

26th September 2019

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

To the Scientific Operations Management Section

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Re: Consultation on increased online access to ingredient information

We would like to thank you for the opportunity for the Consumers Health Forum of Australia (CHF) to provide input into your consultation on whether the TGA should publish the names of excipient ingredients used in therapeutic goods in the public view of the Australian Register for Therapeutic Goods (ARTG).

CHF is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

In regard to this consultation, of the proposed options the CHF supports option 1A: to "publish names of excipient ingredients except those used in flavour or fragrance proprietary ingredient mixes"

We believe that given the serious risks associated with allergies and the increasingly wide range of ingredients that can cause allergic reactions, consumers should be able to know with certainty the entirety of the ingredients that are within medicines they intend to take.

Having any ingredients obscured poses a major health and safety risk, increasing the chances of a person who needs a medicine having an adverse reaction through unknowingly consuming an ingredient they are allergic to. Conversely, by making details

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of excipient ingredients publicly available consumers will be empowered to find out what medicines they can and can't take safely.

The CHF has received numerous messages over the years from consumers complaining about the difficulties encountered trying to find out ingredient information of their medicines, with many consumers being concerned that they are unsure if specific allergens are in their medicine or angry that they were not told that a medicine they were given had an ingredient they were allergic to in it. We believe that by publishing the entirety of the ingredients including excipient ingredients on the ARTG the TGA will be taking the first step to correcting

In addition, given that the same medicine products already have the details of excipient ingredients available in other jurisdictions such as Canada and NZ due to the regulatory requirements there, we do not accept there is any commercial risk in making these excipient ingredients publicly listed in Australia.

Our only concern with the 1A proposal is the intention to exclude excipients that are used in flavour or fragrance proprietary mixes from being made publicly available. Given that these ingredients are still consumed by the consumer, along with active ingredients and other excipient ingredients, we would argue that the same concerns apply. As such they should also be made publicly available to help prevent those with potential allergies from consuming those flavour or fragrance excipients and risking a serious adverse event due to an allergic reaction.

In addition we would argue that given that the overseas equivalents of PIs and CMIs have these excipient ingredients listed, the Australian versions of these documents should also be amended to include excipient ingredients. Providing consumers and health care professionals with a document that purports to list all the ingredients in the medicine may mislead them into incorrectly believing that there are no other ingredients in the medicine that may cause allergic reactions. While publishing the information on the ARTG is a reasonable first step, it should not be the only step taken to make this information publicly accessible given the very low number of Australians who are aware of what the ARTG is and how they can find information in it. We believe that ultimately, any resources where medicine ingredients are listed should contain all ingredients and not just active ingredients.

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Finally, should the TGA move to adopt the 1A proposal and publish the excipient ingredients list the CHF would be interested in collaborating with the TGA to communicate the changes to consumers.

Yours sincerely



Leanne Wells
Chief Executive Officer

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