Australian Government
Department of Health
Therapeutic Goods Administration

Increased online access to ingredient information

Consultation paper

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TGA Health Safety Regulation

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Introduction

Purpose

The Therapeutic Goods Administration (TGA) is seeking feedback on a proposal to publish the names of excipient ingredients used in therapeutic goods in the public view of the Australian Register for Therapeutic Goods (ARTG).

We are responding to consumer frustrations that they cannot easily access this information through existing mechanisms. By making this information available in the public ARTG view, which is available on the TGA website, we hope to help consumers make more informed and safer choices about their medicines.

Background

Generally, Australian consumers have access to information about the ingredients contained in the products we buy, such as food and cosmetics. This information helps us make choices about what products to purchase and which to avoid. It is also important to have this information to identify when specific ingredients may have contributed to an adverse reaction.

Information about the names of ingredients in pre-packaged food[1] and cosmetic products[2] is available to consumers – either on the product label or online. There are some exceptions for ingredients present in small amounts as well as for ingredients in certain ingredient mixes, such as flavours or fragrances.

Ingredients in therapeutic goods

Actives and excipients

Medicines contain both active and inactive ingredients. The active ingredients are responsible for the therapeutic effect of a medicine, such as pain relief. The remaining ingredients are known as excipients and are used to create the tablet, liquid or other dosage form. Excipient ingredients include those used to help improve absorption, stability, taste or appearance.

Some ingredients are made into combinations before they are included in a therapeutic good (for example flavours, excipient mixes or capsule shell formulations). These types of ingredient mixes are known as proprietary ingredients as they are commonly referred to by their trade or proprietary name.

Ingredient information available publicly

All medicines must have the name and amount of the active ingredient(s) on the product label. Consumers can also see the active ingredients for all medicines by looking at the public view of the Australian Register of Therapeutic Goods[3] (ARTG). This is the only formulation information that is in the public view of an ARTG entry.

[1] Ingredient labelling of foods - http://www.foodstandards.gov.au/code/userguide/pages/ingredientlabelling.aspx
[2] Ingredients labelling on cosmetics - https://www.productsafety.gov.au/publication/ingredients-labelling-on-cosmetics-supplier-guide
[3] https://www.tga.gov.au/artg

Allergens

Labels must include a warning if the medicine contains an ingredient that is a common allergen[4], or a common allergen may be present as a result of the manufacturing process. This is required even if the ingredient is in a proprietary ingredient. This helps consumers avoid medicines that are not suitable.

For prescription medicines, the names of active and excipient ingredients are included in the medicine's Product Information (PI) document and the Consumer Medicine Information (CMI) leaflet. PIs and CMIs can also include the names of proprietary ingredient mixes (for example 'Lemon Flavour 1234') and sometimes the names of ingredients contained within those proprietary ingredients. Consumers and health professionals can search the TGA's online PI/CMI[5] database for specific medicines and download PIs or CMIs to help inform their use of a prescription medicine.

Most non-prescription medicines do not have a PI or CMI document. Some of these medicines include the names of excipient ingredients on their label or the information is available online. Suppliers of the medicines do this voluntarily. Some suppliers of proprietary ingredient mixes also voluntarily make their formulation details available online.

Requests to TGA for information about ingredients

There are other ways that consumers can access information about the formulation of therapeutic goods. Consumers can contact the company supplying the goods (contact details are on the label) or contact the TGA directly with a request about whether a specific ingredient is present in the formulation of a particular good.

However, these processes are time consuming and rely on the consumer being able to identify and name the specific ingredient.

The problem

Consumers need better access to ingredient information

Consumers need access to information about their therapeutic goods to be able to select and use products safely and effectively. Although excipient ingredients are meant to be 'inactive', they do still have the potential to cause adverse effects[6] in sensitive individuals.

Allergic diseases are one of the fastest growing chronic disease and public health issues in Australia, with almost 20% of Australians[7] living with a confirmed allergy. These include food, insect and drug allergies, the symptoms of which can range from mild to life threatening allergic reactions known as anaphylaxis. Allergic diseases are increasing in prevalence, complexity and

[4] https://www.tga.gov.au/community-qa/allergies-and-medicines
[5] https://www.tga.gov.au/picmi-search-facility
[6] Pharmaceutical excipients – where do we begin? Australian Prescriber 2011;34:112-41 - https://www.nps.org.au/australian-prescriber/articles/pharmaceutical-excipients-where-do-we-begin
[7] National Allergy Strategy 2015: https://nationalallergystrategy.org.au/images/doc/NAS_Document_Final_WEB.pdf

severity, particularly food and drug allergies. It is becoming more important for consumers to have easy access to the names of ingredients in products to make an informed choice or, where an adverse reaction has occurred, to help identify or eliminate possible causes.

