MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Proposed warning statements for substances (eg, allergens) in medicines that may cause undesirable reactions

September 2020

Consultation outcome

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Executive summary

This Medsafe consultation proposed new warning statements for the labels of medicines and related products that contain substances/groups of substances that may cause an undesirable reaction (eg, allergies) in some people.

The new warning statements will be implemented through the Label Statements Database. This database lists the warning and advisory statements that are required on medicine and related product package labels under the Medicines Regulations 1984. Note that these warning statements do not apply to items such as food, cosmetics, herbal preparations or dietary supplements.

The new statements align with those required on medicine labels in Australia, under Therapeutic Goods Orders (TGO) 91 and 92. Many medicines marketed in New Zealand are also marketed in Australia and have harmonised labels (ie, are distributed in the same pack in Australia and New Zealand).

The consultation opened on 27 June 2019 and closed on 8 August 2019.

There were 260 responses to the consultation. Respondents included members of the public, health care professionals, industry, and government and consumer organisations. Most respondents were supportive of the labelling changes. You can view the submissions that we have permission to publish.

The proposed implementation date for the new warning statements was 1 September 2020. However, based on feedback from industry, the implementation date has been revised to 1 March 2021 for New Medicine Applications and 1 March 2024 for existing products. Medicines released for supply in New Zealand after 1 March 2024 must have updated package labels. However, Medsafe encourages sponsors to update their labels before this date, if feasible.

Based on respondent feedback, we have made some minor changes to the proposed statements – see the Warning statement results section of this document for details.

Key changes are as follows.

- We received feedback that the examples in the Medicine/Group/Class column (called 'inclusions' in the consultation) were too specific. These are examples only and should not be considered a complete list. Therefore, we have modified the text in the Medicine/Group/Class column to say "Examples include:"
- We have removed the word "caution" from the statements to align with the TGA statements.
- For the gluten statement, the source of the gluten should be identified, the statement should apply to all uses, and the threshold has been lowered from the proposed 20 parts per million (ppm) to 3 ppm.

About the consultation

This Medsafe consultation proposed new warning statements for medicines and related products that contain substances/groups of substances that may cause an undesirable reaction (eg, allergies) in some people.

Unlike foods, most medicines and related products are not required to list all the ingredients that are included in the medicine on the product labels. The active ingredient will always be on the label, but only some inactive ingredients, also called excipients, must be on the label. Also, some potential allergens, such as impurities from manufacturing, may not be on the label.

We will implement these new warning statements through the Label Statements Database (see Appendix 1 for more information). This database lists the warning and advisory statements that are required on medicine and related product labels under the Medicines Regulations 1984.

Substances to be included in the Label Statements Database

Antibiotics	Lactose	Sodium salts
Aspartame	Milk and milk products	Sorbic acid and sorbic acid salts
Benzoates	Peanuts and peanut products	Soya beans and soya bean products
Crustacea and crustacean products	Phenylalanine	Sucralose
Egg, egg products	Pollen	Sugar alcohols
Ethanol*	Potassium salts	Sugars
Fish and fish products	Propolis	Sulfites
Galactose	Royal jelly	Tartrazine*
Gluten	Saccharin	Tree nuts and tree nut products
Hydroxybenzoic acid esters	Sesame and sesame seed products	

* Ethanol and tartrazine are already included in the Label Statements Database, but we proposed changes to the conditions and/or statements.

The proposed statements align with those that must be included on medicine labels in Australia by 1 September 2020, under Therapeutic Goods Orders 91 and 92.

Unless specifically indicated, the statements in the Label Statements Database do not normally apply to prescription medicines. Because the Australian labelling requirements for these substances apply to prescription and non-prescription medicines, the proposed statements for New Zealand will also apply to prescription medicines.

The consultation opened on 27 June 2019 and closed on 8 August 2019.

Consultation results

Thank you to everyone who responded to the survey.

We have analysed and summarised the survey results. This results section is divided as follows:

- Overview of respondents
- General comments from respondents and Medsafe responses
- Implementation date
- Warning statement results (listed alphabetically) – each includes a response table organised by category of respondent, a summary of comments from respondents and the Medsafe response/outcome, including the final warning statement
- Other comments and Medsafe responses

The final statements, as they will appear in the Label Statements Database, are also provided in Appendix 1.

Overview of respondents

You can view the submissions that we have permission to publish.

We received 260 responses via the consultation tool. Most respondents were individuals (Table 1) and were based in New Zealand (Table 2).

Note that we received one late submission via email. While this submission was not included in the summary tables, we did consider the comments as part of our analysis.

Table 1: Respondent type – individual or organisation

Respondent	Number	Percentage
As an individual	219	84.2
On behalf of an organisation or group	30	11.5
Not answered	11	4.2
Total	**260**	**100.0**

Table 2: Respondent location

Location	Number	Percentage
New Zealand	221	85.0
Australia	10	3.8
Other	2	0.8
Not answered	27	10.4
Total	**260**	**100.0**

Respondents included members of the public, health care professionals, industry, and government and consumer organisations. For the analysis of results, we categorised the 260 respondents into one of four categories (Table 3):

- Public, n=195
- Health Care Professional (HCP), n=29
- Industry, n=20
- Other, n=16.

Table 3: Respondent category

Respondent	Categorised as[a]	Number	Percentage
Member of the public	Public	193	74.2
Consumer organisation	Public	2	0.8
Health care professional	HCP	27	10.4
Professional body	HCP	2	0.8
Sponsor[b]	Industry	8	3.1
Manufacturer	Industry	6	2.3
Industry organisation	Industry	3	1.2
Supplier	Industry	2	0.8
Regulatory affairs consultant	Industry	1	0.4
Respondent who did not answer	Other	12	4.6
Other[c]	Other	2	0.8
Government	Other	1	0.4
Institution	Other	1	0.4
Total		**260**	**100.0**

Notes

a. For the analysis, the 260 respondents were grouped into one of the following categories: Public (n=195), Health Care Professional (HCP) (n=29), Industry (n=20), Other (n=16).
b. One sponsor self-selected as Consumer Organisation. This was changed to 'Sponsor' in the analysis and therefore included in the Industry category.
c. There were 6 respondents who selected 'Other'. Of these, there were 3 parents of children with allergies, one person with coeliac and 2 who did not answer. The 3 parents and person with coeliac disease were changed to 'Members of the public' for this analysis and therefore included in the Public category.

Of those that answered, most health care professional respondents were pharmacists or worked in a pharmacy (Table 4).

Table 4: Health care professional respondents

Profession	Number	Percentage
Pharmacist/pharmacy	11	40.7
Dietitian/nutritionist	3	11.1
General practitioner	2	7.4
Nurse practitioner	2	7.4
Paediatrician	1	3.7
Public health	1	3.7
Registered nurse	2	7.4
Not answered	5	18.5
Total	**27**	**100.0**

General comments from respondents and Medsafe responses

The following is a summary of general comments or questions received from respondents, and Medsafe's response to each of them. Because these comments apply to some or all warning statements, we have included them here rather than repeating them throughout the document.

1. Please ensure that the Ministry's website is constantly maintained to ensure an accurate source of information for all users.

