PMCPA | Prescription Medicines Code of Practice Authority

Code/21/22
18 March 2021

To: ABPI Members
Companies which have agreed to comply with the Code

Dear Sir/Madam

Consultation on Amendments to the 2021 ABPI Code

Following agreement of the 2021 Code, there is a need to make two amendments as set out below.

1 Amendments as a result of the end of the transition period for leaving the EU

When the 2021 ABPI Code of Practice for the Pharmaceutical Industry was agreed in January 2021 it was made clear that further amendments might be needed due to guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) as a result of the end of the transition period for the UK leaving the EU and possible changes to marketing authorisation numbers and marketing authorisation holder's names and/or addresses. A place holder was put in the 2021 Code in relation to the supplementary information to Clause 12 and the provision of prescribing information.

The PMCPA and MHRA have now agreed guidance which has been published on the PMCPA website.

2 Amendments as a result of changes in terminology regarding the ABPI examinations for representatives

The PMCPA has recently been advised by the ABPI that the terminology for representatives' examinations needs to be changed. This is a result of a takeover of the existing body which accredits the ABPI examinations for representatives. The new accrediting body has advised the ABPI that the terms 'Level 3 Diploma' and 'Level 3 Certificate' can only be used for qualifications directly regulated by Ofqual and under the current arrangements for accreditation the ABPI cannot use those terms to describe the ABPI examinations. The terms 'Level 3 Diploma' and 'Level 3 Certificate' are not used in the Code (Clause 9.4 of the 2021 Code), however the terms 'Level 3' 'Diploma' and 'Certificate' are used. The examination requirements in the Code should not be restricted to qualifications directly regulated by Ofqual and indeed the ABPI qualification is not directly regulated by Ofqual.

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The attached document sets out the proposed amendment to the 2021 Code together with reasons and is provided for consultation. The proposed amendments are supported by the ABPI Board.

It is anticipated that the wording will be before the Annual General Meeting of the ABPI on Friday, 30 April 2021 for agreement.

Please let me have any comments as soon as possible and by no later than Thursday 1 April 2021.

Yours faithfully

Heather Simmonds
Director

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Proposed amendments to the agreed 2021 ABPI Code of Practice for the Pharmaceutical Industry

1 Proposed amendment to the supplementary information to Clause 12

Delete current place holder text

‘Supplementary information to Clause 12 Changes as a result of the end of the transition period for the UK leaving the EU and new arrangements from 1 January 2021.

Place holder for arrangements for changes to marketing authorisation numbers and holders addresses to be added following discussions with the MHRA.‘

Replace with

‘Clause 12 Arrangements for changes to the marketing authorisation number and the marketing authorisation holder name and address following changes resulting from the UK leaving the EU

For the period from 1 January 2021 until 1 January 2023, a complaint that the prescribing information for a previously centrally approved medicine does not have the new marketing authorisation number or any new marketing authorisation holder’s name and address as required by Clause 12.2 (vii) will not be considered to be in breach of that clause and potentially any other relevant clause provided that:

- other changes to the prescribing information have not been needed
- the prescribing information includes the previous information about the marketing authorisation number and
- any new marketing authorisation holder can be contacted via the address given in the prescribing information.

This will also apply to medicines (other than those centrally approved) if the marketing authorisation numbers and marketing authorisation holder name and address are changed from 1 January 2021 as a result of the departure of the UK from the EU.’

Reason

To ensure the 2021 Code reflects the recently agreed guidance from the MHRA.

2 Proposed amendment to Clause 9.4

Current text

‘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. To be acceptable, an appropriate examination must have been accredited to at least Level 3 by an external awarding body recognised by Ofqual.

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.

Such an examination must be a Diploma (equivalent to at least 480 hours Total Qualification Time).

An appropriate examination for **generic sales representatives** is one that requires a broad understanding of body systems and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Certificate (equivalent to at least 330 hours Total Qualification Time).

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 which covers similar content and learning material as the corresponding ABPI examination.'

Add to the first paragraph 'or its equivalent' in relation to the requirement for accreditation 'to at least Level 3'.

Add to the second and third paragraphs 'at the level of' in relation to the 'Diploma' and 'Certificate'.

To read:

'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. To be acceptable, an appropriate examination must have been accredited to at least Level 3 or its equivalent by an external awarding body recognised by Ofqual.

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. Such an examination must be at the level of a Diploma (equivalent to at least 480 hours Total Qualification Time).

An appropriate examination for **generic sales representatives** is one that requires a broad understanding of body systems and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be at the level of a Certificate (equivalent to at least 330 hours Total Qualification Time).'

Reason

The examinations must be equivalent to a 'Level 3', 'Diploma' or a 'Certificate'. The terms 'Level 3 Diploma' and 'Level 3 Certificate' only apply to qualifications directly regulated by Ofqual. (The ABPI qualifications are not directly regulated by Ofqual). The external body regulated by Ofqual which accredits the ABPI examinations cannot therefore use the terms 'Level 3 Diploma' or 'Level 3 Certificate' to describe the qualifications offered by the ABPI. This is a matter only recently identified by the ABPI. The proposed amendment will ensure that the examination requirements in the Code are not restricted to qualifications directly regulated by Ofqual.

There is no change to the actual examinations provided by the ABPI, the only change will be to the name of the qualification. The names of the ABPI qualifications are not used in the ABPI Code.