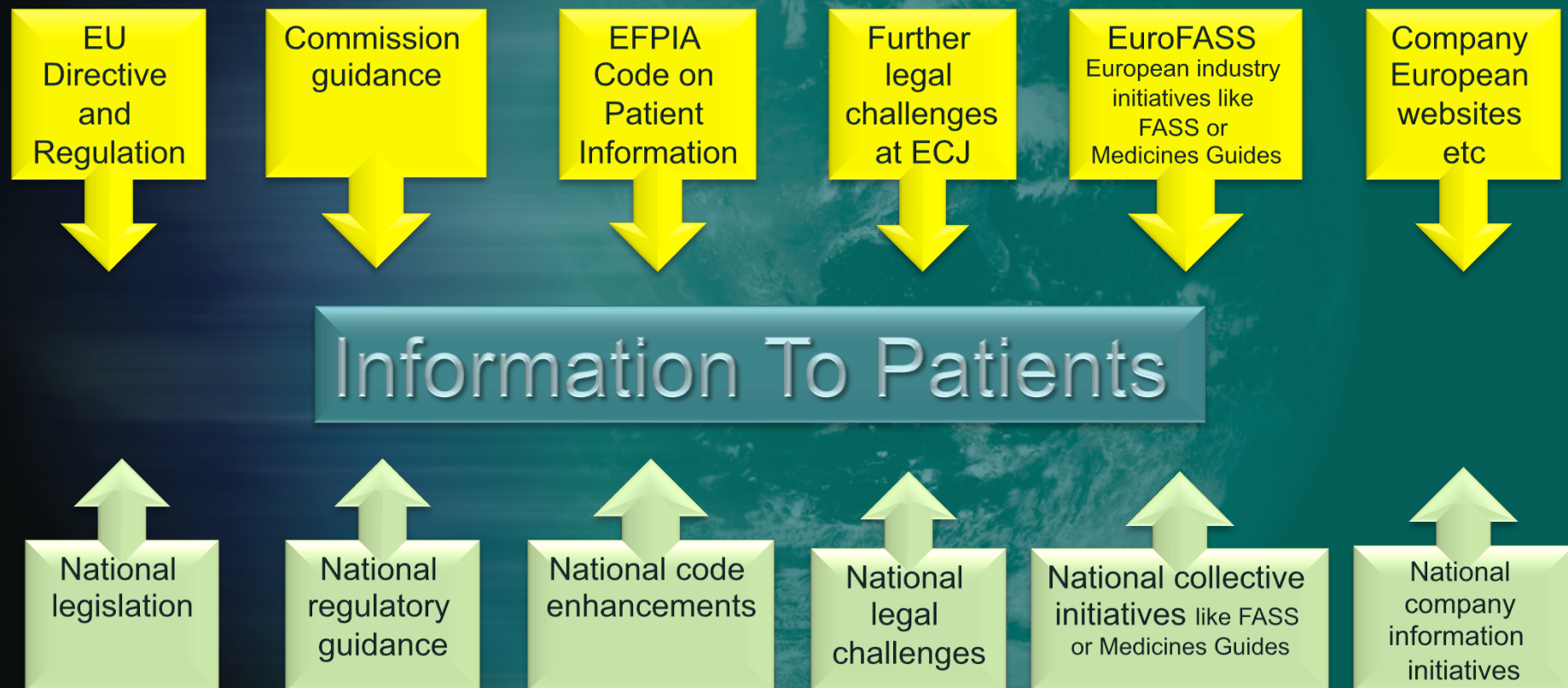
COMMUNICATION FROM
PARLIAMENT, THE COUNCIL
COMMITTEE AND THE

sector-specific multi-
stakeholder platforms

the point of view of
all stakeholders,

for Corporate Social Responsibility

Future possibilities for ITP on Rx Medicines: not just the proposed directive





Comments & Questions