

PMCPA

Prescription Medicines
Code of Practice Authority

Impact of Self Regulation on industry relationships with health professionals, health care organisations and patient organisations

PCF meeting 16 May 2017

Heather Simmonds

Director

Prescription Medicines Code of Practice Authority

www.pmcpa.org.uk

Prescription Medicines Code of Practice Authority

Heather Simmonds, Director
Etta Logan, Deputy Director
Tannyth Cox, Acting Secretary

Appointed by and reports to ABPI Board of Management.

ROLE includes:

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



CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY

2016

PMCPA | Prescription Medicines
Code of Practice Authority

Aim of the Code

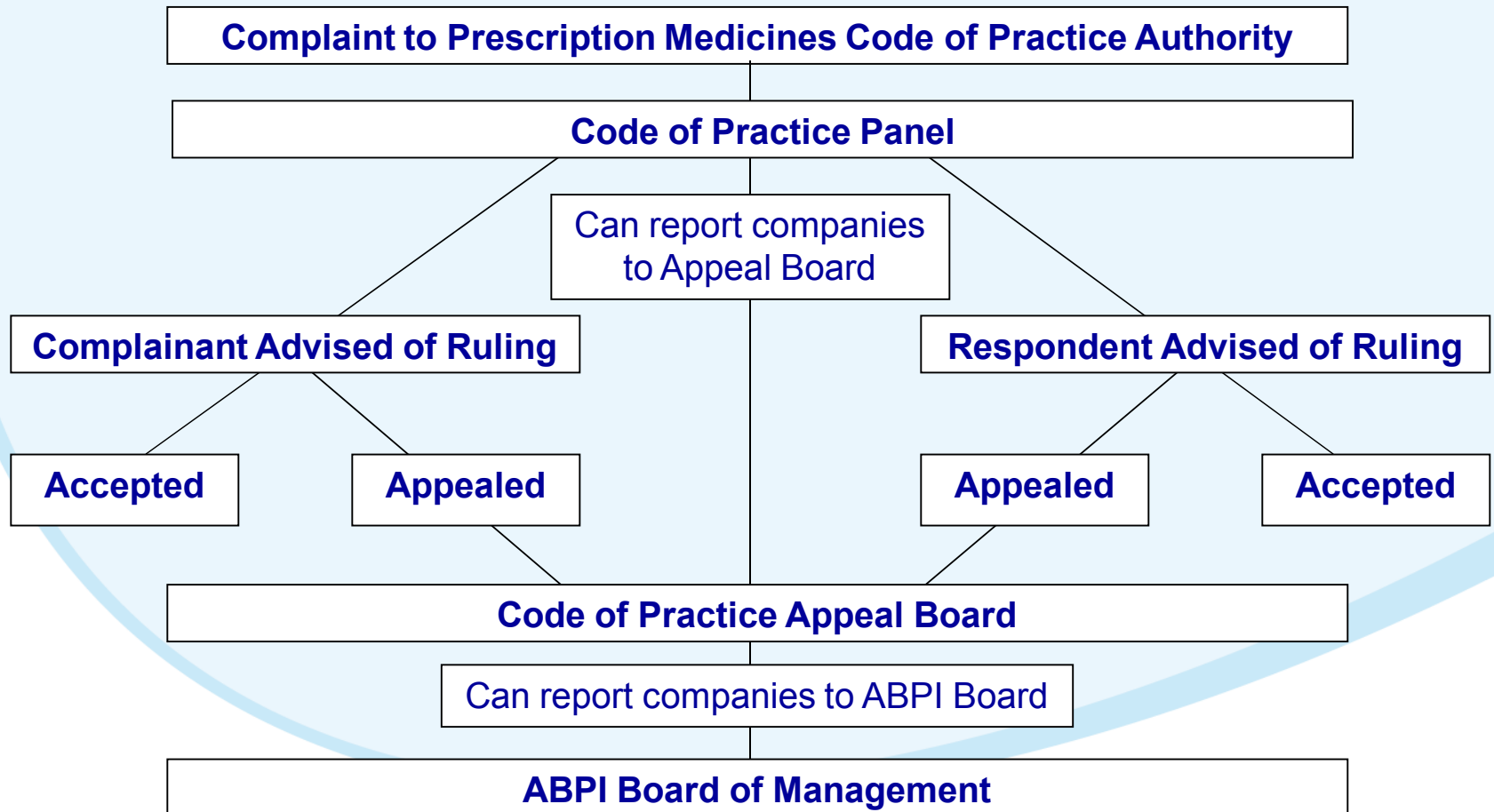
To ensure the promotion of medicines to health professionals and to other relevant decision makers is carried out in a robust framework to support high quality patient care.