Need for better use of TGA online information

In regulating therapeutic goods, we collect and hold full formulation details in the ARTG for medicines and other therapeutic goods approved for supply in Australia, and/or those exported from here. However, currently the names of excipient ingredients are only visible in the internal TGA view of the ARTG.

Australian consumers are increasingly[8] using online sources for health information. Because of the information we hold in the ARTG, we have an opportunity to use it to help better inform consumers and support the safe use of therapeutic goods.

The Australian Government's Public Data Policy Statement[9] recognises that information held by government agencies is important and that publishing, linking and sharing of this data can create opportunities that neither government nor business can currently envisage. Consequently, agencies are encouraged to release non-sensitive data as 'open by default'.

What do they do overseas?

Therapeutic goods are a global industry. As the Australian regulator, we try to align our approach to other similar countries. In Europe (and the United Kingdom), the United States, Canada and New Zealand, prescription medicines have the names of most excipient ingredients in their equivalent of the PI and CMI.

Canada and New Zealand also include the names of excipient ingredients used in all medicines in their respective online registers (equivalent to the ARTG).

Vitamins, sunscreens, herbal products and other complementary medicines are not regulated as medicines in many overseas countries, as they are in Australia. Where these products are classified as foods or cosmetics, the names of ingredients present at more than a certain percentage are included on their labels along with other relevant allergy and substance warnings. Commonly, the formulations of flavour or fragrance mixes are not included on these labels.

Possible solutions

We propose the following options for publishing the names of excipient ingredients used in therapeutic goods in their ARTG public summaries. We understand that there are commercial sensitivities about releasing the names of ingredients within some proprietary ingredients. We have kept these sensitivities in mind when developing these options.

[8] Australia's National Digital Health Strategy: https://conversation.digitalhealth.gov.au/sites/default/files/adha-strategy-doc-2ndaug_0_1.pdf
[9] Australian Government Public Data Policy Statement: https://www.pmc.gov.au/sites/default/files/publications/aust_govt_public_data_policy_statement_1.pdf

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

Under Option 1A, the ARTG public summaries for therapeutic goods would display a list of excipient ingredients present in that good, except ingredients that are part of a flavour or fragrance proprietary ingredient. Flavour and fragrance mixes would only be displayed either by their proprietary name and number (e.g. 'PI1234 Lemon flavour') or by their purpose (e.g. 'flavour') and would not display their constituent ingredients.

This approach broadly aligns with ingredient information available for foods and cosmetics in Australia. This option is also consistent with practices adopted by New Zealand and Canada for both prescription and non-prescription medicines.

1B: Publish names of excipients except those used in any proprietary ingredient mixes

Under Option 1B, the ARTG public summaries for therapeutic goods would display a list of excipient ingredients used in that good, except those ingredients present as part of **any** type of proprietary ingredient.

Currently there are 16 types of proprietary ingredients used in therapeutic goods. Aside from the commonly known flavours and fragrances these include colours, printing inks, preservative mixes, coating solutions, capsule formulations and cream bases. Under this option, any combination of ingredients referred to as a proprietary ingredient mix would be included in the public summary either by its proprietary name and number or by its purpose.

Under this option consumers would still have increased access to information about excipient ingredients in therapeutic goods, especially for non-prescription medicines. However, significant gaps in publicly available information would remain, resulting in continued misalignment with the approaches for food and cosmetics.

Implementation considerations

Under Options 1A and 1B, an 'Excipient ingredients' heading would be added to the ARTG public summary template for the following types of therapeutic goods:

- prescription medicines
- non-prescription medicines (both registered and listed, including complementary medicines)
- biologicals (cell and tissue therapies)
- other therapeutic goods, such as disinfectants and sterilants.

Each individual ARTG public summary pdf would then include an alphabetic listing of excipient ingredients.

Under these options we would also need to update our legislative specifications, which identify the type of information we release to the public under section 61 of the *Therapeutic Goods Act 1989*.

We will also need to work with consumer and health professional representative groups to make sure that consumers can access this information. If either Option 1A or 1B is supported we will set up a group of 'communication champions' to help us disseminate information about the availability of excipient information.

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

Under this option there would be no action by the TGA to publish the names of excipient ingredients in the ARTG public summaries.

Businesses can still voluntarily publish information on the formulation of their products, including proprietary ingredients used in therapeutic goods. However, existing problems outlined above about the lack of easy public access to excipient information would continue.

Questions and next steps

We are seeking feedback on options to improve consumer access to information about excipients in therapeutic goods.

Questions

Q1. Which is your preferred option? Why?

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

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

We will consider any feedback received before a decision is made. We will also publicly announce the outcomes of this consultation.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	SOMS/SEB	August 2019

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