

Balance Guidance in product related materials

Edition 19 of the Code of Conduct requires that companies provide balanced information on products to support their appropriate use. 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 is not of equal standing to the Code, and each company has the responsibility to decide upon the appropriate level of information in their materials to ensure their materials are in line with the Code's principles and support proper assessment of a product's risks and benefits.

CONSIDERATIONS

- "Balanced" refers to "information presented in full, without bias". It is best thought of as providing equal importance to the benefits and risks of a product and recognizing that product and safety information are just as relevant as any claim*.
- 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 & type** of claims will alter balancing considerations.
- Rationale for selection of safety information should be guided by the relevance & recency of the safety balance 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 patients with severe renal impairment are contraindicated, 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 it's audience.
- The age of the product: 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.
- Boxed Warnings/black triangle/safety concerns for the patient population.

* Claim refers to all types of claims, including therapeutic claims, promotional/non-promotional claims.

WATCH-OUT QUESTIONS

- Is the safety and risk information consistent with the medical condition?
- Is the safety information relevant to the claim?
- If viewed in isolation, would the claim be misleading?
- Does it emphasise the benefits whilst downplaying the risks?
- Is it misleading (by omission) or imbalance?

Taken as a whole, are we accurately representing the risks and benefits of the product?

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This Guidance should be read in conjunction with Medicines Australia’s Guidance on “Using QR Codes or Hyperlinks”. The magnitude of each claim should always be considered before determining the complexity and risk of the piece.

