



Bringing medicines to *life*

CODE OF PRACTICE  
*for the*  
PHARMACEUTICAL  
INDUSTRY

SECOND 2012 EDITION

**Addendum**

Changes to Clause 16 of the Second 2012 Edition of the ABPI Code of Practice for the Pharmaceutical Industry were agreed on 25 April 2013. These will come into operation on 1 July 2013. During the period 1 July to 31 October there will be a transition period for the ABPI examinations such that it will not be a breach of Clause 16.3 to fail to comply with the newly introduced requirements in that clause.

There will be a new edition of the Code in 2014.

The text overleaf replaces Clause 16 in the Second 2012 Edition of the Code.

**PMCPA**

Prescription Medicines  
Code of Practice Authority

# Clause 16

## Training

**16.1** All relevant personnel including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions and to appropriate administrative staff or of information to be provided to the public and recognised patient organisations must be fully conversant with the requirements of the Code and the relevant laws and regulations.

**16.2** All personnel (including persons retained by way of contract with third parties) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented.

**16.3** Representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment.

An appropriate examination for medical representatives is one that requires a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry.

An appropriate examination for generic sales representatives is one that requires a broad understanding of body systems, the structure and function of the NHS and of the pharmaceutical industry.

An appropriate examination can be either the relevant ABPI examination (for medical or generic sales representatives) or an examination of at least the same standard as the ABPI examinations and covering similar content and learning material as the corresponding ABPI examination.

**16.4** Details of the numbers of representatives who have passed an examination, together with the examination status of others, must be provided to the Prescription Medicines Code of Practice Authority on request.

## Clause 16 Supplementary Information

### Clause 16.1 Training

*Extensive in house training on the Code is carried out by companies and by the Prescription Medicines Code of Practice Authority.*

*In addition, the Authority runs seminars on the Code which are open to all companies and personnel from advertising agencies, public relations agencies and the like which act for the pharmaceutical industry. Details of these seminars can be obtained from the Authority.*

### Clause 16.3 Examinations

*The ABPI offers two examinations and further details can be obtained from the ABPI.*

*Examinations may also be offered by other providers. A company using an examination provider other than the ABPI must be able to demonstrate that such examinations are at least equivalent to those offered by the ABPI. The ABPI intends that its examinations will be accredited at least at Level 3 by an external awarding body recognised by Ofqual. Once this is achieved proposals will be made to amend the Code to require the examinations of all providers to be accredited at least at Level 3.*

*The ABPI Medical Representatives Examination is appropriate for representatives whose duties comprise or include one or both of:*

- *calling upon doctors and/or dentists and/or other prescribers*
- *the promotion of medicines on the basis, inter alia, of their particular therapeutic properties.*

*The ABPI Generic Sales Representatives Examination is appropriate for representatives who promote medicines primarily on the basis of price, quality and availability to those who do not prescribe medicines.*

*The ABPI examinations for medical representatives and generic sales representatives are based on material published by the ABPI.*

*Persons who have passed the ABPI Medical Representatives Examination or similar whose duties change to those specified for generic sales representatives do not need to take another examination. However, persons who have passed the ABPI Generic Sales Representatives Examination or similar whose duties change to those specified for medical sales representatives must take an appropriate examination within one year of their change of duties and pass it within two years.*

### Clause 16.3 Information from Examination Provider

*A company must take steps to ensure that its examination provider would respond to requests for information from the Authority.*

### Clause 16.3 Time Allowed to Pass an Examination

*Prior to passing an appropriate examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. A representative cannot, for example, work eighteen months with one company and eighteen months with another and so on, thus avoiding an examination. Maternity or paternity leave does not count towards the specified time periods.*

*In the event of extenuating circumstances, such as prolonged illness or no or inadequate opportunity to take an appropriate examination, the Director of the Prescription Medicines Code of Practice Authority may agree to the continued employment of a person as a representative past the end of the two year period, subject to the representative passing an appropriate examination within a reasonable time.*

*Similarly, in the event of failure to take an appropriate examination within the first year, the Director may agree to an extension, subject to the representative taking an examination within a reasonable time.*

*Service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code does not count towards the two year limit on employment as a representative prior to passing the appropriate examination.*