Also sets standards for the provision of information to patients and the public as well as relationships with patient groups.

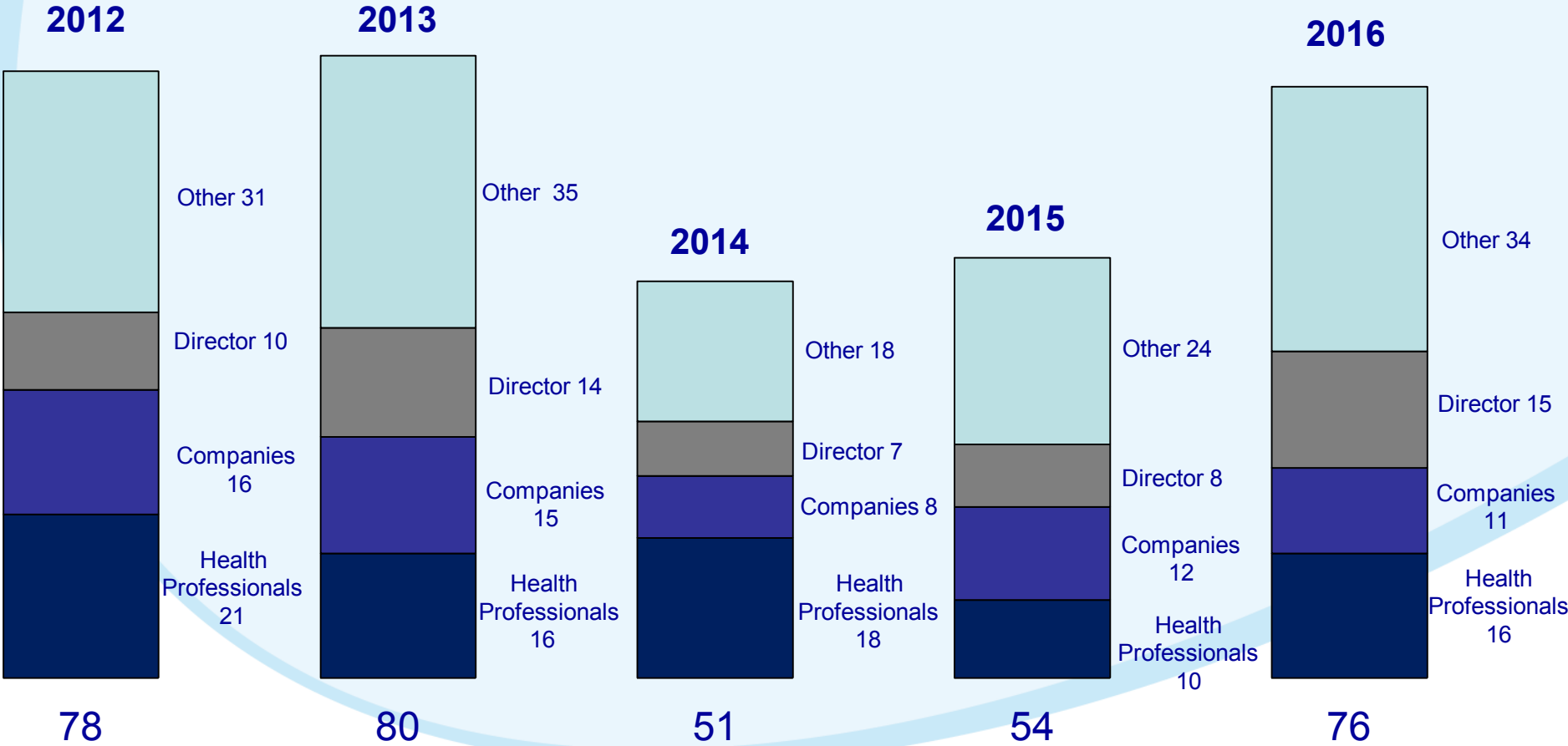
International Codes, Guidelines & Legislation

