23rd November 2015

To whom it may concern:

On behalf of Allergy & Anaphylaxis Australia I wish to make a submission on Therapeutic Goods Orders TGO 91 and 92

Background

Allergy & Anaphylaxis Australia (A&AA) is a charitable, non-profit organisation established in 1993 to support and assist those affected by allergy and anaphylaxis. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions including food allergy. A&AA’s aim is to enable individuals and their families to enjoy an optimum quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergy in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of several allergy specialists who are also members of Australia’s peak medical body, ASCIA (Australasian Society of Clinical Immunology and Allergy).

Summary

A&AA wishes to comment only on those issues which are concerned with allergens in medicines and is pleased to see substantial consistency with the ANZ Food Standards Code (FSC). Schedule 1 does not however resolve the ambiguities apparent in the corresponding FSC relevant standard. FSANZ is currently seeking advice on such issues, and their ultimate recommendations may assist the TGA in the future.

The TGA would be aware that there are many allergens other than those in Schedule 1, and that those listed are based on an historical priority. A&AA would urge the TGA to give urgent consideration to the inclusion of mammalian alphagal, see below.

Specific issues

A&AA notes that substances listed in Schedule 1 must be declared “if present”, which would presumably cover direct addition, carry-over from addition to another ingredient as well as present as a contaminant. This approach is a substantial improvement over the FSC by the inclusion of contaminants, and is most welcome.

The label presentation requirements under section 7 are considered as essential to provide adequate legibility for allergic consumers to make an informed choice and protect their health.

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The requirement to declare the relevant substance by use only of the name or names listed in column 4 of Schedule 1 is also a substantial improvement on the FSC where the specific name may be used. This can create a problem where customers may not be aware, for example, that caseinate is a milk product.

The schedule lists “pollen” rather than “bee pollen” as per the FSC. This is also considered a substantial improvement.

Schedule 1 does not yet resolve the ambiguities apparent in the corresponding FSC standard. FSANZ is currently seeking advice on such issues, and their ultimate recommendations may assist the TGA in the future. For example:

- Crustacea are generically considered to be within the category of fish, and yet fish and fish products are also listed separately.
- Eggs and egg products could mean those of the domestic fowl, therefore would egg and egg products from other birds be excluded?
- Fish and fish products could be inferred to exclude crustacea which are listed separately. It is not clear therefore if other “fish” such as molluscs are included.
- Milk and milk products could be interpreted as either the lacteal secretion of the cow, or that of all mammalian animals. This may be particularly relevant for goat milk or its products.

Schedule 1 column 1 lists “gluten”. This may be a potential issue for those with a wheat allergy. FSANZ acknowledges that the corresponding section in the FSC is intended to provide protection for both those with coeliac disease and those with a wheat allergy. The FSC requires the declaration of any product derived from wheat, regardless of the presence or absence of gluten, providing an effective warning to a wheat allergic individual. There may be two issues here with the TGA proposal. A person with a wheat allergy would need to avoid that medicine even when the gluten came from a non-wheat source, and may experience difficulty sourcing a safe alternative. Secondly, the medicine may contain wheat protein other than gluten, which would not be required to be declared, posing a potential hazard for the wheat allergic individual.

A&AA considers the listing in column 1 of some products under “including” can be potentially misleading. A&AA considers that examples of allergen products should be left in the accompanying notes, or in the guidance document.

- For example under crustaceans and crustacean products there is listed “white prawns”. It is difficult to see what this achieves beyond doubts about whether other prawn species are actually crustaceans.
- Fish and fish products lists three species out of the thousands in existence, to no obvious purpose, and includes “cod”, a fish name which probably arouses more controversy internationally than any other.
- Sesame seed and sesame seed product includes sesame seed.
- Likewise soya beans includes soy bean.
- A proposal for the exclusion of soya oil that is fully refined is under review by FSANZ at the moment, and it may be premature to exclude it at present.
- For tree nuts, nominating just a few may also be confusing.

A&AA agree that the listing of the botanical name is appropriate, however it should appear after the common name viz Peanuts (Arachis hypogaea) and peanut products rather than under “including”. Listing Arachis hypogaea might indicate there are peanuts other than Arachis hypogaea.

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Mammalian meat anaphylaxis and allergy is an emergent allergy around the world (ref 1). Australia has the highest prevalence of this condition world-wide (> 1:550 [ref 2]). Individuals with this complaint are allergic to the molecule alphagal. Alphagal is a carbohydrate moiety present in all mammals except humans, great apes and Old World monkeys. The presence of alphagal in medicines (e.g. cetuximab) means alphagal-sensitised individuals are at risk of allergic reactions to these alphagal-containing therapeutic agents. Cetuximab, for example, has resulted in at least 7 fatal reactions world-wide (ref 3) and we have had one death very likely due to alphagal sensitisation (personal communication to A/Professor Van Nunen from the gentleman’s widow) here in Australia. Alphagal allergy confers a risk in treatment with a wide range of therapeutic substances (cetuximab, cat gut sutures, porcine valves, snake antivenene, vaccines… ) and this list is growing (ref 4). Reactions to alphagal are more likely to be more severe, as many are injected or administered parenterally. US pharmacies can currently access a list of alphagal-containing therapeutic agents. It would be prudent if the similar information were to be available to patients here in Australia. Furthermore, a significant minority of mammalian meat allergic individuals are allergic to mammalian-derived gelatine, also present in many therapeutic agents e.g. vaccines (ref 5). Identification of alphagal in medicines will potentially save lives.

Thank you for the opportunity to provide comments

Yours sincerely,

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References:

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