

**PMCPA**

Prescription Medicines  
Code of Practice Authority

# Pharmaceutical Compliance Congress and Best Practice Forum

## European Transparency and Disclosure: Perspectives in light of ABPI Code

Thursday, 5 May 2011

Heather Simmonds  
Director

Prescription Medicines Code of Practice Authority  
[www.pmcpa.org.uk](http://www.pmcpa.org.uk)

# **Prescription Medicines Code of Practice Authority**

**Heather Simmonds, Director**  
**Etta Logan, Deputy Director**  
**Jane Landles, Secretary**  
**A N Other, Deputy Secretary**

Appointed by and reports to ABPI Board of Management.

## **ROLE:**

Responsible for administration of the Code and complaints procedure including provision of advice, guidance and training.



CODE OF PRACTICE  
*for the*  
PHARMACEUTICAL  
INDUSTRY  
2011

**PMCPA**

Prescription Medicines  
Code of Practice Authority

# International Codes, Guidelines & Legislation

- IFPMA, EFPIA
- WHO
- UK & European Law

# Changes due to:

- Experience of using 2008 Code
- Regular updating – usually every 2-3 years
- ABPI Trust Imperative activities

# MOVING BEYOND SPONSORS

## JOINT WORKING BETWEEN THE NHS AND PHARMACEUTICAL INDUSTRY

### Welcome

This toolkit has been jointly developed by the Department of Health and the Association of the British Pharmaceutical Industry to enable NHS organisations and the pharmaceutical industry to work together in the interests of patients.

The NHS is in a challenging phase of reform. The White Paper, "Our health, our care, our say: a new direction for community services", describes the strategic shift in services from secondary to primary care. The World Class Commissioning vision calls for "better health and well-being for all, better care for all, and better value for all."

NHS organisations, and Practice-based Commissioning are increasingly calling on external expertise to enable them to meet these challenges, recognising that joint working with partners who can supplement their own skills and resources can provide benefits that are not otherwise achievable.

One such partner is the pharmaceutical industry, which, apart from supplying medicines that improve the quality of patients' lives, is also an expert in business and its ethics, management and its ethics, the therapy areas relevant to the challenges of a rapidly changing service by providing practice tools, based on best practice working projects with the industry can be set up rapidly reducing duplication of effort, efficiency, and minimising workload and stress. It is a need to use everything we have - how much you need will vary with the nature and complexity of your project.

Click here to enter site

How to Use the Toolkit

Items essential to any joint project marked by red flag and i

## Pads, pens, prescriptions

### Drug industry influences Rx's in other ways

By Kevin Pho

Have you ever noticed the pens, coffee mugs and prescription pads at your doctor's office?

► **Limited drug evaluation.**

Research shows that many doctors rely more on the pharmaceutical industry's own information about a medication than on independent sources for the drug.

e, a report by Biakard found that more doctors in a group of "ibing" physicians ion from drug com primary source on ons, compared with 1% who used medical nials.

Doctors should seek information on new drugs from reputable medical journals or in-

formation and the growing cost of drugs we should seriously ask whether it is right that such an industry rather than an independent education is following our health decisions. There are many possibilities to make strategic decisions, but what is not in doubt is the reality that there is a conflict of interests between doctor commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products, listed as international expert medical professors David Rosenblatt adds, "We would like people companies - just more than a billion dollars a year into continuing medical education without the expectation of getting anything from it." This poses a significant challenge and government must work with the medical profession to meet it.

#### Key points

1. There is a significant degree of contact between the pharmaceutical industry and medical professionals.
2. The pharmaceutical industry benefits heavily in following doctors.
3. There is a conflict of interest between doctors' need to treat patients, and the pharmaceutical industry's need to sell their drugs.
4. Influence by the pharmaceutical industry can alter the prescribing habits of doctors, who could end up increasing costs to the NHS and increasing risks to the patient.

