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Dear TGA

## Consultation: Increased online access to ingredient information

Thank you for seeking input on medicine ingredient information, specifically, excipients. You have posed the following questions.



### 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?

### Q1

Options 1A and 1B, below, both fall short of providing clear, accessible, comprehensive information to a consumer who experiences severe allergies. Consumers' ability to know exactly what is in each pharmaceutical product is empowering. The TGA acknowledges this. However, there are problems with simply making information available via a website.

Option 2, the status quo option, is not acceptable as there is a clear need for greater level of information about excipients to be available to consumers.

#### **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.

## Q2

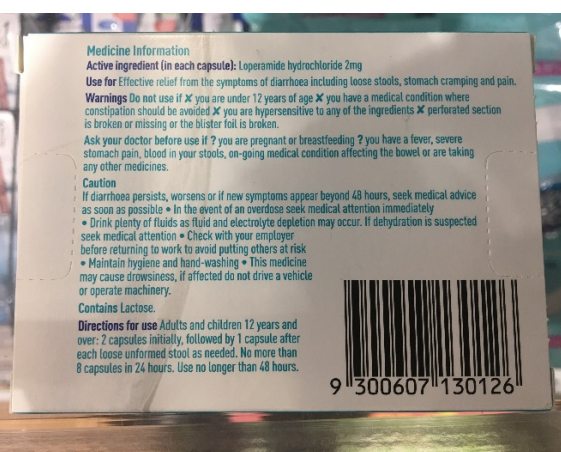
Neither of Options 1A or 1B go far enough in protecting vulnerable consumers. Neither option solves enough problems. The risk is that consumers will continue to be uninformed as they won't know where to find the lists, won't be able to access them or understand them and that the lists won't capture things that people themselves know they are allergic to.

The list of [common allergen](#) on the TGA website is not comprehensive. It does not, for example address rice allergies and it lumps sorbitol into one category without disclosing its origin. People can be allergic to sorbitol from one source but not another source.

It can be impossible or very difficult for someone to look up the ingredients on the internet. This can be because:

- They don't know the TGA exists.
- The shop selling the medication does not have reliable internet, the consumer might not have a way of connecting to the internet, they might have no money left on their phone account.
- The consumer might not speak enough English to ask the shop keeper for the list of excipients. If the excipients are **listed on the outside of the package** someone who does not speak English but is allergic can use a program like Google translate to look up the listed excipients to check they will not cause problems. If they have to go through another step and look up a website they have to juggle their device between a web address provided by the TGA (and possibly at that point they have no internet coverage) and another that provides translation software. Imagine trying to do this when you are a tourist whose bus has stopped at a Roadhouse so you can run in to collect some medication for your diarrhoea or headache.
- The shop might be a supermarket or general store, not a pharmacy. They might sell a wide range of OTC products, but the shop assistant can be unaware of the TGA. They might not have a printer they could use or would be willing to use to print out the list from the TGA even if they did have the internet.
- Below is the display at my local stationery shop. I took photos of the Claratyne, both Advil boxes, Imodium and Zantac. The only one of those to have a full list of excipients

on the outside of the box was the small white Advil box. I know Advil in this box as a US product.



I offer 3 examples from within my personal experience of people who suffer extreme adverse reactions to undisclosed excipients. These will be far from isolated cases.

### Case examples

**Annie** is 3 years old. She lives on a rural property 3 hours' drive west of Canberra. She is a bubbly, intelligent, farm kid who loves riding her pony. She has FPIES. 'FPIES is not rare, with

an estimated incidence of 15.4/100,000/y. Rice is the most common food trigger in Australia?<sup>1</sup> It is not listed on the TGA's list of common allergens. There are only about 20 individual food items Annie can tolerate. Ingesting anything outside this narrow range triggers the following reaction. First, she vomits to shock, she then becomes unconscious, she stops breathing and needs to be resuscitated if not caught early enough. She has had to be resuscitated over 25 times in her short life. The nearest hospital with paediatric expertise is a 2-hour drive from home.

