



Regulatory Affairs Department
Pfizer Australia Pty Ltd
Level 15-18, 151 Clarence Street
Sydney, NSW, 2000

10 October 2019

To whom it may concern,

RE: Increased online access to ingredient information – Version 1.0 October 2019

Thank you for providing Pfizer Australia with the opportunity to comment on the draft guidance document *Increased online access to ingredient information*.

Pfizer Australia's detailed feedback on the draft guidance document is contained in Attachment 1.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia. We support MA's submission and encourage TGA to carefully consider the insights and recommendations presented within it. Pfizer acknowledges that whilst Option 1B is preferred over the options presented, it has limitations as described in MA's submission with respect to addressing the problem statement.

Thank you again for the opportunity to contribute to this consultation. Pfizer Australia is available at any time to provide further information to TGA, as required.

Yours sincerely,

A large black rectangular redaction box covering the signature area.

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ATTACHMENT 1

Submission to the TGA's consultation on the Increased online access to ingredient information

1. Which is your preferred option? Why?

Pfizer's preferred option is *Option 1B: Publish names of excipients except those used in any proprietary ingredient mixes*.

Option 1B allows consumer access to information that is consistent with other comparable jurisdictions e.g. Canada and New Zealand, and does not release commercially confidential formulation information that is contained in proprietary ingredients and those used as anti-counterfeiting measures.

Pfizer acknowledges that whilst Option 1B is preferred over the options presented, it has limitations as described in MA's submission with respect to addressing the problem statement.

2. What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?

Risks and benefits - Option 1A: Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes

The Proprietary Ingredient system is intended to protect proprietary information relevant to the components.

Formulations should be treated in the same way irrespective of intended purpose (i.e. they should be treated in the same way as for flavours and fragrance proprietary ingredient mixes).

The disclosure of proprietary ingredient formulations is considered to be disadvantageous to both sponsors and consumers for the following reasons:

- disclosing the formulation of proprietary ingredients may act as a deterrent for new technologies being registered in Australia;
- some medicines include proprietary ingredients that are used as counterfeiting markers. Disclosure of those ingredients potentially allows counterfeiting to be more readily achieved as controls restricting them are by-passed;
- disclosing all ingredient information without the context of the PI/CMI for prescriptions medicines, it may lead to patients not taking their medicines for which their healthcare professional(s) have determined that their use are on balance, in the patient's best interest to treat their condition.

All ingredients of known effect are already required to be listed on the product packaging in accordance with Schedule 1 to the Therapeutic Goods Orders Nos. 91 and 92, the Standards for labels of prescription and non-prescription medicines.

Risks and benefits - Option 1B: Publish names of excipients except those used in any proprietary ingredient mixes

Pfizer considers benefits of Option 1B as follows:

- medicine sponsors and proprietary ingredient manufacturers' confidential information is retained;
- there is no hindrance to the continued use of new or existing proprietary ingredients in Australia due to loss of commercially protected information;
- there may be a decreased risk of counterfeiting of medicines that include proprietary ingredients as a counterfeiting marker;
- consumers will have more readily available information available for medicines by publishing the names of excipients on the ARTG except those used in any proprietary ingredient mixes.

Excipients of known effect are already required to be declared on product labels per TGOs 91 and 92 as described in the response to the Risks and benefits of Option 1A above.

Risks and benefits - Option 2: Status quo - no action by the TGA to publish excipient names in ARTG summaries

No comment.

3. If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

Pfizer would welcome the opportunity to work collaboratively with the TGA and other key stakeholders to ensure the information is communicated to consumers in an accurate, balanced and usable manner in line with the National Medicines Policy.

Empowering consumers by providing greater access to useable health information is important. It does however need to be combined with education aimed to improve the health literacy of consumers to ensure the information is understood in context under the Quality Use of Medicine principles.