#### Possible solutions

There are some alternative methods of ensuring new-based prescribing practices:

- Use the "no free lunch" (NFL) rules. "I am committed to providing medicine to the interests of my patients and not the interests of the pharmaceutical industry. This is an interesting challenge and has huge potential. It is being taken seriously by many doctors in the UK as many doctors recognise no longer allow pharmaceutical representatives to visit."
- Draw inspiration from medical education, a group critical of pharmaceutical marketing, suggests that medical education could be funded by the taxpayer through a system of competitive grants.<sup>12</sup>



Gate

## INNOVATING FOR HEALTH

### Patients, physicians, the pharmaceutical industry and the NHS

Report of a Working Party

February 2008



### Ethical rules for the pharmaceutical industry in Sweden



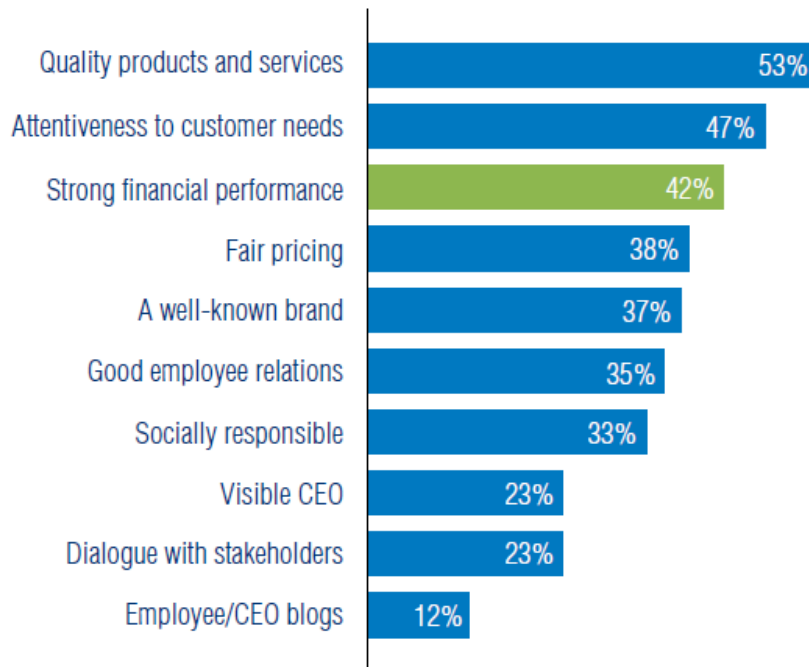
The research-based pharmaceutical industry

Revised May 23, 2008  
(Correction in translation Aug 12, 2008)