- IFPMA, EFPIA
- WHO
- UK & European Law

Complaints Procedure



Complaints received



Sanctions

- Rapid cessation of promotion
- Publication of case reports
- Audit of company's procedures can be followed by pre-vetting
- Public reprimand
- Recovery of items
- Corrective statements
- Advertising of certain cases in medical, pharmaceutical and nursing press
- Suspension/expulsion by ABPI Board of Management

CODE OF PRACTICE REVIEW

PMCPA | Prescription Medicines
Code of Practice Authority

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England & Wales no 09826787, registered office 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT.

ANNUAL REPORT FOR 2015

The Annual Report of the Prescription Medicines Code of Practice Authority for 2015 will be published on our website (www.pmcps.org.uk) shortly.

There were 54 complaints in 2015 compared with 51 in 2014. There were 80 complaints in 2013.

The 54 complaints in 2015 gave rise to 86 cases (35 cases ruled in breach of the Code). The number of cases usually differs from the number of complaints, the reason being that some complaints involve more than one respondent company and some complaints do not become cases at all because they are withdrawn.

Of the 198 rulings made by the Code of Practice Panel in 2015, 179 (90%) were accepted by the parties, 13 (7%) were unsuccessfully appealed and 6 (3%) were successfully appealed. This compares with the 5% of rulings which were successfully appealed in 2014. The average time to deal with all cases in 2015 was 9.8 weeks (11.7 weeks in 2014). There was also a decrease in the time taken for cases settled at the Panel level, 8.5 weeks in 2015 (10 weeks in 2014) and cases which were appealed, 19.2 weeks in 2015 (23.3 weeks in 2014).

Each quarter the Authority advertises brief details of cases completed in the previous three months where companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. These advertisements which are published on the PMCPA website and placed in the BMJ, The Pharmaceutical journal and the Nursing Standard act as a sanction and highlight what constitutes a serious breach of the Code.

REPRESENTATIVES EXAMINATION – IMPORTANT BOOKING ADVICE

It is sometimes the case that representatives request an extension to the time in which to either sit or pass an appropriate examination because they have left it too late to book an examination and get a place within the required time (1 year in which to sit an examination and 2 years in which to pass it). Candidates, or those booking places on their behalf, must ensure that they think well ahead and do not leave booking the first examination until the last minute and that if re-sits are needed they book them as quickly as possible within the second year so that candidates can be sure of passing the examination by the end of that year.

PUBLIC REPRIMANDS AND SUSPENSION FOR ASTELLAS

Astellas Pharma Europe and Astellas UK have been publicly reprimanded twice by the Code of Practice Appeal Board. Once for breaches of the Code in relation to providing false information in response to a previous case and for reporting the outcome of the previous case in a dismissive manner. Secondly for providing inaccurate information to the Authority.

In Case AUTH/2780/7/15, the Code of Practice Panel ruled breaches of the Code with regard to the provision of false information in response to a previous case (Case AUTH/2747/1/15) and for the dismissive manner in which a senior employee reported the outcome of that case to Astellas staff. The Panel reported Astellas UK and Astellas Europe to the Appeal Board. The Appeal Board required a corrective statement to be issued; both companies were also publicly reprimanded and required to undergo audits of their procedures in relation to the Code.

Following the audits the Appeal Board decided that both companies should be re-audited in September 2016. In addition Astellas Europe subsequently admitted it had provided inaccurate information. This was considered by the Code of Practice Panel which again reported both companies to the Appeal Board. The Appeal Board decided to require a third corrective statement, to publicly reprimand both companies for a second time and to report them to the ABPI Board.

