

## **Clause 12 Q&As for 2024 Code (came 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 in 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 click link to prescribing information.

### **2. If a QR code is also a link, can it be included in digital material to be accessed by a recipient on their own device?**

Clause 12.1 requires that for digital material accessed by a recipient on their own device, prescribing information must be provided within the promotional material either by inclusion as text, or by way of a clear and prominent, direct, single click link.

If a click of the QR code directly leads to the prescribing information, this would be considered a direct, single click link and would likely satisfy the requirements for the provision of prescribing information in digital material accessed by a recipient on their own device. There would need to be clear instructions to click the QR Code for the prescribing information.

### **3. 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.

**4. 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.

**5. 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.

**6. 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”.

**7. Can a QR Code, or a link, lead to prescribing information for more than one product?**

While the Code does not necessarily prohibit prescribing information for more than one medicine being on a single webpage, it is important that health professionals can access the required prescribing information quickly, easily and directly.

It would not be permissible for the QR Code or the link to lead to a landing page which required the user to make a second click to another webpage to access the prescribing information for the medicine of interest.

It would also likely be unacceptable for a health professional to have to scroll through the prescribing information of numerous other medicines to reach the prescribing information of interest.

It is also important to note that the supplementary information to Clause 12.1 of the 2024 Code, Multiple Prescribing Information, states: ‘Where more than one QR code or link is displayed, it should be clear which medicine each relates to’. This is a new requirement of the 2024 Code.

**8. The supplementary information to Clause 12.2 states that “Where elements i–viii are provided in the form of the summary of product characteristics and these are included as a QR code, single click link or as an accompanying document, then the legal classification and cost should be provided as text within the promotional material.” Can companies meet the requirements of the Code by having the legal classification and cost on the same webpage/document as that containing the SPC?**

The Code defines prescribing information to consist of three parts: the legal classification, the cost and other elements (listed as i–viii) in Clause 12.2.

Where the QR Code, link or accompanying document contains the summary of product characteristics (SPC) along with the legal classification and cost, this would be considered as meeting the requirements for prescribing information. Therefore, there would be no requirement to state the legal classification and cost again within the promotional material itself.

In the instance where the QR Code, link or accompanying document contains just the SPC, then the legal classification and cost should be stated within the promotional material itself to fulfil the provision of prescribing information.

**9. 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.

**10. 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.

**11. Why has the reference to the black triangle symbol in promotional material changed from ‘once’ in the 2021 Code to ‘at least once’ in the 2024 Code (Clause 12.7)?**

This is to make clear that it is not prohibited for the symbol to appear more than once in promotional material. Depending on the content and layout of material, it may be beneficial for it to appear more than once.