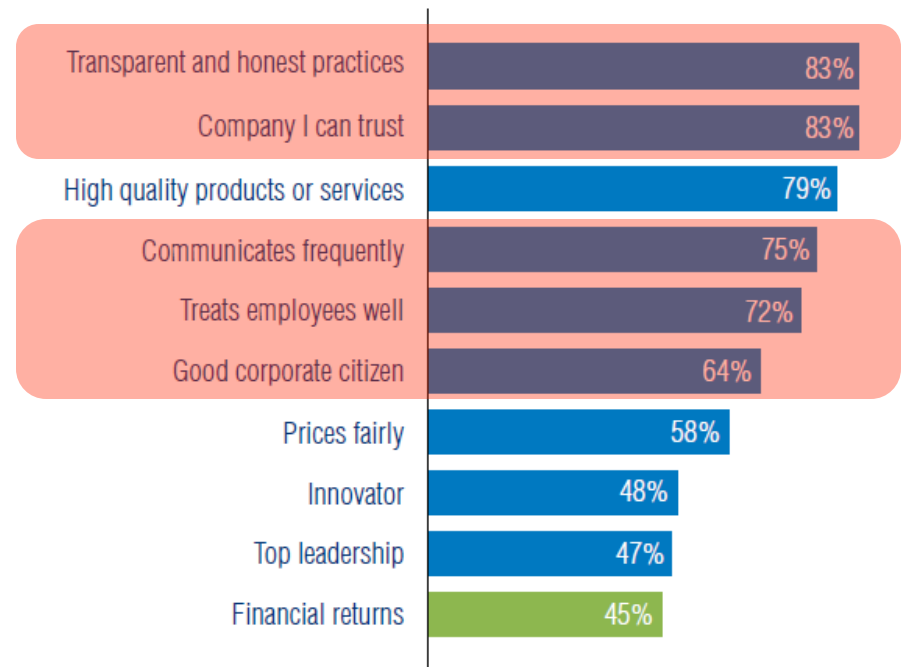
# Evolving stakeholder expectations

How important are each of the following factors to the overall reputation of the company?

