

Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

10 October 2019

Dear Madam or Sir

Consultation: Increased online access to ingredient information

ABOUT ASTHMA AUSTRALIA

Asthma Australia supports the 1 in 9 Australians with asthma to breathe better. For over 50 years Asthma Australia and the Asthma Foundations have been leaders in asthma health care, education, research and advocacy. Asthma Australia delivers evidence-based preventative health strategies through our information provision, phone line and asthma referral and coaching service.

The organisation also provides education and training to promote best practice asthma care and first aid training to schools, childcare centres, workplaces and sporting and recreational settings to ensure asthma emergencies are addressed swiftly and appropriately.

Asthma Australia supports research that contributes to national and international understandings of asthma and how best to manage the disease.

The organisation engages in advocacy on the issues that are important to people with asthma, to ensure policies are in place to support people with asthma achieve optimal health. Through this work, we reach more than 500,000 Australians each year.

To find out more about our work, visit www.asthmaaustralia.org.au.

Our Vision

Our vision is a community free from asthma.

At Asthma Australia we are committed to **halving the number of avoidable asthma-related hospital presentations by 2030**. That will mean more than 50,000 fewer avoidable trips to the emergency department in Australia.¹

What is Asthma?

Asthma is a lifelong condition of the airways. About 1 in 9 people in Australia have Asthma, one of the highest rates in the world. Asthma leads to the deaths of over 400 Australians each year, however in many cases is a manageable condition. It affects people of all ages

¹ Australian Institute of Health and Welfare, '*Chronic respiratory conditions – Asthma*' (Commonwealth Department of Health) August 2019.

and can appear at any stage of life, with symptoms including wheezing, coughing, breathlessness or shortness of breath, and chest tightness. This is due to a temporary narrowing of the airways. People with Asthma often experience symptoms at night, early in the morning or after physical activity. Exposure to smoke and pollution exacerbates asthma. Everyone is different, and with the right medication and an action plan, people with asthma can control their condition and live their lives fully.

Asthma Australia welcomes this TGA Consultation, particularly as it has the potential to directly impact on the lives of people with asthma in the following ways:

- Asthma and related allergic symptoms can be triggered by various chemical compounds, some of which are found in the excipient ingredient list of commonly used medicines, including medicines used to treat asthma.²
- Such reactions have been documented as mild to severe, and include classical asthma symptoms from cough, wheeze, chest tightness and shortness of breath.
- It is currently unclear how to predict when mild symptoms progress to serious exacerbations and when simple exacerbations progress to life-threatening ones.
- People with asthma are encouraged and empowered to understand their asthma triggers and avoid or manage them where possible.
- It is critical that they have access to the best available information relevant to their asthma triggers at all times. Poor access could be dangerous.

BACKGROUND

With regards to this consultation, the Therapeutic Goods Administration (TGA) has presented a range of three primary options:

Option 1A
<p>Publish names of excipients EXCEPT those used in flavour or fragrance proprietary ingredient mixes.</p> <p>This is the most preferred option and is currently adopted by jurisdictions such as Canada and New Zealand.</p>
Option 1B
<p>Publish names of excipients EXCEPT those used in ANY proprietary ingredient mixes.</p> <p>This would exempt the publishing of all types of proprietary ingredients. These include mixes, preservative mixes, adhesives, capsule formulations, coatings, colours, sweeteners as well as flavours and fragrances covered in Option 1A.</p>
Status Quo
<p>This would involve taking no action.</p> <p>The status quo does not stop businesses from independently publishing information about their products, however public access to excipient information would not be as transparent and straightforward.</p>

² Reker, D. et al., '*Inactive ingredients in oral medications*', Science Translational Medicine 11 (483) 2019.

