

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

Dear Sir/Madam

Consultation on Increased Online Access to Ingredient Information

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation relating to publishing the names of excipient ingredients in the public view of the ARTG.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector.

Overall, Medicines Australia, and its members, supports initiatives to improve health literacy and improves the consumer empowerment to ensure the quality use of medicines, whilst respecting any intellectual property rights pertinent to proprietary ingredients. We also advocate the importance of a consistent approach across prescription, OTC and complementary medicine products with the intent to achieve the purpose of the initiative, that being to allow consumers to make safer decisions with respect to their medicines.

Our submission has been structured to address each question proposed in the consultation paper. These responses can be found in Appendix 1 accompanying this letter.

Medicines Australia is available to discuss the content of its submission further if you have any questions. Please do not hesitate to contact Betsy Anderson-Smith (banderson-smith@medaus.com.au) to organize a mutually convenient time if you would like to discuss any aspect of our submission further.

Yours faithfully



Dr Vicki Gardiner
Director of Policy and Research
Medicines Australia

Appendix 1: Response to TGA Questions:

Q1. Which is your preferred option? Why?

- **Option 1. Publish the names of excipient ingredients in the ARTG**
- **1A: Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes**
- **1B: Publish names of excipients except those used in any proprietary ingredient mixes**
- **Option 2: Status quo - no action by the TGA to publish excipient names in ARTG summaries**

Medicines Australia fully supports making it easier for consumers to identify the excipients in medicines that may cause allergies so they can make informed choices about which medicines to avoid, whilst respecting any intellectual property rights pertinent to proprietary ingredients.

Any proposal implemented must provide equivalent transparency for prescription, OTC and complementary medicines, recognizing the latter can contain particularly large numbers of ingredients and excipients that may be of interest to consumers with allergies. This is important to ensure consumers do not make assumptions that a lack of information means a medicine does not contain an allergen that may cause an adverse reaction.

A solution that makes information readily accessible from a common platform is also desirable considering prescription medicines have associated Prescribing and Consumer Information documents, whilst OTC and complementary medicines typically have only the medicine label, which makes provision of an excipient list impractical due to size constraints.

Of the different options proposed by the TGA Medicines Australia does not support Option 2. However, it is the view of Medicines Australia that neither Option 1A nor 1B will fully address the problem statement outlined in the consultation, since transparency of excipient names alone is unlikely to help consumers when trying to identify allergens. Typical medical information requests are made to obtain confirmation as to whether a product contains a particular allergen e.g. gluten; lactose; egg etc. which may derive from the use of excipients containing these components. It may thus be difficult for consumers to link the list of excipients on the ARTG to the allergen they are seeking to avoid. Similarly, use of scientific rather than common names in the ARTG may also limit the usefulness to consumers. This could be particularly challenging for complementary medicines that contain large numbers of actives and excipients including herbal ingredients. The consequences of misinterpretation could be a consumer assuming a medicine is safe when an allergen that causes them to have a significant reaction is in fact present. The limited usefulness of presenting only a list of excipients is thus unlikely to reduce the volume of calls to medical information lines or to the TGA.

Whilst having an alphabetic list of excipients available from a single source i.e. ARTG on the TGA website is desirable there is a general lack of awareness of the ARTG and the information it contains amongst consumers. Thus increased transparency of ingredients will not automatically change consumer behaviour without a public awareness and education campaign. This will be necessary to assist consumers in accessing information and helping them to identify what information will be available and what to do if they have further questions.

A process for managing formulation changes also needs to be developed to manage situations where both old and new formulations remain available with different excipients, and potential to cause allergic reactions

Since the Proprietary Ingredient system is intended to protect proprietary information relevant to the components, Option 1A seems incompatible with the intent of the scheme. For excipients that have an impact on product performance specific to a brand or other brand specific aesthetics like flavor or fragrance, that represent a unique commercial proposition, full disclosure of proprietary information would make copying easier by competitors. These aspects are likely to be of particular concern to the OTC and complementary medicines sector where medicines are self-selected.

In the EU manufacturers of flavours and fragrances are required to disclose the potential allergens they might commonly contain. An option would therefore be for the TGA to require all suppliers to disclose potential allergens, consistent with the requirements for Sponsors of therapeutic goods.

To develop a proposal that will more effectively address the problem statement, Medicines Australia would be pleased to participate in a multi-stakeholder workshop to identify how to best to meet the information needs of consumers and other Health Care Professionals.

Q2. What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?

Medicines Australia agrees that having all information on excipients available from a single source which can be accessed from the TGA website will make it easier for Consumers and Health Care Professionals to find information on excipients they need in a timely manner. Thus Option 2 does not provide any benefits for consumers.

The major risk is that a lack of an effective communication plan means that Australian consumers are not aware of the ARTG or how to access the publically available information and thus no benefit is realized from the change.

Q3. If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

Subject to an acceptable proposal being developed, Medicines Australia will be pleased to support any multi-stakeholder initiatives including other industry bodies to ensure broad communication of the availability of ingredient information online in the ARTG public view. An effective communication plan will be key to ensuring consumers are aware of the new information available so they can benefit from it.