U.S. 2006

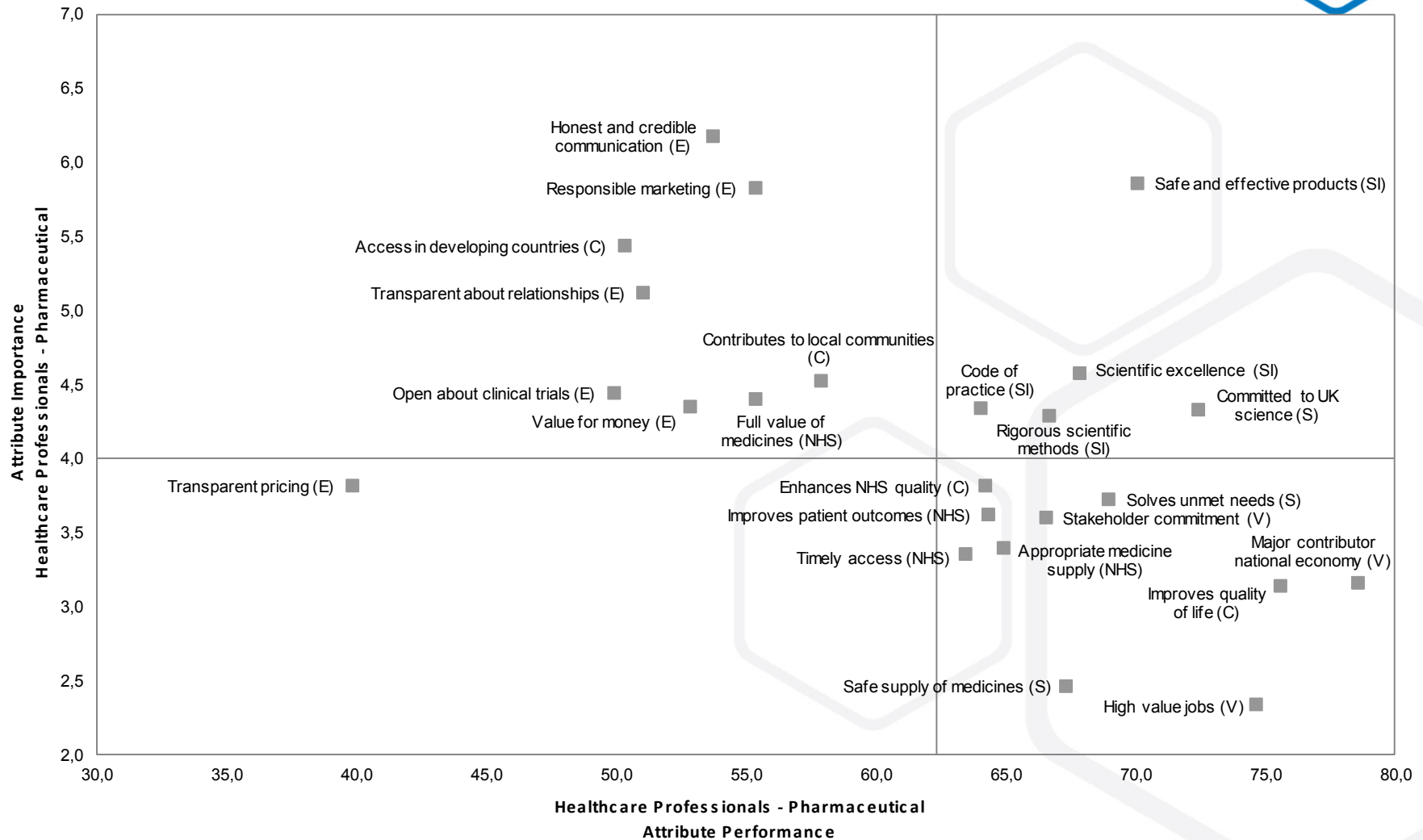


U.S. 2010



Source: Edelman's Trustbarometer 2010

# Healthcare professionals – driver weights and scores/reputation strengths and challenges – the attributes that matter



Q310/Q320: Please select a number from "1" to "7" where "1" means "Does not describe" and "7" means "Describes very well".  
Health Professionals: All score differences > 5.3 are significant at 95% confidence interval

n = 299

Adj R Squared = 0.688



# 2011 Code agreed on 2 November 2010

Changes include:

- promotional aids

- increased transparency

  - payments to health professionals

  - payments to patient organisations

  - payments to organisations

  - non interventional trials

Full details on the PMCPA website ([www.pmcpa.org.uk](http://www.pmcpa.org.uk))

# Process for changing Code

Two ABPI led groups

transparency

sponsorship and meetings

Company consultation

Public consultation

Stakeholder consultation – BMA, RPS, RCN, MHRA

# CLAUSE 20    The Use of Consultants

Detailed requirements including:

- Written contract/agreement
- Legitimate need for the services
- Appropriate criteria for selection and payment
- Hiring must not be an inducement to prescribe etc
- Contract to require consultants to declare interests when they write or speak in public

# Main changes **Clause 20.2 Use of consultants**

- Declare fees paid to consultants in the UK for certain services such as speaking at meetings, participation in advisory boards
- Disclose 2012 payments in 2013. Declare total amount and total number of consultants. No requirement to name individuals
- Disclose fees paid by local operating company and best estimates when paid by overseas affiliates, head offices and UK based European offices

# **Main changes Clause 19.4 Meetings, Hospitality and Sponsorship**

- Declare sponsorship to attend meetings organised by third parties (registration fees, cost of all accommodation and travel outside the UK)
- Disclose 2012 payments in 2013. Declare total amount paid in a calendar year, total number of recipients and total number of attendees
- No requirement to name individuals

## CLAUSE 18.6 Donations to Institutions etc

Medical and educational goods and services in the form of donations, grants etc to institutions which are comprised of health professionals and/or provide healthcare or conduct research not otherwise covered by the Code are allowed if they:

- comply with Clause 18.4 or made to support research
- do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- are documented and kept on record

Donations and grants in 2012 to be declared. Until then encouraged to make information public and to ask recipients to do so.

## Clause 23.7 Patient organisations

- Monetary support and/or significant indirect/non financial support with a value of £250 per project or more to be declared
- Activities commenced on or after 1 May 2011 or ongoing on that date

# Timetable for Code amendments

New Code dated 1 January 2011

Transition period for most requirements until 1 May 2011

Separate transition periods for some of the transparency changes (Clauses 20.2, 20.3, 18.6 and 19.4). Either payments made in 2012 or payments made in 2013



## REFRAMING RELATIONS WITH PHARMA It takes two to tango



**PLUS** Acupuncture for pain

Long term survival after myocardial infarction

Uncertainties: treating interstitial cystitis

**JOBS, COURSES, CAREERS**



Dear colleague

## Evolving the relationship between the medical community and the pharmaceutical industry

On 1st January 2011, important changes to the Association of the British Pharmaceutical Industry (ABPI) Code of Practice took place. We would like to draw your attention to some of the key changes:

- The industry will no longer provide branded promotional aids, such as pens, pads and mugs to health professionals. This will take effect from 1st May 2011. Some companies have already made this change and others may do so ahead of this date.
- From 2012, companies will be required to collect and declare on an annual basis aggregate total amounts paid to health professionals and others for certain services such as speaker fees and participation in advisory boards. Similarly companies will be required to declare sponsorship for attendance at meetings organised by third parties. The first declaration of payments will be in 2013 for payments made in 2012. The Code does not require individual health professionals to be named but does require the total number of health professionals involved to be declared and the total number of meeting attendances sponsored.