Medsafe response

We always aim to keep the website updated.

The Product/Application search on the Medsafe website contains information about each product, including the ingredients, and is updated whenever a product has an approved change.

Medsafe also publishes data sheets and consumer medicine information (CMI) documents. Pharmaceutical companies are responsible for the content of data sheets and CMIs, including keeping the information up-to-date.

Medsafe will also produce information for consumers about these new statements, likely in the form of a Consumer information leaflet that will be published on the Medsafe website.

2. Warning statements should only be in data sheets and/or CMIs on Medsafe website, with efforts made to promote these as sources of information

- Some medicines are sold as bulk packs from which individual prescriptions are dispensed so allergen info on label is lost upon dispensing.
- Only put on label if in its one of the top 10 allergens causing problems in NZ.

Medsafe response

Dispensing packs must include warning statements. We would expect that pharmacists would discuss potential allergens with patients and the warning statements on the dispensing pack would provide a prompt for this discussion. Medsafe will maintain other information sources (for example, the Product/Application search).

Sponsors are not required to produce CMIs (although they are encouraged to), and it's not mandatory for CMIs to be given out by pharmacists when medicines are dispensed.

Note that where it is impractical to put the warning statement on the label because the container is too small, the warning statement may be printed on a separate information sheet, which is supplied to the customer with the medicine (for example, a package insert).

3. These statements should only apply to non-prescription products.

Medsafe response

Medsafe disagrees – allergies can occur with prescription and non-prescription medicines, and warning statements on package labels provide a prompt for the pharmacist to discuss potential allergens with the patient.

4. Will Medsafe accept:

- additional explanatory information or words with a similar meaning, e.g. "contains bee pollen" (instead of pollen), or "contains hydroxybenzoates (preservatives)" (instead of "contains hydroxybenzoates")
- the use of a shortened statement, eg 'contains fish' or 'contains fish products'
- combined statements, eg, contains fish and pollen.

Medsafe response

Yes. The Label Statements Database states:

> *Words of a similar meaning to the statements in the database may be used and individual statements may be combined provided the intent is not changed.*

5. The inclusions may focus the supplier/manufacturer on the specific list rather than on the class. The class, conditions and statement should be sufficient to capture the requirements.

Medsafe response

As with the Australian TGOs, the inclusions are examples that sit underneath the primary substance name. These are examples only and should not be considered a complete list. We have modified the text in the Medicine/Group/Class column to say, "Examples include:". Sponsors may also check with Medsafe if a particular substance should be declared on the label.

Sponsors must determine whether any other substances in their medicine fit the definition and need to be declared. Sponsors should speak to their manufacturers about whether any declarable substances are an ingredient or component in the medicine or a known part of the manufacture of the medicine.

6. The entries in the 'Conditions' column should include a threshold below which a substance doesn't need to be declared on the label.

Medsafe response

As per the Australian guidance document for TGO 91 and TGO 92[1], when there is no cut-off specified in the 'Conditions' column, sponsors should declare the substance if:

- it has been added during any of the manufacturing processes (even as a manufacturing aid) and there is any likelihood that it remains in the finished goods
- it is a known component, or likely to be a component, of one of the ingredients in the medicine.

Sponsors should assess the risk to consumers to determine whether a substance may be present and should be declared.

1 Therapeutic Goods Administration. 2019. *Medicine labels. Guidance on TGO 91 and TGO 92*. Version 2.1, July 2019. URL: tga.gov.au/sites/default/files/medicine-labels-guidance-tgo-91-and-tgo-92.pdf (accessed 3 September 2019).

Tests to determine presence of an ingredient may not be sensitive enough to detect potential allergens but can be used to provide further information to consumers. Sponsors may choose to include additional information about the allergen on their label, website, data sheet or CMI documents. Information could include the level of residue detected, the measures taken to remove the substance or how the substance has been used in the manufacturing process. When including additional information, the statement, '*contains x*' must still be declared on the label as required by the Label Statements Database warning statements.

If it is unlikely that a substance is present, declarations should **not** be made simply as disclaimers. Sponsors are not required to introduce tests for *all* allergens.

Medsafe will consider the TGA's interpretation of when a substance should be declared, if the sponsor provides all correspondence with the TGA and related documentation with the application.

7. Consider cross-contamination during manufacturing. Eg, May contain traces of the allergen.

Medsafe response

The proposed label warning statements relate to medicines rather than food. Medicines must be manufactured in accordance with GMP (Good Manufacturing Practice)[2]; any cross-contamination would be a serious quality issue and would potentially require a recall. GMP manufacture requires controls to be in place to reduce the risk of cross contamination. For example, cleaning validation is required between manufacture of different medicines to ensure that there is no carry over from one product to the next.

8. No need for "Caution" prefix in the statement.

- "Caution" not used in Australian TGOs. Many New Zealand Sponsors use a 'shared' Australian /New Zealand pack and the addition of 'caution:' may lead to product withdrawals due to the inability to maintain a harmonised pack.
- The word "caution" may overtly alarm patients who do not have an intolerance to the ingredient, and patients identified as having adverse reactions to the ingredient should be sufficiently warned by the ingredient appearing clearly on the label – even without the word "caution" preceding it.

Medsafe response

Medsafe agrees with the first point and has removed the word "Caution" from the statements.

2 Medsafe. 2017. The Medsafe Files – Episode Four: New Medicines Assessment (Part 3): GMP. Prescriber Update 38(4) 56–7. URL: medsafe.govt.nz/profs/PUArticles/December2017/EpisodeFourGMP.htm (accessed 28 November 2019).

9. Include more information on the label:

- specify the form in the statement. For example, 'Contains sulfites [specify form]'
- have an allergy warning. For example, 'Allergen warning: contains propolis'
- have an explanation of the allergy.

Medsafe response

Specifying the form on the package label is at the manufacturer's or sponsor's discretion and would be considered words of a similar meaning. The form could also be included in the CMI and data sheet at the sponsor's discretion.

Short concise messages on the package labels are easier to read and understand. To align with Australia, there is no requirement to add 'allergen warning' or to have an explanation of the allergy on the label. These warning statements are prompts for patients and their health care professionals to find out more information (for example, from the data sheet or CMI). However, sponsors may choose to add additional information at their discretion.

Implementation date

- Do you agree with the proposed implementation date of 1 September 2020 (1/09/2020)?

Implementation date responses

Table 5: Implementation date responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Agree with date	Yes	98	37.7	77	39.5	17	58.6	1	5.0	3	18.8
	No	25	9.6	9	4.6	1	3.4	15	75.0	0	0.0
	Not answered	137	52.7	109	55.9	11	37.9	4	20.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

Implementation concerns from Industry

- Of those that answered, most industry respondents disagreed with the proposed implementation date.
    - The proposed date is too soon, need 3–4 years to allow for stock to be turned over, source allergen info from suppliers, update artwork, Medsafe CMN review and approval timeframes. Medsafe may need to consider labelling exemptions.
    - A definition of the implementation date is also sought, ie, no further stock would be released using the existing label, however stock already released for sale to market will continue to be sold through. TGA has defined it as those products released for supply after 1 September 2020 must have updated labels.
- There were concerns about new Therapeutics Bill legislation and whether this would also mean future label changes. Consider waiting until new legislation is in force and then all changes are made at once.
- Need to consider future changes to the Australian TGOs.