Annie's mother is a highly educated animal nutrition expert. She does look up the excipients for every medication, but as she points out, you need a huge amount of knowledge to know what these ingredients are derived from.

Even specialists in the paediatric ward question what Annie's mother is asking about because they, also, have no idea what the excipients are in the medication they propose giving Annie. They don't seem to get that it might be the excipients that a patient is reacting to.

It has taken a long time for Annie's family to track down information about all ingredients in everyday medication. This is exacerbated in rural areas where the internet connection is not always reliable.

**Brigid** is 52. She lives in Sydney. She has severe Down's Syndrome and is epileptic. It is hard to understand her speech. Medications for epilepsy are Epilim and Valpro. The active ingredients in both products are the same. Brigid's family has no idea what the excipients are. Brigid is rendered almost comatose from Epilim and is perfectly fine with Valpro.

Both Annie and Brigid have become very ill after taking standard, usually prescription, medication. In both cases their families know what food items need to be avoided but did not know the item was in the medication.

**Rodney** takes Crestor for high cholesterol. <https://www.rxlist.com/crestor-drug.htm#indications> He has been taking Crestor 10mg for quite some time however in his experience the pharmacies tend to push generic medication on the premise of reduced cost. The comparable generic product Apotex Rosuvastatin reacts badly with him; causing a bad reaction in relation to muscle fatigue, soreness and general unwellness. The difference between the products is the excipients.

Rodney has also used the Rosuvastatin Sandoz without too many issues (muscle soreness & muscle fatigue an ongoing problem for him on this medication). Rodney's experience would indicate that not all generic products are the same.

Sadly, a foreseeable risk is that as consumers become increasingly litigious, it is conceivable that drug companies may be sued for causing a consumer to suffer permanent health problems if non-disclosed excipients are shown to have caused the problem.

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<sup>1</sup> Sam Mehr, Katie Frith, Elizabeth H. Barnes, Dianne E. Campbell. 'Food allergy and gastrointestinal disease Food protein-induced enterocolitis syndrome in Australia: A population-based study, 2012-2014' November 2017, Journal of Allergy Clinical Immunology, 1323.



### Q3

Because of Annie's experience with hospitals (see above), please include informing/ educating people who work in hospitals about the potential danger of excipients for patients with allergies.

### My preferred option is Option 1C.

Require manufacturers of all pharmaceuticals to list **all** excipients, on the **outside** of the packet. This is especially important in products that are ingested. It is useless to include the information only inside the package as by that time the consumer has made the purchase, opened the packet and the bus is rolling along towards the next Roadhouse!

This would enable consumers to take personal responsibility. The manufacturers know exactly what the excipients are in every product they sell. They already report this to the TGA.

The cost to manufacturers would be minimal, in that they would have to find room on the package to include the full list. They could be written in order of greatest to smallest, as they are in food items, or alphabetically. It would not matter if they were in small font as I expect most consumers have access to a phone, can take a photo of the information and blow it up to read it.

The Australian Competition and Consumer Commission (ACCC) is the high-level regulator charged with consumer protection. When prioritising product safety risk, the ACCC uses five risk factors.

1. there is a high risk to public safety due to the potential number or severity of injuries.
2. users are unable to perceive or safeguard against the risk.
3. users of the product expose other people to the risk of death or injury.
4. the product is subject to those 66 compulsory safety standards and bans.
5. ACCC action is likely to have a broader public benefit.

The 3 examples I have provided serve to illustrate that pharmaceutical products, especially ingestible ones, fall within risk factors 1, 2 and 5 identified by the ACCC, they should be identified and addressed in the ACCC's proposed General Safety Provision.

In the meantime, the action proposed by the TGA in Option 1A in the consultation paper is a useful first step.

I am happy to engage with this issue further if the TGA would find that useful. I can be contacted at UNSW Sydney. My contact details are below.

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