USING QR CODES OR HYPERLINKS

for accessing prescribing information in product related materials

Medicines Australia
Better health through research & innovation

KEY PRINCIPLES

- Companies must ensure that all promotional materials are balanced and include adequate information to support proper assessment of the risks and benefits of a product in accordance with Code Principles 3 and 7.

- QR Codes and hyperlinks can be used in product related materials to provide easy and immediate access to up-to-date information that supports prescribing.

- The QR Code or hyperlink must link directly (i.e. not to a search engine) to either the full approved Product Information (PI) or to a digital Minimum PI which then provides a direct link to the full approved PI.

- When considering including a link to prescribing information remember to ensure balanced information on the risks and benefits of the product is available within the body of the material.

- **DO NOT** rely solely on linking to a digital MPI and PI to provide that balance.

Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials .... to support proper assessment of their risks and benefits.

OVERARCHING PRINCIPLE 7, CODE OF CONDUCT (abbreviated)

As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use...

OVERARCHING PRINCIPLE 3, CODE OF CONDUCT (abbreviated)

MANDATORY REQUIREMENTS FOR PRODUCT-RELATED MATERIALS

WITH PROMOTIONAL CLAIMS
(Edition 19, Section 2.1)

- Brand name of the Product + the AAN
- The MPI, OR a link to the PI or dMPI when appropriate *
- Information about the reimbursement status of the product
- Supplier's name and contact
- Date material was prepared or revised.
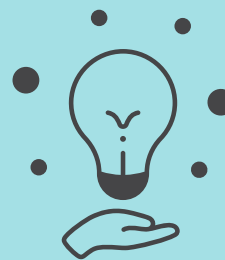
WITHOUT PROMOTIONAL CLAIMS
(Edition 19, Section 2.3)

- The MPI, OR a link to the PI or dMPI when appropriate *
- Information about the reimbursement status of the product
- Supplier's name and contact
- Date material was prepared or revised.

*When considering linking, remember to ensure balanced information on the risks and benefits of the product is available and don't rely solely on linking prescribing information to provide that balance

APPROPRIATE USE OF QR CODES AND HYPERLINKS

SAFETY BALANCE IN MATERIALS

Edition 19 of the Code of Conduct (Code) requires that companies provide current, accurate, balanced, and scientifically valid information on products to support their appropriate use, regardless of whether the material is print or digital format.

Balance in promotional materials (with or without claims) may be achieved through the inclusion of safety and precautionary information. In all promotional material there must be adequate information to support proper assessment of the risks and benefits of a product in accordance with Principles 3 and 7.

Materials with claims will need more safety and risk information to balance those claims. The question of balance may also depend on the type of product, the medical condition it is used to treat and whether there are significant safety concerns with the product, which therefore need to be communicated to healthcare professionals. It is the company's responsibility to decide upon the level of safety and precautionary information to be included in promotional materials - which can include adverse events, warnings, precautions, contraindications and interactions. Although the digital MPI/link to full PI may contribute to availability of safety information accessed directly from the material, you should not rely solely on linking to a MPI and PI to provide that balance.

CAN A QR CODE REPLACE THE MPI IN A PRINT MATERIAL?

As the Code has evolved into a principles-based Code, the approach taken to promotional materials is also evolving to a broader set of principles that apply universally, rather than specific to print or digital formats. Whilst Code Edition 19 does imply a slight differentiation for mandatory information (Sections 2.1 and 2.3), it does so to support the principle that information relevant to prescribing, in particular product and safety information, is readily available (such as via a hyperlink in electronically accessed materials). Since Edition 19 has been in effect, QR codes played a significant role during the COVID-19 pandemic and it is now accepted they play a legitimate role in the everyday life of Australians, including healthcare professionals. Because of this development, it can be reasonable to use a QR code in print materials that link to the full approved PI (including via a digital MPI) to provide that immediate access to product and safety information to support prescribing in much the same way as in electronically accessed materials.