Public + HCP + Other

- Of those that answered, most Public, HCP and Other respondents agreed with the proposed implementation date of 1 September 2020. The 10 respondents that disagreed said that the implementation date should be sooner than 1 September 2020.

Medsafe response/outcome

Information for Industry

The usual timeframe for implementation of LSD changes is 1 year after the outcome is published on the Medsafe website. However, given the number of proposed changes and the feedback received from industry for this consultation, the implementation date will be 1 March 2021 for New Medicine Applications and 1 March 2024 for existing medicines.

Medicines released for supply in New Zealand after 1 March 2024 must have updated package labels. However, Medsafe encourages sponsors to update their labels at the earliest opportunity and before this date, if feasible.

Information for patients and health care professionals

As part of the approval process to market a medicine, sponsors submit the proposed package labels to Medsafe. Many medicines marketed in Australia are also marketed in New Zealand and have harmonised package labels. Because the Australian TGO 91 and 92 labelling requirements come into effect on 1 September 2020, sponsors that market their medicines in both countries have already been submitting updated labels to Medsafe for approval. So even though the New Zealand implementation date for updated package labels is 1 March 2024, many medicines will have updated labels before this date.

In the interim, you can use Medsafe's Product/Application search to check the ingredients in a medicine.

Warning statement results

Antibiotics

Proposed warning statement for residual antibiotics.

Medicine/Group/Class	Conditions	Statement
Antibiotics	For all classifications, including prescription, and all uses – when the antibiotic is not an active ingredient and is present only as a residual impurity	Caution: contains residual [antibiotic name]

Antibiotic responses

- Of those that answered, most respondents agreed with having a statement for antibiotics, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 6: Antibiotic responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	142	54.6	108	55.4	21	72.4	10	50.0	3	18.8
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	116	44.6	87	44.6	7	24.1	9	45.0	13	81.3
Agree with conditions	Yes	136	52.3	103	52.8	21	72.4	9	45.0	3	18.8
	No	2	0.8	0	0.0	0	0.0	2	10.0	0	0.0
	Not answered	122	46.9	92	47.2	8	27.6	9	45.0	13	81.3
Proposed statement	Yes	125	48.1	98	50.3	21	72.4	3	15.0	3	18.8
	No	12	4.6	3	1.5	1	3.4	8	40.0	0	0.0
	Not answered	123	47.3	94	48.2	7	24.1	9	45.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include statement

- No. High resistance around use of antibiotics among some populations. Statement may cause unwillingness taking or giving medicine (especially to child) as 'residual' may still not be seen as harmless (HCP).

Agree with proposed statement

- No. Use laymen's terms so all can understand. (Public)

- No. If labelled, it should be clear to public that it is an antibiotic. Suggest using the word ‘antibiotic’, in brackets the specific antibiotic. Public do not know the names of all antibiotics. Eg, "Caution: contains residual antibiotic [antibiotic name]" or “Caution: contains residual [antibiotic name] (antibiotic)”. (Public, HCP)

Medsafe response/outcome

- The statement is a prompt for the pharmacist to discuss the potential allergen with the patient and what it means for them.
- Sponsors can alter the statement to include the word “antibiotic”, providing that the intent is not changed.

The antibiotics statement will be:

Medicine/Group/Class	Conditions	Statement
Antibiotics	For all classifications, including prescription, and all uses – when the antibiotic is not an active ingredient and is present only as a residual impurity	Contains residual [antibiotic name]

Aspartame

Proposed warning statement for aspartame.

Medicine/Group/Class	Conditions	Statement
Aspartame	For all classifications, including prescription, and for oral use	Caution: contains aspartame

Aspartame responses

- Of those that answered, most respondents agreed with having a statement for aspartame, and agreed with the conditions and statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 7: Aspartame responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	107	41.2	75	38.5	19	65.5	10	50.0	3	18.8
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	151	58.1	120	61.5	9	31.0	9	45.0	13	81.3
Agree with conditions	Yes	106	40.8	74	37.9	19	65.5	10	50.0	3	18.8
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	152	58.5	121	62.1	9	31.0	9	45.0	13	81.3
Proposed statement	Yes	98	37.7	74	37.9	19	65.5	3	15.0	2	12.5
	No	10	3.8	0	0.0	1	3.4	8	40.0	1	6.3
	Not answered	152	58.5	121	62.1	9	31.0	9	45.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with statement

- No. This should apply to products containing aspartame or aspartame-acesulphame salt which both are sources of phenylalanine. Therefore, the warning statement should be ie "Contains phenylalanine". This will then be consistent with the Food Standards Code Sched 9-2. (Other)

Medsafe response/outcome

- This statement applies to a very specific group of patients who will know that aspartame is a source of phenylalanine.
- As stated in the consultation document, we are aligning with the labelling requirements in Australia – where there are separate statements for aspartame and phenylalanine.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The aspartame statement will be:

Medicine/Group/Class	Conditions	Statement
Aspartame	For all classifications, including prescription, when for oral use	Contains aspartame

Benzoates

Proposed warning statement for benzoates.

Medicine/Group/Class	Conditions	Statement
Benzoates Includes: Benzoic acid Sodium benzoate	For all classifications, including prescription, and uses	Caution: contains benzoates

Benzoate responses

- Of those that answered, most respondents agreed with having a statement for benzoates, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 8: Benzoates responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	85	32.7	57	29.2	16	55.2	10	50.0	2	12.5
	No	3	1.2	0	0.0	1	3.4	2	10.0	0	0.0
	Not answered	172	66.2	138	70.8	12	41.4	8	40.0	14	87.5
Agree with inclusions	Yes	82	31.5	54	27.7	16	55.2	11	55.0	1	6.3
	No	4	1.5	1	0.5	1	3.4	1	5.0	1	6.3
	Not answered	174	66.9	140	71.8	12	41.4	8	40.0	14	87.5
Agree with conditions	Yes	85	32.7	56	28.7	16	55.2	11	55.0	2	12.5
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	173	66.5	139	71.3	12	41.4	8	40.0	14	87.5
Proposed statement	Yes	77	29.6	56	28.7	16	55.2	3	15.0	2	12.5
	No	10	3.8	0	0.0	1	3.4	9	45.0	0	0.0
	Not answered	173	66.5	139	71.3	12	41.4	8	40.0	14	87.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. All benzoates should be included, i.e. Benzoic acid, sodium benzoate, calcium benzoate and potassium benzoate (E 210, 211, 212, 213). "Benzoates Includes: Benzoic acid, calcium benzoate, potassium benzoate and sodium benzoate". (Public, Other)

Agree with conditions

- No. Benzoates should only require a warning statement when they are added to the product for the purpose of a preservative (benzoic acid and its simple salts), consistent with TGA guidance on TGO 91 and TGO 92. Low levels of naturally occurring benzoates / benzoic acid in food ingredients or flavours should not require a warning statement. Where an ingredient contains a benzoate as a preservative, but it is at very low levels in the final product then a benzoate warning statement should not be required. (Industry)

Medsafe response/outcome

- As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only. However, as the TGA's Medicine labels: Guidance on TGO 91 and TGO 92 document[3] states that sodium benzoate and potassium benzoate should be declared, we have included these as examples in the list. We have also modified the wording in the Medicine/Group/Class column to state "Examples include:".
- See the General comments section, point 6, for guidance on thresholds.