These changes have been made by the industry following extensive consultation with stakeholder organisations representing the NHS, patient groups, health professionals and industry and have received strong support.

The changes aim to support greater openness and transparency in the relationship between the industry and health professionals, something that our stakeholders in the medical profession, wider healthcare and across industry have told us that they want.

In 2008 the Royal College of Physicians (RCP) published the 'Innovating for Health' report calling on the ABPI to "change its Code of Practice to bring to an end the practice of industry representatives giving gifts to doctors and their support staff. Acting on this single recommendation alone would do much to rebalance the relationship between medicine and industry"<sup>1</sup>. Since publication of the report, the RCP and ABPI have been working together through a multi-stakeholder forum to examine issues and identify best practice.

...more

<sup>1</sup> Innovating for Health, Royal College of Physicians, 2008

Whilst these changes to the Code will not in themselves address all the challenges of ensuring that the relationship between health professionals and the industry continues to meet the high expectations of our stakeholders and society, they are strong symbolic indicators of change and will help to address some common criticisms that are made of how we work with each other.

By tackling some of these criticisms, we can together continue to evolve the relationship between industry and the medical profession, based on high standards of transparency and good practice. This is crucial to all of us: crucial for future collaboration, joint working and partnerships; for the continued trust and confidence of patients and stakeholders in health; and ultimately for better health outcomes for patients.

As partners in the healthcare system, we consider these changes to be significant in strengthening the relationship between health professionals and the industry. We commend the changes to you and hope you will strongly support their implementation in your own clinical setting.

Further details on the changes to the Code can be found at the Prescription Medicines Code of Practice Authority website at [www.pmcpa.org.uk](http://www.pmcpa.org.uk).

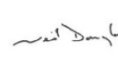
Yours faithfully,



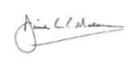
**Simon Jose**  
President  
ASPI



**Sir Richard Thompson**  
President  
Royal College of Physicians



**Professor Sir Neil Douglas**  
Chairman  
Academy of Medical Royal Colleges



**Dr Hamish Meldrum**  
Chairman  
British Medical Association



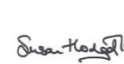
**Professor Ray Hill**  
President  
British Pharmacological Society



**Sir David Nicholson**  
NHS Chief Executive  
Department of Health



**Dr Richard Tiner**  
President  
Faculty of Pharmaceutical Medicine



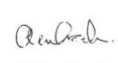
**Sue Hodgetts**  
Chief Executive  
Institute of Healthcare Management



**Mike Ramsden**  
Chief Executive  
National Association for Primary Care



**Professor Hugo Mascie-Taylor**  
Medical Director  
NHS Confederation



**Dr Clare Gerada**  
Chair of Council  
Royal College of General Practitioners



**Dr Peter Carter OBE**  
Chief Executive  
& General Secretary  
Royal College of Nursing



**Dr Neil Dewhurst**  
President  
Royal College of Physicians  
of Edinburgh



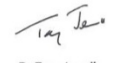
**David Tolley**  
President  
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**Helen Gordon**  
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Royal Pharmaceutical Society  
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# Code Awareness 2011

E-learning module for health professionals

Focuses on points relevant to health professionals including:

- printed promotional materials
- meetings, hospitality and sponsorship
- representatives
- samples
- items for patients
- working as a consultant

Refers to health professionals' own codes and standards and application of UK law

# The ABPI Code of Practice

An introduction for health professionals

**PMCPA** Prescription Medicines  
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## Course map



MENU



CLOSE

# What is next?

# Q & A