

9 October 2019

ARTG excipients project
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern,

Increased online access to ingredient information

The Australian Small Business and Family Enterprise Ombudsman acknowledges the importance of public access to the ingredients used in therapeutic goods, and the need for consumers to access ingredients lists to enable them to make informed decisions about their use of medicines and therapeutic goods.

The August 2019 Therapeutic Goods Administration (TGA) Consultation Paper explains that much of the information on excipient ingredients in therapeutic goods is already held by TGA internally. However, the paper does not detail any additional information provision requirements that adopting either of the options presented in the paper will place on manufacturers or importers in the sector.

In line with key principles established in the *Australian Government Guide to Regulation*, the cost burden of new regulation must be fully offset by reductions in existing regulatory burden. Before TGA proceeds beyond the consultation phase, there is a need to fully understand the regulatory burden associated with adopting either option 1A or 1B on small businesses in the sector. The TGA should then examine how to either streamline existing regulation or offset the burden of the new regulations. The Office of Best Practice Regulation (OBPR) has developed a [Regulatory Burden Measure](#) to assist Agencies in calculate the regulatory costs of changes to legislation and regulation.

Other considerations that should be examined by the TGA before implementing any new regulatory requirements:

- Where practical, ensuring consistency with existing standards in food and cosmetics manufacturing;
- Ensuring that relevant intellectual property rights and commercial sensitivities are protected; and
- Developing simple and accessible processes to allow manufacturers and importers to provide all relevant ingredient lists to the ARTG.

Thank you for the opportunity to comment. If you would like to discuss this matter further, please contact [REDACTED] on [REDACTED] or at [REDACTED].

Yours sincerely

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Kate Carnell AO
Australian Small Business and Family Enterprise Ombudsman