The benzoates statement will be:

Medicine/Group/Class	Conditions	Statement
Benzoates Examples include: Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate	For all classifications, including prescription, and uses	Contains benzoates

3 Therapeutic Goods Administration. 2019. *Medicine labels. Guidance on TGO 91 and TGO 92*. Version 2.1, July 2019. URL: tga.gov.au/sites/default/files/medicine-labels-guidance-tgo-91-and-tgo-92.pdf (accessed 3 September 2019).

Crustacea and crustacean products

Proposed warning statement for crustacea and crustacean products.

Medicine/Group/Class	Conditions	Statement
Crustacea and crustacean products Includes: Crab Crayfish Lobster Prawn Shrimp	For all classifications, including prescription, and uses	Caution: contains crustacea [or] crustacean products

Crustacea responses

- Of those that answered, most respondents agreed with having a statement for crustacea, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 9: Crustacea responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	97	37.3	66	33.8	19	65.5	9	45.0	3	18.8
	No	2	0.8	0	0.0	0	0.0	2	10.0	0	0.0
	Not answered	161	61.9	129	66.2	10	34.5	9	45.0	13	81.3
Agree with inclusions	Yes	92	35.4	62	31.8	17	58.6	10	50.0	3	18.8
	No	6	2.3	3	1.5	2	6.9	1	5.0	0	0.0
	Not answered	162	62.3	130	66.7	10	34.5	9	45.0	13	81.3
Agree with conditions	Yes	91	37.3	65	33.3	19	65.5	10	50.0	3	18.8
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	162	62.3	130	66.7	10	34.5	9	45.0	13	81.3
Proposed statement	Yes	86	33.1	65	33.3	18	62.1	0	0.0	3	18.8
	No	12	4.6	0	0.0	1	3.4	11	55.0	0	0.0
	Not answered	162	62.3	130	66.7	10	34.5	9	45.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Should include all shellfish. (Public)
- No. Inclusions are confusing – not sure what is in or out. Where would krill or mussels fit. (Public, Industry)
- No. May result in focussing on just those inclusions rather than species as a whole. (HCP)

Agree with statement

- No. Need to use laymen's terms, eg, shellfish. Suggest 'Contains Shellfish – Crustacea.' This may also prompt those with allergies to molluscs to ask questions to determine whether the medicine is safe for them. (HCP, Industry)

Medsafe response/outcome

- This statement likely refers to the use of crustacea as an excipient in complementary medicines. Unlike Australia, complementary medicines are not regulated in New Zealand. We are including this statement to align with Australian labelling requirements – but it is unlikely that crustacea would be an excipient in a medicine regulated under the New Zealand Medicines Act 1981.
- Medsafe is aware that there is a current proposal to amend the Food Standards Code to include a separate declaration for molluscs. However, to remain aligned with the Australian labelling requirements for medicines, we are not proposing a separate mollusc statement at this stage. This may be considered in the future.
- The TGO crustacea statement only included crab, lobster and white shrimp but there is also an explanatory note (below), with other examples. Because the Label Statements Database does not have the ability for explanatory notes, we put the additional examples in the proposed inclusions.

  Note 1 (from TGO): *Crustacea* *include various species of aquatic animals which have an inedible chitinous outer shell. These include but are not limited to crab, crayfish, lobster, prawn and shrimp.*
- As stated in the General comments section, the inclusions are not an exhaustive list and are meant to be examples only. We have modified the wording in the Medicine/Group/Class column to state "Examples include".
- Sponsors may choose to add 'Shellfish' or other words of a similar meaning (or the specific type of crustacea) to the statement on the package label if the intent of the statement is not changed.

The crustacea statement will be:

Medicine/Group/Class	Conditions	Statement
Crustacea and crustacean products (aquatic animals which have an inedible chitinous outer shell) Examples include: Crab Crayfish Lobster Prawn Shrimp	For all classifications, including prescription, and uses	Contains crustacea [or] crustacean products

Egg products

Proposed warning statement for egg products.

Medicine/Group/Class	Conditions	Statement
Egg products Includes: Dried egg yolk Egg Egg lecithin Influenza vaccine Products manufactured in eggs	For all classifications, including prescription, and all uses	Caution: contains egg [or] egg products [or] manufactured in eggs

Egg responses

- Of those that answered, most respondents agreed with having a statement for egg products, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 10: Egg responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	112	43.1	74	37.9	22	75.9	10	50.0	6	37.5
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	147	56.5	121	62.1	7	24.1	9	45.0	10	62.5
Agree with inclusions	Yes	107	41.2	72	36.9	19	65.5	10	50.0	6	37.5
	No	6	2.3	1	0.5	4	13.8	1	5.0	0	0.0
	Not answered	147	56.5	122	62.6	6	20.7	9	45.0	10	62.5
Agree with conditions	Yes	110	42.3	72	36.9	23	79.3	10	50.0	5	31.3
	No	3	1.2	1	0.5	0	0.0	1	5.0	1	6.3
	Not answered	47	56.5	122	62.6	6	20.7	9	45.0	10	62.5
Proposed statement	Yes	100	38.5	71	36.4	21	72.4	3	15.0	5	31.3
	No	13	5.0	2	1.0	2	6.9	8	40.0	1	6.3
	Not answered	147	56.5	122	62.6	6	20.7	9	45.0	10	62.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Include egg shells – some products are made from egg shells. Also, does this only cover chicken eggs, or other birds? Do people have allergies to other bird eggs? (Public)

- No. Listing the types of egg product and influenza vaccine as a specific inclusion may cause confusion. If the medicine contains egg products the conditions and statement should be sufficient. (HCP)
- No. Any vaccine containing egg should be declared – not just influenza vaccine. (Public)
- No. We are concerned about the influenza vaccine. It contains egg but now in such low doses it is considered safe even for those with egg allergy. An additional statement may be needed e.g. (as per the Immunisation handbook 2017): "Egg allergy, including anaphylaxis, is not a contraindication to influenza vaccination. Influenza vaccine can be safely administered to people with a history of egg allergy, including anaphylaxis, at general practices, pharmacies or at the workplace. " (HCP)
- Yes. Should egg white also be included? (Industry)

Agree with conditions

- No. The amount of trace egg is important as almost all people with egg allergy will tolerate the present influenza vaccines. (HCP, Public)

Agree with statement

- Ensure the statements differentiate between products that actually contain egg, and those which are cultured/manufactured in egg. Some people may be allergic to eggs but tolerate vaccinations that used egg in the manufacturing process. It would be a bad outcome if people avoided vaccinations or other medication due to a generic statement about the product containing egg. (Public)
- Include how much egg is present. (HCP)

Medsafe response/comment

- Biological medicines are sometimes manufactured using substances such as chicken egg. These substances must be included on the label. Similarly, if the medicine contains egg or egg products, then this must be included on the label. Further information can be included in the data sheet and CMI.
- The proposed warning statement is not a contraindication to influenza vaccination. It's there as a prompt for vaccinators to closely supervise those people with allergies to eggs or egg products, after they have been vaccinated.
- The inclusions are not an exhaustive list and are meant to be examples only. We have modified the wording in the Medicine/Group/Class column to state "Examples include".

