Clause 12 Q&As for 2024 Code (comes into operation on 1 October 2024)

Please note that the PMCPA cannot approve any activities or materials, it can only give informal advice based on its interpretation of the ABPI Code. In the event of a complaint being received about a matter upon which advice had been given, it would be considered in the usual way. The Code of Practice Appeal Board would make the final decision if a case went to appeal. It is important to note that each case is considered upon its own merits and based upon the allegations raised by the complainant.

The Q&As below are not a substitute for a detailed study of Clause 12 and its supplementary information, which should be read in conjunction.

1. Why are companies not permitted to include QR Codes on digital materials to be accessed by a recipient on their own device, such as a website?

Prescribing information should be easily accessible and therefore recipients should not be required to use two devices to access prescribing information.

In the instance of a website, rather than expecting recipients to locate another device to scan the Quick Response (QR) Code, the appropriate mechanism would either be inclusion of prescribing information as text on the webpage or to have a clear and prominent, direct, single link to prescribing information.

2. What does the Code mean by 'scanning a QR code should directly access the up-to-date version of the prescribing information which can be updated remotely'?

Companies are expected to use a QR code which allows access to the up-to-date version of the prescribing information which can be updated remotely by the company as required. This ensures promotional material that is in the possession of health professionals continues to directly link to the up-to-date version of the prescribing information.

For example, this can be done by means of a dynamic QR code which, when scanned, directs to a destination URL that can be changed remotely, on demand, even after the QR code has been printed. This is different to a static QR code which directly embeds information and cannot be updated remotely.

3. Where the prescribing information is updated remotely for a QR code, do printed materials need to be withdrawn or re-approved?

Companies are expected to assess the impact of the summary of product characteristics (SPC) update, that led to the prescribing information update, on the full material.

Companies will each have existing processes and procedures in place for withdrawing, reviewing and approving materials following a prescribing information update. The process for updating the prescribing information hosted through a QR code will be similar to updating prescribing information that is available via a link on digital materials such as a website.

4. What size should a QR code be and where should it be positioned?

It is for companies to ensure that the QR code is clear and prominent and of sufficient size and clarity to allow it to be easily scanned. Its position should be immediately apparent or else there should be a clear prominent statement as to where it can be found.

5. What statement is required with a QR code linked to prescribing information?

The QR code should be accompanied with clear instructions such as “scan the QR code for prescribing information”.

6. What is the change to accessing the adverse event reporting statement?

While it remains best practice for the adverse event reporting statement to remain in the body of the material as text, the adverse event reporting statement, as described in Clause 12.6, may now be provided in the same manner as prescribing information as set out in Clause 12.1 of the 2024 Code. For example, the adverse event reporting statement can be provided by way of a clear and prominent, direct single click link in a banner advertisement where space is limited. The rationale for this change was to align the requirements for adverse event reporting statements with prescribing information. However, wherever possible, it is preferred that companies keep the adverse event reporting statement as text in the body of the material.

7. What does Clause 12.3 and Clause 12.6 mean by immediately apparent?

A reader should be able to see where the prescribing information and adverse event reporting statement can be found at their first glance of the promotional material, without the need to scroll through or turn pages of the material. Where this is not so, there should be a clear prominent statement as to where the prescribing information and adverse event reporting statement can be found.