

5th September 2019

Response to TGA consultation on Increased online access to ingredient information
(Version 1.0 , August 2019)

Currently, information provided in PIs on the TGA website appears to be inconsistent e.g. on viewing the PI for bevacizumab (Avastin), there appears to be no information provided on excipients.

Arguably, both consumers and healthcare professionals need quick and easy access to excipient information in order that they can make the necessary decisions impacting a patient. To facilitate this, it is absolutely essential that the information is included in the public view of an ARTG entry.

Options 1A, 1B and 2

- It seems that none of the three options proposed by the TGA are sufficient/appropriate to address the problem. In principle, it would make sense that all excipients in a medicinal product (prescription or non-prescription) are listed, whether they are included flavours, fragrances or proprietary ingredient mixes.
- For proprietary ingredient mixes, flavours and fragrances, it could be sufficient to state the excipient name(s) without stating the quantity used.
- To help guide the decision making process in order to arrive at a suitable way forward, one important question that has to be addressed is what might happen to a patient were they to use/consume a medicine which includes an excipient that might potentially cause a serious adverse reaction leading to incapacitation, debilitation or even contribute to the demise of that patient. Under these circumstances, is there any justification that might be considered suitable in order to protect commercially sensitive information concerning an excipient?