The egg statement will be:

Medicine/Group/Class	Conditions	Statement
Egg, egg products and products manufactured in eggs Examples include: Dried egg yolk Egg lecithin Influenza vaccine	For all classifications, including prescription, and all uses	Contains egg [or] egg products [or] manufactured in eggs

Ethanol

Proposed warning statement for ethanol. There is already a warning statement for ethanol (see 'Current warning statement' table). However, to align with the Australian labelling requirements, we are proposing to amend the conditions for all uses and classifications and to include the quantity of ethanol on the label (see 'Proposed warning statement' table).

Current ethanol warning statement

Medicine/Group/Class	Conditions	Statement
Ethanol	When present at 3% or greater for internal use	Caution: contains alcohol

Proposed ethanol warning statement

Medicine/Group/Class	Conditions	Statement
Ethanol	For all classifications, including prescription, and for all uses – when ethanol is present in a concentration of 3% v/v or more	Caution: contains [quantity of ethanol as % v/v] alcohol

Ethanol responses

- Of those that answered, most respondents agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 11: Ethanol responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Agree with conditions	Yes	74	28.5	46	23.6	15	51.7	11	55.0	2	12.5
	No	4	1.5	2	1.0	2	6.9	0	0.0	0	0.0
	Not answered	182	70.0	147	75.4	12	41.4	9	45.0	14	87.5
Proposed statement	Yes	69	26.5	48	24.6	16	55.2	3	15.0	2	12.5
	No	9	3.5	0	0.0	1	3.4	8	40.0	0	0.0
	Not answered	182	70.0	147	75.4	12	41.4	9	45.0	14	87.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with conditions

- No. Lower or no threshold. (Public, HCP)

Agree with statement

- No. needs to be clearer to state, "Contains Alcohol" as it could be confused to state "Contains Ethanol", or Contains alcohol ([quantity of ethanol as % v/v])". (Industry)

Medsafe response/outcome

- We are not consulting on changing the threshold.
- The proposed statement may have been misread, as the text in the square brackets relates to the volume that needs to be stated – the word 'ethanol' doesn't need to be included. For example, if the product contains 4% ethanol, the label would say: "C*ontains 4% alcohol*."
- We have also removed the word 'Caution' from the statement.

The ethanol statement will be:

Medicine/Group/Class	Conditions	Statement
Ethanol	For all classifications, including prescription, and for all uses – when ethanol is present in a concentration of 3% v/v or more	Contains [quantity of ethanol as % v/v] alcohol

Fish and fish products

Proposed warning statement for fish and fish products.

Medicine/Group/Class	Conditions	Statement
Fish and fish products Includes: Cod Cod liver oil Halibut Shark Tuna	For all classifications, including prescription, and all uses	Caution: contains fish [or] fish products

Fish and fish products responses

- Of those that answered, most respondents agreed with having a statement for fish products, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 12: Fish and fish products responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	87	33.5	54	27.7	19	65.5	12	60.0	2	12.5
	No	2	0.8	1	0.5	0	0.0	1	5.0	0	0.0
	Not answered	171	65.8	140	71.8	10	34.5	7	35.0	14	87.5
Agree with inclusions	Yes	77	29.6	50	25.6	16	55.2	10	50.0	1	6.3
	No	11	4.2	4	2.1	3	10.3	3	15.0	1	6.3
	Not answered	172	66.2	141	72.3	10	34.5	7	35.0	14	87.5
Agree with conditions	Yes	85	32.7	54	27.7	18	62.1	12	60.0	1	6.3
	No	3	1.2	0	0.0	1	3.4	1	5.0	1	6.3
	Not answered	172	66.2	141	72.3	10	34.5	7	35.0	14	87.5
Proposed statement	Yes	77	29.6	53	27.2	19	65.5	3	15.0	2	12.5
	No	10	3.8	1	0.5	0	0.0	9	45.0	0	0.0
	Not answered	173	66.5	141	72.3	10	34.5	8	40.0	14	87.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Should be anything to do with fish not limited. Include all fish. Why is this list so specific? (HCP, Public)
- No. Unsure where shellfish fit in. This is very confusing with the crustacea section. (Public)

- No. Consumers understand 'fish' to mean fin fish in general, including freshwater and marine fish. There is limited testing for specific species in relation to diagnosing fish allergy. Use similar terminology to Australia's TGA and refer to 'freshwater, marine species etc. (Public, Other)
- No. The TGO 92 statement for fish is accompanied by a requirement that it includes freshwater fish, diadromous fish and marine fish, including shark. The statement proposed by Medsafe states that it includes cod, cod liver oil, halibut, shark, tuna but does not refer to the classes of fish, i.e. freshwater, marine and diadromous. We recommend clarification of this discrepancy and alignment with TGO 92, which is a more inclusive statement. (Industry)
- No. Suggest rewording to: Fish and fish products – Includes but not limited to: Cod, Cod liver oil, Halibut, Shark, Tuna. (Industry)

Agree with statement

- No. Name specific fish, eg: "Caution: contains specific fish [or] specific fish products"

Medsafe response/outcome

- The TGO fish statement only included cod, cod liver oil, halibut and tuna but there is also an explanatory note (below), with other examples. Because the Label Statements Database does not have the ability for explanatory notes, we put the additional examples in the proposed inclusions. We have changed the wording in the Medicine/Group/Class column to include 'freshwater fish, diadromous fish and marine fish'. The TGO statement is:

  fish and fish products *(see Note 2), including: cod, cod – liver oil, halibut, tuna.*

  Note 2: ***Fish*** *includes freshwater fish, diadromous fish and marine fish, including shark.*

- The inclusions are not an exhaustive list, and we have added the words "examples include".
- Sponsors may choose to add the specific type of fish to the statement on the package label, but this is not a requirement.

The fish statement will be:

Medicine/Group/Class	Conditions	Statement
Fish and fish products (freshwater fish, diadromous fish and marine fish) Examples include: Cod Cod liver oil Halibut Tuna Shark	For all classifications, including prescription, and all uses	Contains fish [or] fish products

Galactose

Proposed warning statement for galactose.