The ABPI Board was extremely concerned at the multiple organisational and cultural failings. There was institutional failure. Very senior staff at Astellas Europe had lied and there was deception on a grand scale which was appalling and shocking. The totally unacceptable behaviour of senior staff was potentially harmful to the integrity of self-regulation.

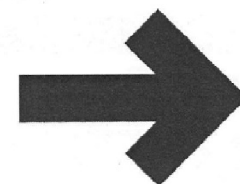
The ABPI Board suspended Astellas UK from membership of the ABPI for 12 months commencing on 24 June. It also decided that it wanted sight of the reports of the September 2016 re-audits of the companies so that it could review the position, including the length of the suspension, before the end of 2016. The re-audits must show demonstrable improvements at both companies particularly in relation to corporate culture. Astellas Europe and Astellas UK will continue to be required to comply with the Code and accept the jurisdiction of the PMCPA during the period of suspension.

Full details of Case AUTH/2780/7/15 and Case AUTH/2747/1/15, including the corrective statements, can be found on the PMCPA website.

Managing Conflicts of Interest in the NHS

Guidance for staff and organisations

Publications Gateway Reference: 06419



Hospitality

What are the issues?

Delivery of services across the NHS relies on working with a wide range of partners (including industry and academia) in different places and, sometimes, outside of 'traditional' working hours. As a result, staff will sometimes appropriately receive hospitality. Staff receiving hospitality should always be prepared to justify why it has been accepted, and be mindful that even hospitality of a small value may give rise to perceptions of impropriety and might influence behaviour.

Hospitality means offers of meals, refreshments, travel, accommodation, and other expenses in relation to attendance at meetings, conferences, education and training events, etc.

Principles and rules

Overarching principles applying in all circumstances:

- Staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement.
- Hospitality must only be accepted when there is a legitimate business reason and it is proportionate to the nature and purpose of the event.
- Particular caution should be exercised when hospitality is offered by actual or potential suppliers or contractors – these can be accepted if modest and reasonable but individuals should always obtain senior approval and declare these.

Meals and refreshments:

- Under a value of £25 - may be accepted and need not be declared.
- Of a value between £25 and £75* - may be accepted and must be declared.
- Over a value of £75* - should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept.
- A common sense approach should be applied to the valuing of meals and refreshments (using an actual amount, if known, or an estimate that a reasonable person would make as to its value).

*The £75 value has been selected with reference to existing industry guidance issued by the ABPI
<http://www.pmcpa.org.uk/thecode/Pages/default.aspx>

6. Transparency: Maintenance and publication of register(s)

Maintenance of Register(s)

6.1. Organisations must ensure that a nominated team or individual collates and maintains up to date organisational register(s) of interests. An interest should remain on the register(s) for a minimum of 6 months after the interest has expired. Organisations should retain a private record of historic interests for a minimum of 6 years after the date on which it expired.

6.2. Template declaration of interests and register of interests forms for organisations to use are provided at [Annex C and D](#). They should always contain:

- The returnee's name and their role with the organisation
- A description of the interest declared (reflecting the content of section 5 of this guidance for common situations)
- Relevant dates relating to the interest
- Space for comments (e.g. action taken to mitigate conflict)

6.3. Using the common format in the templates will help minimise burdens on staff who might need to submit returns to multiple organisations.



[Declaration of interests template](#)

Publication

6.4. All staff should declare interests and, as a minimum, organisations should publish the interests of decision making staff at least annually in a prominent place on their website. Organisations without websites should maintain registers locally, available for inspection on request.

6.5. The format of published registers should be accessible and contain meaningful information. Adopting the templates and advice on content in this guidance will assist organisations in this task.

6.6. Organisations should put in place processes for staff to make representations that information on their interests should not be published. This will allow for, in exceptional circumstances, an individual's name and/or other information to be redacted from any publicly available registers where the public disclosure of information could give rise to a real risk of harm or is prohibited by law.

6.7. As well as taking these steps, organisations should seek to ensure that staff who are subject to wider transparency initiatives such as the ABPI Disclosure UK scheme are aware of and comply with them:

<http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx>



[Register of interests template](#)