Therefore, it may be appropriate to omit the MPI within the material when including a QR Code directly to the PI (including via a digital MPI). However, this is only when the promotional material satisfies Overarching Principles 3 and 7, where it is balanced and contains sufficient information within the material to support proper assessment of the risks and benefits of the product (see above). Calling out other key safety elements such as Black Triangle or Boxed warnings as required within the material.

ACCESSING THE MPI DIGITALLY

Using a hyperlink to the current full PI in digital materials allows quick and easy access to up-to-date prescribing information on a product. As described above, QR Codes offer this benefit from print materials as well.

Online options also present a potential improvement in the industry's commitment to sustainability, reducing the need for frequent updates of print materials containing printed MPIs.

Accessing the current full PI digitally is very helpful for HCPs, however there are some issues to navigate:

- PIs can be lengthy. Reading a full PI on a mobile device can be challenging. More and more HCPs are also accessing digital materials on their mobile devices.
- Printed MPIs go out of date over time. Even after ceasing distribution of a print material because of a label update, HCPs may still have older versions on hand.
- Printed MPIs increase the number of updates required to a print material. Changes in PI that don't affect the body of a material may still require an update to the printed MPI.
- Printed MPIs are formatted as smaller compact text due to space limitations in a print material (minimum legibility requirements do apply), and as such can be a very short precis of the PI.

Supporting a personalised educational engagement journey is critical to ensuring the industry continues to meet the needs, expectations and preferences of our HCPs as to how they wish to receive and digest information to support prescribing. Online market research of GPs completed in 2022 by Medicines Australia, highlighted that HCP preferences for access to Product Information have evolved from review of traditional abbreviated or minimum print versions. This research demonstrated an appetite for access to a digital MPI accessible on a microsite via a hyperlink or a QR code, with 85% of GPs preferring it over current access mechanisms.

A centralised digital MPI that materials link to (via QR Code or hyperlink) offer additional benefits such as:

- Mobile friendly formatting and navigation
- Greater real estate which enables including a more useful summary than current print MPIs (more detail where needed).
- Ability to include additional information such as a summary of recent PI updates, links for reporting adverse events or to company medical information.
- Central updates which apply immediately to all materials linking to them (as with links to full PIs).

A digital MPI, if used, should always provide a direct link to the full approved PI, thereby still allowing for detailed review of the full information for prescribing purposes.

Ultimately, it is a decision for each individual company as to whether a QR Code or hyperlink is used to link directly to the full PI or initially to a digital MPI, and further if a print MPI is going to be included or not in a specific material. In any case the company must ensure that the information accessed via the link is maintained and kept up to date, is always accessible, and that materials contain sufficient safety balance within them.

DIGITAL MPI CONSIDERATIONS

If you would like to consider the use of a digital MPI within your organisation, here is a list of some things to consider:

Company considerations:

- Internal or external governance on managing the digital portal that houses the digital MPI.
- Creation and maintenance of Links (digital communications) & QR Codes (Paper-based communications), ensuring links do not break over time or with updates.
- It should be non-searchable on the web
- Alignment with internal colleagues. E.g. Marketing, Regulatory, etc.
- Consider the creation of a template for consistency. This mock-up example gives you a suggestion on how this could look.

HCP/Audience considerations:

- Consider the mobile friendly format
- Readability for the user
- Preference from HCPs to receive the information in a simple and easy to access digital form

EXAMPLE

The QR Code should be accompanied with text that draws the reader's attention to its use. This example is for context only, and can be adapted to meet specific material needs.

PBS Information: This product is listed on the PBS. Refer to the Schedule for information

SCAN QR CODE
to access the [product name] Product Information

Please review full Product Information before prescribing. Available from MyPharmaCo Australia Pty Ltd.

Phone: 1800 000 000 or at www.mypharmaco.com.au/product.PI

IF IN DOUBT, REACH OUT

- Download Edition 19 of the Code of Conduct from our website

- SCAN THE QR CODE to send an email to the Code Help Desk