Medicine/Group/Class	Conditions	Statement
Galactose	For all classifications, including prescription, and for oral use	Caution: contains galactose

Galactose responses

- Of those that answered, most respondents agreed with having a statement for galactose, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 13: Galactose responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	67	25.8	42	21.5	14	48.3	10	50.0	1	6.3
	No	3	1.2	0	0.0	2	6.9	1	5.0	0	0.0
	Not answered	190	73.1	153	78.5	13	44.8	9	45.0	15	93.8
Agree with conditions	Yes	63	24.2	41	21.0	14	48.3	8	40.0	0	0.0
	No	5	1.9	0	0.0	2	6.9	3	15.0	0	0.0
	Not answered	192	73.8	154	79.0	13	44.8	9	45.0	16	100.0
Proposed statement	Yes	56	21.5	41	21.0	13	44.8	2	10.0	0	0.0
	No	11	4.2	0	0.0	3	10.3	8	40.0	0	0.0
	Not answered	193	74.2	154	79.0	13	44.8	10	50.0	16	100.0

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include a warning statement

- No. Unsure of this allergy and the need for this. (HCP)
- Yes. In the Food Code, galactose is only required to be in Nutrition information panel (NIP) when a lactose claim is made. (Other)

Agree with conditions

- No. Where galactose is added to a product then a warning statement should be required. A cut off level should be considered, below which a warning statement for galactose is not required. Some food type ingredients that may be used as ingredients in medicine products could contain trace levels of galactose resulting in extremely low levels of galactose in a product. Insignificant levels of galactose should not require a warning statement. The intention should be to ensure that consumers that are intolerant to galactose are aware of products that contain galactose in quantities that are likely to cause them a problem. (Industry)

Agree with statement

- No. Needs an amount present. (HCP)

Medsafe response/outcome

- As stated in the consultation document, we have included this statement to align with Australia.
- Products containing galactose in New Zealand include vaccines and infusions.
- Some people may have an alpha-gal allergy:

  Alpha-gal (galactose-α-1,3-galactose) is a sugar molecule found in products made from mammals (including some medications, cosmetics, vaccines, gelatin, and milk products)[4]. An alpha-gal allergy is an allergy to the alpha-gal sugar molecule. Allergic reactions typically occur after people eat meat from mammals that have alpha-gal or are exposed to products made from mammals.
- See the General comments section, point 6, for guidance on thresholds.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The galactose statement will be:

Medicine/Group/Class	Conditions	Statement
Galactose	For all classifications, including prescription, when for oral use	Contains galactose

4 Centers for Disease Control and Prevention. 2019. *Alpha-gal allergy*. 28 March 2019. URL: cdc.gov/ticks/alpha-gal/index.html (accessed 27 November 2019).

Gluten

The following questions relate to the proposed warning statement for gluten.

Medicine/Group/Class	Conditions	Statement
Gluten Includes: Ingredient derived from gluten-containing grain Wheat starch	For all classifications, including prescription, and all uses, other than skin and mucous membrane applications – where gluten is present in a concentration of 20 parts per million or more	Caution: contains gluten

Gluten responses

- Of those that answered, most respondents agreed with having a statement for gluten, and agreed with the statement.
- A significant proportion of Public respondents did not agree with the inclusions or the conditions – see the Summary of comments section below.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 14: Gluten responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	220	84.6	174	89.2	24	82.8	12	60.0	10	62.5
	No	2	0.8	2	1.0	0	0.0	0	0.0	0	0.0
	Not answered	38	14.6	19	9.7	5	17.2	8	40.0	6	37.5
Agree with inclusions	Yes	180	69.2	140	71.8	22	75.9	11	55.0	7	43.8
	No	41	15.8	35	17.9	2	6.9	1	5.0	3	18.8
	Not answered	39	15.0	20	10.3	5	17.2	8	40.0	6	37.5
Agree with conditions	Yes	146	56.2	106	54.4	20	69.0	11	55.0	9	56.3
	No	71	27.3	65	33.3	4	13.8	1	5.0	1	6.3
	Not answered	43	16.5	24	12.3	5	17.2	8	40.0	6	37.5
Proposed statement	Yes	184	70.8	150	76.9	22	75.9	4	20.0	8	50.0
	No	34	13.1	23	11.8	1	3.4	8	40.0	2	12.5
	Not answered	42	16.2	22	11.3	6	20.7	8	40.0	6	37.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include gluten warning statement

- No. Wheat is a common food allergy. A 'gluten' statement is not sufficient to protect wheat-allergic consumers. Either the Medicine/group/class should be changed to 'cereals containing gluten (and the cereal gluten is derived from to be identified) or 'wheat' should be added as a substance requiring a warning statement, in its own right. (Public)

Agree with inclusions

- No. Align with FSANZ standards 1.2.3–4. Needs all forms of gluten-containing grains – wheat, barley, rye, oat, spelt or their derivatives. "Wheat starch " should not be specified as this will exclude rye, barley and oats. (Public, Other).
- No. Include other types gluten. Eg: maize starch, modified wheat and/or barley starch, maltodextrin, ryecorn, triticale. (Public)
- No. Ingredients derived from a gluten containing grain do not always contain gluten (ie wheat glucose). This inclusion may create confusion and mislabelling. Need a distinction between just wheat for those with wheat allergy, and wheat that contains gluten for those with gluten allergy. (Public)

Agree with conditions

- No. The limit should be lowered to no detectable gluten or 3 ppm. The 20 parts per million limit could still create adverse effects for people with coeliac disease - it is too high (Public, HCP)
- No. There should be no exceptions. Mucous membranes, skin, topical application, oral eye, needs to be included. Shampoo, face creams, lip balm, moisturiser, anything that touches your hands can be easily transferred to your mouth and can cause problems for coeliacs. Conditions such as FPIES require clear information of all trace allergens present in a formulation. This information needs to be clear and easy to read. (Public, HCP)
- No. Should also cover topical products. The form of coeliac that get dermatitis herpetiformis can react severely with blustering lesions on the skin. Young children often lick the skin of themselves or others and may also have a local reaction to allergens. (Public, HCP)

Agree with proposed statement

- No. Specify the form. Allow a declaration of the gluten-containing ingredient and source grain, as some people are allergic to particular gluten containing grains but not gluten in general. Eg, “contains starch from wheat”, or “contains wheat starch”, or “contains gluten from wheat”. (Public, Industry, Other)
- No. Contains gluten and/or is made in a factory/laboratory where other products containing gluten are also made. (Public)
- No. Differentiate between gluten and wheat: “Caution: contains gluten” OR “Caution: contains products derived from wheat (no gluten detected)”. Or have a separate statement for wheat. (Public)

Medsafe response/outcome

- Medsafe has discussed respondents' concerns to the proposed gluten statement with the Australian Therapeutic Goods Agency (TGA) – the agency responsible for the TGO 91 and 92 statements. Medsafe and the TGA have agreed that:
    - the source of the gluten should be identified
    - the statement should apply to all uses
    - the threshold should be lowered from 20 ppm to 3 ppm.
- Food labelling standards in New Zealand and Australia are regulated by Food Standards Australia and New Zealand (FSANZ). For foods to be labelled gluten-free, they must contain no detectable gluten, which is currently at a level above 3 ppm (although this level may reduce as tests become more sensitive). Manufacturing standards are higher for medicines than foods, so it does not make sense for the detectable gluten limit in medicines to be higher than for foods. Therefore, Medsafe will require medicine labels to include the gluten warning statement if the gluten content is higher than 3 ppm.
- The New Zealand Label Statements Database warning statement for gluten will be different from TGO 91 and 92. The TGA has confirmed that they will accept the New Zealand gluten statement on package labels used in Australia. The implementation date for this statement in New Zealand is 1 March 2024 – meaning that there will be a transition period when some medicines will contain the Australian warning statement. Medsafe encourages sponsors to use the New Zealand warning statement as soon as possible, but it is not a requirement until 1 March 2024. See the Implementation date section for more information.
- At this stage, there are no plans to introduce a separate wheat statement.
- See the General comments section, point 7, for information about medicines manufacture and cross-contamination.
- This statement only applies to medicines and related products regulated under the Medicines Act 1981, it does not cover cosmetics or other products.

