

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 Overarching Principles 3 and 7.
- Hyperlinks and QR codes can be used in product related materials to provide easy and immediate access to up-to-date information that supports prescribing.
- The hyperlink or QR Code must link directly (i.e. not to a search engine) to the approved Product Information (PI). It may link to the Minimum PI* as long as the approved PI is then immediately available from it.
- When considering including a link to the PI, 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 the PI to provide that balance.
- The Minimum PI is no longer required to be included in print materials or in any type of digital product-related materials, but may continue to be used as a succinct summary of key prescribing information.

*The Minimum PI (MinPI or MPI) is a succinct precis of the Product Information. The content of the MinPI was described in Code Edition 19, Section 2.2. Digital forms of the MinPI include a link to the approved PI at the top of the document.



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)

ENSURING HCPs HAVE ACCESS TO PRESCRIBING INFORMATION

BALANCING CLAIMS WITH SAFETY INFORMATION IN MATERIALS

Edition 20 of the Code of Conduct ('the Code') requires that companies provide current, accurate, balanced, and scientifically valid information on products to support their appropriate use, regardless of the material's format – print or digital.

All promotional materials, regardless of whether they contain claims, must be balanced. This balance can be achieved by including safety and precautionary information within the materials. In all promotional materials there must be sufficient information to support proper assessment of the product's risks and benefits, in accordance with Overarching Principles 3 and 7. Materials with claims will need to include more safety and risk information to balance those claims (refer to the Guidance on Balance in product-related materials). Although linking to the full PI may provide more comprehensive and detailed safety information than is contained within the promotional material, you should not rely solely on linking to the PI to provide that balance.

CAN COMPANIES CONTINUE TO USE THE MINIMUM PI IN PRODUCT-RELATED MATERIALS?

The Code now uses principles-based guidelines, applying Overarching Principles to all promotional materials, regardless of format. Code Edition 20 further advances this 'system neutral' approach compared to Edition 19. With easy digital access to information, Minimum Product Information (MinPI) in print or digital materials is no longer a required inclusion. **However**, companies can still include MinPI in the body of their promotional content if it provides a useful format to provide a succinct summary of the Product Information, including safety details and any warnings. There is no need for Companies to revise materials to remove the MinPI.

Although the MinPI is no longer required to be included in any form of promotional material, Code Edition 20 continues to require the inclusion of **some** important information to enable a healthcare professional to appropriately prescribe a product consistent with its approved use. This information is described in Section 2.1 of the Code, as below:

MANDATORY REQUIREMENTS FOR PRODUCT-RELATED MATERIALS (with or without promotional claims; abbreviated from Edition 20, Section 2.1)

- Brand name of the Product
- The AAN(s) of active ingredient(s)
- Any boxed warning or black triangle statement
- Statement referring HCPs to review the PI + mechanism to access the PI
- Information about the reimbursement status of the Product
- Supplier's name and city, town or locality of registered office
- Date the material was prepared or last revised

HOW 'IMMEDIATE' DOES ACCESS TO THE PI NEED TO BE?

This is often interpreted as being accessible via 'one click', or 'one scan'. While the Code does not prescribe this level of specificity, the intent behind this principle is to ensure mandatory prescribing information is **very easily accessible** to healthcare professionals. Access should be seamless and as immediate as possible, with the PI prominently displayed. A single click or scan might take the reader to a landing page that includes additional information; however, the PI should be upfront and obvious to avoid any need for searching for the Product Information,

DO COMPANIES NEED TO REVISE PRODUCT-RELATED MATERIALS TO COMPLY WITH CODE EDITION 20?

Most product-related materials should NOT need to be revised to comply with Code Edition 20.

Code Edition 20 requires promotional product-related materials to include a statement directing the HCP to review the PI before prescribing. Whilst this is common practice, it was not an explicit requirement in Code Edition 19. Companies should check this is included on all relevant materials.

For an advertisement that **does not include** any promotional claim which directs a reader to the MinPI within a second advertisement in the same publication some pages away, this will need to be reviewed to ensure that each advertisement includes a statement and mechanism within it that provides the means for the HCP to access the full PI immediately in electronic or other form.

'Paired' advertisements for the same product that are viewed by the reader in one spread or one view (for example, on adjacent printed pages that are viewed together, or on the same webpage in different banners or footers) may be treated as a single advertisement. Similarly, an online scrolling 'banner' advertisement is treated as a single advertisement.

CAN A QR CODE OR URL REPLACE THE SAFETY INFORMATION IN PROMOTIONAL MATERIAL?

QR codes play a legitimate role in the everyday life of Australians to access information, including healthcare professionals. It is acceptable to use a QR code in materials that link to the approved PI to provide immediate access to product and safety information to support prescribing.

However, the promotional material needs to satisfy Overarching Principles 3 and 7 and **Section 1.1 Balance**, so that it is balanced and contains sufficient information **within** the material to support proper assessment of the risks and benefits of the product. Providing access to the PI via QR Code may not necessarily or automatically provide the balance required by the piece.

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 20 of the Code of Conduct from our [website](#)
- SCAN THE QR CODE to send an email to the [Code Help Desk](#)

