

CHANGES TO THE 2015 ABPI CODE

The new provisions of the 2015 ABPI Code of Practice will become fully effective from 1 May 2015. Here, **CompliMed** examines some of the key amendments and their likely impact – from changes to standard operating procedures and training, to implementing new systems

Clarifications

In relation to transfers of value, a possible loophole in the Code has now been closed. A healthcare organisation that consists of only one health professional should be treated as an individual HCP. Disclosure policies based on “follow the money” will have to consider the individual. This also means certain services cannot be provided to such organisations as this would result in unacceptable benefit to individuals.

“Unacceptable payments” have been added to the list of activities ruled to bring discredit upon the industry. So if an advisory board is ruled to be promotional, any payments made are likely to be unacceptable.

The much anticipated “tidying up” of a previously lengthy Clause has resulted in the introduction of three new Clauses (for medical and educational goods and services, joint working and relationships and contracts with certain organisations). The change in numbering will potentially affect SOPs and training material.

Updates

The future is digital and the Code has updated some language to reflect that. The use of emoticons in digital communications is now deemed unacceptable. For those expecting detailed guidance on “how to do digital” there could be some disappointment.

Thanks to updates in legislation, as long as the legal category and cost are provided, the prescribing information (PI) can be replaced with the summary of product characteristics

(SmPC). Although the benefits of replacing the PI with a lengthy SmPC in hard copy materials is not entirely clear (and not even possible for size-restricted journal advertisements), online material may provide a direct link to the SmPC. Note that emails are regarded as offline material.

Although the Code now mandates that transfers of value be disclosed on a central platform developed by the ABPI, should this site crash companies would be held liable for any non-disclosure. Companies should therefore ensure their own systems are adequate in this regard.

Process Improvement

Certification is a mandatory process that has seen some recent improvements. For example, from 1 Jan 2014 pharmacists

have been able to act as full medical signatories. The 2015 Code attempts to simplify the process for printed items by permitting only one signatory to check that the printed material is identical to the electronic version previously certified by two signatories. The status quo may be preferred until the significance of this change on electronic approval systems and archiving is fully understood.

For multi-company projects such as joint working, two final signatories can certify material on behalf of all the companies involved. However, as all companies would be responsible in the event of a complaint (even if none of its signatories were involved) and given such projects are likely to involve competitors, this change may not be one that is widely implemented.

The arrangements for meetings that involve travel outside the UK must be certified, but the 2015 Code now stipulates that this is not required if the company’s only involvement is to support a speaker to present at a third party meeting. While it may be rare for companies to provide such support, this is a move towards accepting the practical difficulties in certifying overseas meetings.

The changes described may seem simple at face value but they will have a ripple effect on company processes and policies; the full impact will become more evident throughout 2015.

CompliMed specialises in the ABPI Code of Practice. Its 2015 Healthcare Compliance Conference is on 27 April 2015. Visit www.complimedltd.co.uk