The gluten warning statement will be:

Medicine/Group/Class	Conditions	Statement
Gluten Examples include: Wheat Barley Rye Oats Spelt Derivatives of the above that may contain gluten	For all classifications, including prescription, and all uses – where gluten is present in a concentration of 3 parts per million or more	Contains gluten from [specify source]

Hydroxybenzoic acid esters

Proposed warning statement for hydroxybenzoic acid esters.

Medicine/Group/Class	Conditions	Statement
Hydroxybenzoic acid esters Includes: Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate	For all classifications, including prescription, and all uses	Caution: contains hydroxybenzoates

Hydroxybenzoic acid esters responses

- Of those that answered, most respondents agreed with having a statement for hydroxybenzoic acid esters, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 15: Hydroxybenzoic acid esters responses

		Respondent category[a]									
		All (n=260)		**Public** (n=195)		**HCP** (n=29)		**Industry** (n=20)		**Other** (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	63	24.2	39	20.0	13	44.8	10	50.0	1	6.3
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	195	75.0	156	80.0	15	51.7	9	45.0	15	93.8
Agree with inclusions	Yes	61	23.5	38	19.5	12	41.4	10	50.0	1	6.3
	No	3	1.2	0	0.0	2	6.9	1	5.0	0	0.0
	Not answered	196	75.4	157	80.5	15	51.7	9	45.0	15	93.8
Agree with conditions	Yes	61	23.5	38	19.5	13	44.8	9	45.0	1	6.3
	No	3	1.2	0	0.0	1	3.4	2	10.0	0	0.0
	Not answered	196	75.4	157	80.5	15	51.7	9	45.0	15	93.8
Proposed statement[b]	Yes	20	7.7	20	10.3	4	13.8	0	0.0	0	0.0
	No	9	3.5	0	0.0	0	0.0	9	45.0	0	0.0
	Not answered	231	88.8	175	89.7	25	86.2	11	55.0	16	100.0

Notes:

a. See Table 3 for a description of respondent categories.

b. The Yes/No radio box was mistakenly left off this question. The Yes/No answers shown here are obtained from those respondents who answered using the Comment box – and therefore may not represent the views of everyone who would have answered this question if the radio button was included.

Summary of comments

See also the General comments section.

Agree with conditions

- No. Consistent with TGA guidelines on TGO 91 and TGO 92 the warning statement should only apply to parabens and not to other hydroxybenzoates such as salicylates. Where an ingredient contains a hydroxybenzoate as a preservative, but it is at very low levels in the final product then a benzoate warning statement should not be required. (Industry)

Medsafe response/outcome

- We have included a definition in the Medicine/Group/Class column and added salicylates as an exclusion in the Conditions column.
- See the General comments section, point 6, for guidance on thresholds.

The statement will be:

Medicine/Group/Class	Conditions	Statement
Hydroxybenzoic acid esters (parabens with hydroxybenzoate in the substance name) Examples include: Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate	Excludes salicylates For all classifications, including prescription, and all uses	Contains hydroxybenzoates

Lactose

Proposed warning statement for lactose.

Medicine/Group/Class	Conditions	Statement
Lactose	For all classifications, including prescription, and for oral use When lactose is obtained from milk, the label does not require the 'contains milk product' statement	Caution: contains lactose

Lactose responses

- Of those that answered, most respondents agreed with having a statement for lactose, and agreed with the statement. A small minority disagreed with the conditions – see the Summary of comments section below.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 16: Lactose responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	97	37.3	62	31.8	20	69.0	11	55.0	4	25.0
	No	3	1.2	2	1.0	0	0.0	1	5.0	0	0.0
	Not answered	160	61.5	131	67.2	9	31.0	8	40.0	12	75.0
Agree with conditions	Yes	86	33.1	56	28.7	17	58.6	9	45.0	4	25.0
	No	15	5.8	8	4.1	3	10.3	3	15.0	1	6.3
	Not answered	159	61.2	131	67.2	9	31.0	8	40.0	11	68.8
Proposed statement	Yes	86	33.1	60	30.8	20	69.0	2	10.0	4	25.0
	No	14	5.4	5	2.6	0	0.0	9	45.0	0	0.0
	Not answered	160	61.5	130	66.7	9	31.0	9	45.0	12	75.0

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include warning statement

- No. Milk warning should be enough. Under the Food Code Std 1.2.3 clause 4, any product derived from milk, including lactose, is required to declare milk. Medicines containing lactose should be covered by the 'contains milk product' statement. People with lactose intolerance know to avoid any product with a 'contains milk' statement. The only value in having a separate 'contains lactose' statement would be if lactose was safe for milk-allergic individuals - however Medsafe has not provided any evidence of this. Therefore, having two different warning statements indicating the presence of milk/milk products will be confusing for both milk-allergic and lactose intolerant consumers. (Public, Other)

Agree with conditions

- No. The Food Safety Code does not have this exemption when lactose is derived from milk. Should state if lactose comes from milk: "Contains milk product (lactose)" or "Contains lactose derived from milk products". Change "When lactose is obtained from milk, the label does not require the 'contains milk product' statement" to "When lactose is obtained from milk, the label should say Caution: contains lactose (derived from cows milk)" statement (Public, HCP, Other)
- No. Where lactose is added as an ingredient there should be a lactose warning statement. Where a product contains an ingredient derived from milk and has a milk or milk product warning statement then a lactose warning statement should not also be required. Consumers who are avoiding low levels of lactose would already also be avoiding milk and the use of multiple warning statements in this case does not provide any additional helpful information to consumers. (Industry)
- No. Needs to apply to topical and inhaled medicines also. (Public)

Proposed statement – comments

- No. "Dairy milk products and lactose are in this product." (Public)
- No. "Contain lactose derived from milk". (HCP)
- No. Statement not consistent with the Food Code; will be confusing for both milk-allergic and lactose intolerant people. (Public)

Medsafe response/outcome

- As per the consultation document, we are aligning with the Australian labelling requirements, and there are separate statements for lactose and milk products.
- From Health Navigator – Lactose intolerance[5]:

  Lactose intolerance occurs when your body doesn't produce enough of the enzyme lactase, which breaks down lactose in your gut. It is not the same as a milk allergy, which has more severe symptoms that can result in anaphylaxis. A milk allergy is related to the protein in milk rather than the lactose.
- The lactose statement applies to oral products only because lactose intolerance affects the gut.
- Lactose used in medicines is controlled to pharmacopoeial quality standards. Therefore, the lactose will be pure and is unlikely to contain allergenic milk products.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The lactose statement will be:

Medicine/Group/Class	Conditions	Statement
Lactose	For all classifications, including prescription, when for oral use When lactose is obtained from milk, the label does not require the 'contains milk product' statement	Contains lactose

5 Health Navigator. 2019. Lactose intolerance. 20 July 2020. URL: healthnavigator.org.nz/health-a-z/l/lactose-intolerance (accessed 28 July 2020).

