

NFTHD #47: Mandatories - are they always mandatory?

The Code requires that any product-specific promotional material, claim or no claim, needs to include mandatory information in that material. Section 2.1 supports the Overarching Principle 7, emphasising the importance of clearly communicating information relevant to prescribing, in particular product and safety information, and the need to support proper assessment of the product's risks and benefits.

There are circumstances though where the inclusion of mandatories may not be appropriate. For example, a question came to our Code Help Desk about whether mandatories need to be included on a media release, aimed at consumer media, announcing the registration of the product. Whilst the material is product-specific in nature, the release was going to a non-HCP audience and thus strictly a non-promotional piece. The mandatory information set out in 2.1 of the Code does not apply in this context. Instead, Section 10.1 outlines the required inclusions for this kind of media statement.

In addition to providing the 'mandatories', companies are responsible for providing balanced information on products to support their appropriate use – and providing this balance is key to all communications. Balance and mandatories are not the same thing. In general, mandatory information does not provide balance. For example, enabling immediate access to the PI and the PBS status of a product will not provide balance for multiple or complex promotional claims.

Another scenario is scientific exchange between a company's medical personnel and a HCP – for example, does a company need to include mandatories when providing information about an unregistered product? Whilst product-specific, scientific exchange is non-promotional, by its very nature and definition. The mandatory information set out in 2.1 of the Code does not apply in this context, nor are they likely to be relevant or available.

That said, companies are still required to provide current, accurate, balanced, and scientifically valid information on their products to support their appropriate use. Using that principle, information given about nonregistered product/usage should still be consistent with the PI in the country where the product is registered, and it is appropriate that this PI is made available in this scientific exchange. But we do know that all product-specific promotional materials require mandatories, claim or no claim.

Concluding, there may be scenarios where the use-of-mandatories is not required or are not appropriate – and these will depend on context – as illustrated above.

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