

# Guidance on Balance in product related materials

Edition 20 of the Code of Conduct emphasises that companies are responsible for ensuring they provide balanced information on products to support their appropriate use consistent with the Product Information. This Guidance is designed to support and guide a company's ethical decision-making so they can achieve adequate balance in their product-related materials. However, this Guidance does not replace the Code; each company has the responsibility to decide upon the appropriate level of information in their materials to ensure they are in line with the Code's principles and Section 1.1 in particular and support proper assessment of a product's risks and benefits.

## CONSIDERATIONS

- "Balance" refers to "information that provides proportionate weight to the benefits and risks of a product". Balanced promotional materials recognise that product and risk information are as relevant as any therapeutic, promotional or non-promotional claim.<sup>1</sup>
- The proportion of space available in the promotional material dedicated to the benefits versus the risks should be considered, however, there is no expectation that an equal amount of space needs to be dedicated to each.
- The **magnitude, number and type** of claims will influence balancing considerations.
- Rationale for selection of safety information should be guided by the relevance and recency of the safety information in relation to the claim being made and the objective of the piece. e.g. If the claim is about prevention of worsening renal disease, then information that the product is contraindicated in patients with severe renal impairment should be included in the body of the piece.
- Position and prominence of safety information should be considered relevant to the claim being made, the intention of the piece and its audience.
- The stage of product lifecycle: healthcare professionals will not be familiar with 'new' Australian products and therefore there are higher expectations to provide as much information as possible to support their appropriate use.
- The complexity of the medical condition being treated; e.g. a claim relating to a complex medical condition may require more safety information to be included.
- Boxed Warnings, black triangle statements or other safety warnings required by the TGA must be included.

## WATCH-OUT QUESTIONS

- Taken as a whole, are we giving proportionate weight to the risks and benefits of the product?
- Is the safety and risk information proportionate to the medical condition?
- Does the safety information have proportionate weight to the claim/s?
- If viewed in isolation, would the promotional material be misleading?<sup>2</sup>
- Does the material emphasise the benefits whilst downplaying the risks?
- Is the claim misleading (by omission) or lack of balance?

[1] Section 1.1, point b)

[2] Section 2, point e)

# Balance Guidance in product related materials

This Guidance should be read in conjunction with Medicines Australia’s Guidance on “Prescribing Information in product-related materials” found on the [Code Resource Toolkit](#). The **magnitude** of each claim should always be considered before determining the **complexity and risk** of the piece.

COMPLEXITY OF PIECE	EXPECTATIONS	RATIONALE
<p><b>Complex</b></p> <ul style="list-style-type: none"><li>Multiple therapeutic claims and</li><li>Substantial volume of the material, for example an EDM, multiple-page leave behind, website or e-detailer...</li></ul>	<p><b>Higher</b></p> <ul style="list-style-type: none"><li>Include relevant safety information specific to the claim/s and data being provided.</li><li>Consider, safety data endpoints, AEs, dosing info, contraindications, precautions to balance the claims.</li><li>Include safety info in detail (see Code Section 1.1 and refer to Prescribing Information guidance).</li><li>If there is not enough space in the material to provide adequate balance, then reconsider the messaging and claims in the piece.</li></ul>	<p>Risks associated with the product, and prescribing information, are embedded inside the material and visible, in close proximity to the claims of benefit (prominently displayed).</p> <p>Complex and moderate messaging require ample space to give proportionate weight to risks to balance multiple claims.</p>
<p><b>Moderate</b></p> <ul style="list-style-type: none"><li>More than one therapeutic claims and</li><li>Moderate space in the material, for example a 4-page leave behind, Rx Guide, conference trade display</li></ul>		
<p><b>Simple</b></p> <ul style="list-style-type: none"><li>One therapeutic claim and</li><li>Minimal space in the material, for example a digital banner, a single-stand panel at a trade display</li></ul>	<p><b>Lower</b></p> <ul style="list-style-type: none"><li>It is a company’s responsibility to decide what risk information is adequate to balance any claims made.</li><li>In addition, QR codes and hyperlinks are appropriate for providing Product Information.</li></ul>	<p>Risks associated with the product that are relevant are embedded inside the material and visible alongside the claims of benefit.</p>
<p><b>Elementary</b></p> <ul style="list-style-type: none"><li>No therapeutic claims however</li><li>Includes product name</li></ul>	<ul style="list-style-type: none"><li>Mandatory information as per Code Section 2.1</li><li>QR codes and hyperlinks are appropriate for providing Product Information</li></ul>	<p>No claims are being made and thus no safety information required to balance those benefits (any boxed warning or black triangle statement must be included).</p>

Mandatory information as per Code Section 2.1