In addition to information on excipient ingredients being accessible in the comparable jurisdictions of New Zealand³ and Canada⁴, other jurisdictions such as the European Union have gone as far as to publish excipient ingredients on therapeutic goods labelling.⁵

Furthermore, with innovations in medical technology, excipients play an ever-evolving role in medicines and their uses continue to expand. For instance, advances in 3D printing have resulted in the development of pharmaceutical applications, such as *Spritam* (levetiracetam) where the use of excipients allows for the dosage form to be built up layer by layer.⁶

RESPONSE TO QUESTIONS

PREFERRED OPTION (Q1)

In our opinion **Option 1A is the most-preferred option** as it provides consumers and patients with greater transparency and ease of information, carries the lowest risk-to-benefit ratio, and brings Australia into line with other comparable developed nation jurisdictions.

Asthma Australia consulted with the Consumer Advisory Council (a diverse body of people with asthma and consumers in the community) regarding the proposed changes. Consumer and patient feedback overwhelmingly supported the most transparent option available. Sentiment ranged from general support, to strong support with consumer experiences of difficulty accessing full medicine ingredients.

RISKS AND BENEFITS (Q2)

From the perspective of Asthma Australia, the principal risks and benefits can be summarised in the table below:

Risks and Benefits

	Risks	Benefits
Option 1A	<ul style="list-style-type: none"> Awareness of excipient ingredients might result in patients making ill-informed and unnecessary self-management choices to stop or avoid their medications. (It is important for consumers and patients to clarify with their health professionals) Potential risk that not publishing flavour and fragrance excipients may put some consumers at risk. 	<ul style="list-style-type: none"> Greater transparency for consumers. Overall improvement in accessibility of medicine information. In line with other comparable jurisdictions e.g. New Zealand and Canada. Bolsters faith in Australia's regulatory system.

³ *Medicines Act 1981 (NZ)*; Medsafe, *New Zealand Regulatory Guidelines for Medicine* (New Zealand Ministry of Health) 2014.

⁴ Therapeutic Goods Administration, *'Increased online access to ingredient information'*, Consultation paper (Commonwealth Department of Health) August 2019 at 6.

⁵ European Commission, *Excipients in the Labelling and Package Leaflet of Medicinal Products for Human Use, Medicinal Products for Human Use: Safety, environment and information* (2018).

⁶ Moreton, R.C., *'Excipients to the year 2025 and beyond'*, *Journal of Excipients and Food Chemistry* 10 (2) 2019 at 29-40.

	Risks	Benefits
Option 1B	<ul style="list-style-type: none"> Knowledge of some excipient ingredients may discourage patients from taking certain medications. Potential risk that not publishing flavour and fragrance excipients may put some consumers at risk. Measure perceived as a half-hearted approach. 	<ul style="list-style-type: none"> Some degree of increased transparency and identification.
Status Quo	<ul style="list-style-type: none"> Patients and consumers have limited access and transparency with regards to medicine ingredients. Australia falls behind comparable international standards and benchmarks. 	<ul style="list-style-type: none"> Immediate-term cost saving.

COMMUNICATION OF INFORMATION TO CONSUMERS (Q3)

Should Option 1A (or Option 1B) be implemented, Asthma Australia would be supportive of and interested in collaborating with the Therapeutic Goods Administration (or any other relevant stakeholder) in implementing and communicating this information to consumers. We welcome any interest group or working group, as well as further opportunities to advocate for people with asthma.

CONCLUSION

Asthma Australia welcomes the TGA Consultation on Increased Online Access to Ingredient Information, and supports efforts of reform aimed at increasing transparency for consumers and patients in line with the *Therapeutic Goods Act*.⁷

We would be happy to discuss any aspect of the Consultation or our Submission with the TGA, and appreciate being kept abreast of developments. For any further inquiries, please contact Edwin Ho (Senior Policy Advisor) at EHo@asthma.org.au.

Yours sincerely,



Michele Goldman
Chief Executive Officer
Asthma Australia

⁷ *Therapeutic Goods Act 1989* (Cth) s 61

References

Australian Institute of Health and Welfare, '*Chronic respiratory conditions – Asthma*' (Commonwealth Department of Health) August 2019.

European Commission, *Excipients in the Labelling and Package Leaflet of Medicinal Products for Human Use, Medicinal Products for Human Use: Safety, environment and information* (2018).

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