CHANGES IN THE ABPI CODE OF PRACTICE 2019

By Rachael Reed & Rina Newton

The compliance team at CompliMed is regularly asked for the key changes to the ABPI Code, so we are well-versed with simplifying. Here, we describe the most significant changes.

A new version of the ABPI Code of Practice came into operation on 1st January 2019, further to a review by industry representatives forming the ABPI Code Working Group to simplify and clarify certain areas of the 2016 ABPI Code. The new provisions are not enforceable until 1st May 2019, allowing companies time to consider each change, implement if necessary and transition properly.

Summarised below are some of the key changes that affect the Medical Information and Reviewer roles, the majority of these changes being minor. We have grouped these into eight categories:

1. Marketing Authorisation and Promotion

- 'Risk minimisation materials' are not included in the definition of promotion. This means that even though such materials discuss medicines, companies do not need to consider them in the same way as promotional material and therefore they will not require certification.
- Medicines with a conditional licence can be promoted within the specific terms of that licence but promotional materials must clearly state that the medicine has a conditional licence.

A conditional licence is granted 'where the benefit of immediate availability [of a medicine] outweighs the risk of less comprehensive data than normally required' specifically where there is an unmet medical need in seriously debilitating or life-threatening disease or in emergency situations.

- Medicines in 'Early Access to Medicines Schemes' cannot be promoted as the medicine/indication will not have a marketing authorisation.

The early access to medicines scheme (EAMS) aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. The MHRA provides a scientific opinion on the benefit/risk balance of the medicine and if approved, a company can provide the medicine free of charge to patients via the scheme.

- Unlicensed medicines provided via compassionate use cannot be promoted.

An unlicensed medicine or use of a medicine in an unlicensed indication can be provided on a compassionate basis for an unmet medical need.

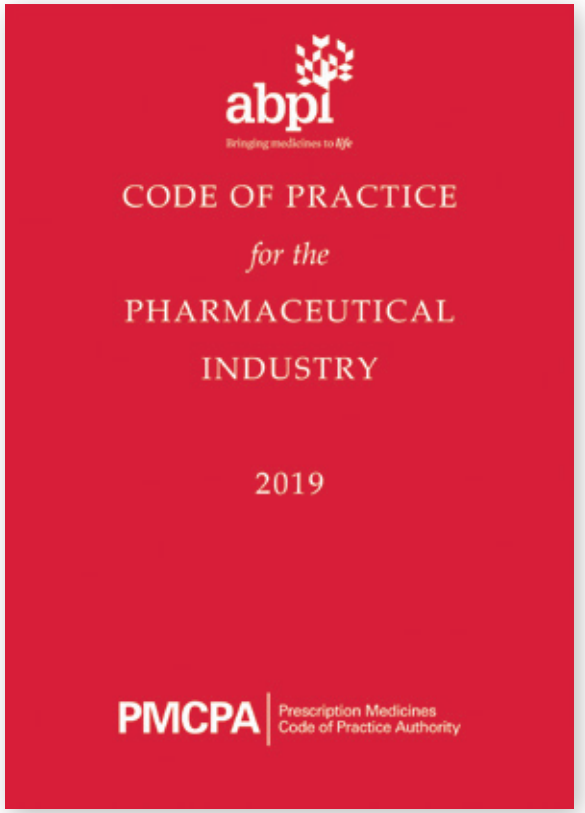
- There is now clarification regarding the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure within the NHS. Changes in the *patient pathway and/or service delivery* i.e. not just in relation to the cost of the medicine itself, are now allowed as circumstances for advance notification.

Advance Notification of new medicines or changes to existing medicines is sent to NHS organisations and others involved in the purchase of medicines to allow them to estimate their budgets in advance.

2. Obligatory Information

- Specific requirements for the 'Legibility of Prescribing Information (PI)' have been removed in favour of a statement that PI should be 'clear and legible'. Guidance is due to be added to a Q&A in the future…
- To reflect the increasing availability of internet access, the Code now allows PI to be provided as a link in promotional emails rather than forming part of the email itself. The table below helps describe this:

Channel	e.g.	How may PI be provided?
Digital	Banner advertisement, website, email	Link
Electronic	E-detail, budget impact model, slide presentations	Embedded OR With
Hard Copy	Sales aid, journal advertisement	Embedded



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- The Code no longer contains the specific web address for the adverse event reporting statement, instead referring to *'a web address which links directly to the MHRA yellow card site'*. This allows for potential changes to this MHRA address in the future.

3. Digital

- When certifying the dynamic content of websites, the Code now states that not every possible combination of the content needs to be certified. This allows reviewers and signatories to assess the compliance of stand-alone web-pages.
- The Code also clarifies when material falls within the scope of the UK Code if placed on the internet outside the UK.

4. Certification

- The final copy of printed material which previously was required to be checked by a final medical signatory (after the electronic version had been certified), may now be checked by an 'appropriately qualified person'. This allows for anyone whom the company considers suitably qualified as a proof-reader e.g. medical information, to perform this check, which is then recorded within the approval system.
- Meetings involving travel outside the UK can now be certified by an 'appropriately qualified person'. Such individuals must have appropriate Code, Industry and product knowledge. However, confusingly the process is still termed as 'certification' and these individuals must be notified to the PMCPA and MHRA beforehand.

5. Journal Advertising

Clarification is given that the requirements relating to the two-page limit and restriction on size for product advertisements, is for print journals only.

6. Reprints and Quotations

The wording of the Code has been updated with more standard terminology stating 'reprints of articles must not be provided *proactively* unless they have been *peer reviewed.*' This previously stated 'articles must not be provided *unsolicited* unless they have been *refereed*'.

7. Patient support items

The maximum cost of patient support items has increased from £6 to £10 (in line with inflation), excluding VAT and the perceived value to the HCP and patient must be similar. It is not clear why the cost of promotional aids has not also increased…

8. Principles and PMCPA Constitution and Procedure

Thirteen principles are now provided at the beginning of the 2019 ABPI Code which succinctly inform the reader about the aims, values and guidance in the Code.

Within the PMCPA Constitution, there have been minor changes to terms and roles.

The Code also includes changes relating to disclosure, as well as Package Deals, which have not been fully covered here.

A package deal is essentially where associated benefits e.g. apparatus for administration or provision of training are included as part of the purchase price of a medicine

We are expecting Q&As to be produced which we hope will provide extra guidance, however these are still described as "under development" and will likely be released when the new PMCPA website goes live.

For further information please contact us at info@complimed.co.uk.

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