Milk and milk products

Proposed warning statement for milk and milk products.

Medicine/Group/Class	Conditions	Statement
Milk and milk products Includes: Casein Hydrolysed milk protein Non-fat dry milk Whey powder Whole dry milk	For all classifications, including prescription, and all uses	Caution: contains milk [or] milk products

Milk and milk products responses

- Of those that answered, most respondents agreed with having a statement for milk products, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 17: Milk and milk products responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP[c] (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	116	44.6	78	40.0	22	75.9	10	50.0	6	37.5
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	143	55.0	117	60.0	7	24.1	9	45.0	10	62.5
Agree with inclusions	Yes	106	40.8	72	36.9	20	69.0	9	45.0	5	31.3
	No	10	3.8	5	2.6	2	6.9	2	10.0	1	6.3
	Not answered	144	55.4	118	60.5	7	24.1	9	45.0	10	62.5
Agree with conditions	Yes	114	43.8	77	39.5	22	75.9	10	50.0	5	31.3
	No	2	0.8	0	0.0	0	0.0	1	5.0	1	6.3
	Not answered	144	55.4	118	60.5	7	24.1	9	45.0	10	62.5
Proposed statement	Yes	105	40.4	77	39.5	21	39.5	2	10.0	5	31.3
	No	10	3.8	0	0.0	1	3.4	8	40.0	1	6.3
	Not answered	145	55.8	118	60.5	7	24.1	10	50.0	10	62.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. These are examples and not an exhaustive list. All milk and milk products should require a statement (ie, covered by the Class) not just those listed. May need to provide an explanatory statement instead. (HCP, Other)

- No. Also include: lactose, goats milk protein, yoghurt, lactalbumin, casamino acids, colostrum, hydrolysed milk protein, non-fat dry milk, whey powder, whole dry milk, lactose from sources other than milk. (Public, Industry)

Agree with proposed statement

- No. Caution: contains milk [or] milk products [or] milk protein. (HCP)

Medsafe response/outcome

- As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only. We have modified the wording in the Medicine/Group/Class column to state "Examples include:".
- See also the Medsafe response to the Lactose statement.

The milk and milk products statement will be:

Medicine/Group/Class	Conditions	Statement
Milk and milk products Examples include: Casein Hydrolysed milk protein Non-fat dry milk Whey powder Whole dry milk	For all classifications, including prescription, and all uses	Contains milk [or] milk products

Peanuts and peanut products

Proposed warning statement for peanuts and peanut products.

Medicine/Group/Class	Conditions	Statement
Peanuts and peanut products Includes: *Arachis hypogaea* Arachis (peanut) oil	For all classifications, including prescription, and all uses	Caution: contains peanuts [or] peanut products

Peanut and peanut products responses

- Of those that answered, most respondents agreed with having a statement for peanut products, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 18: Peanuts and peanut products responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	106	40.8	69	35.4	21	72.4	11	55.0	5	31.3
	No	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not answered	154	59.2	126	64.6	8	27.6	9	45.0	11	68.8
Agree with inclusions	Yes	102	39.2	67	34.4	20	69.0	10	50.0	5	31.3
	No	3	1.2	1	0.5	1	3.4	1	5.0	0	0.0
	Not answered	155	59.6	127	65.1	8	27.6	9	45.0	11	68.8
Agree with conditions	Yes	103	39.6	68	34.9	20	69.0	10	50.0	5	31.3
	No	2	0.8	0	0.0	0	0.0	1	5.0	1	6.3
	Not answered	155	59.6	127	65.1	9	31.0	9	45.0	10	62.5
Proposed statement	Yes	96	36.9	66	33.8	21	72.4	3	15.0	6	37.5
	No	10	3.8	2	1.0	0	0.0	8	40.0	0	0.0
	Not answered	154	59.2	127	65.1	8	27.6	9	45.0	10	62.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include peanut warning statement

- Yes. In this instance, since peanut allergy is the most widely reported cause of death from allergy, it is appropriate to have a warning on a product's labelling even if the product is sold in bulk by the manufacturer for dispensing. The warning should also be included in the product's datasheet, CMI and insert (if used). (Industry)

Agree with inclusions

- No. Should be all nuts especially including almonds. (Public)

Agree with statement

- No. Would like to see it include warnings for anyone with other nut allergies as well, not just peanuts. (Public)
- No. Use above and include "or processed in a facility [machines] where peanuts or peanut products have been processed". (Public)
- Yes. Peanut allergy is the most widely reported cause of death from exposure, therefore we consider it appropriate that this has a strong statement (ie, use of the word “Caution”) on inclusion. (Industry)

Medsafe response/outcome

- This statement is for peanuts only, which are legumes. There is a separate statement for tree nuts.
- As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only. However, we have modified the wording in the Medicine/Group/Class column to state “Examples include:”.
- See the General comments section, point 7, for information about medicines manufacture and cross-contamination.

The peanuts and peanut products statement will be:

Medicine/Group/Class	Conditions	Statement
Peanuts and peanut products Examples include: *Arachis hypogaea* Arachis (peanut) oil	For all classifications, including prescription, and all uses	Contains peanuts [or] peanut products

Phenylalanine

Proposed warning statement for phenylalanine.

Medicine/Group/Class	Conditions	Statement
Phenylalanine	For all classifications, including prescription, and all uses other than skin and mucous membrane applications	Caution: contains phenylalanine

Phenylalanine responses

- Of those that answered, most respondents agreed with having a statement for phenylalanine, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 19: Phenylalanine responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	66	25.4	41	21.0	14	48.3	10	50.0	1	6.3
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	193	74.2	154	79.0	15	51.7	9	45.0	15	93.8
Agree with conditions	Yes	59	22.7	36	18.5	14	48.3	8	40.0	1	6.3
	No	7	2.7	4	2.1	0	0.0	3	15.0	0	0.0
	Not answered	194	74.6	155	79.5	15	51.7	9	45.0	15	93.8
Proposed statement	Yes	57	21.9	40	20.5	14	48.3	2	10.0	1	6.3
	No	9	3.5	0	0.0	0	0.0	9	45.0	0	0.0
	Not answered	194	74.6	155	79.5	15	51.7	9	45.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with conditions

- No. Why exclude skin and mucous membranes? (Public)
- No. A warning statement for phenylalanine should only be required when phenylalanine is present in amounts that are important in the context of phenylketonuria. Naturally occurring phenylalanine in trace amounts from ingredients should not require a warning statement. (Industry)

Medsafe response/outcome

- This entry is important for people who have phenylketonuria (PKU), which is a metabolic problem not an allergy. Therefore, skin and mucous membranes are excluded.
- See also the General comments section, point 6.

The phenylalanine statement will be:

Medicine/Group/Class	Conditions	Statement
Phenylalanine	For all classifications, including prescription, and all uses other than skin and mucous membrane applications	Contains phenylalanine

Pollen

Proposed warning statement for pollen.

Medicine/Group/Class	Conditions	Statement
Pollen	For all classifications, including prescription, and for oral use	Caution: contains pollen

Pollen responses

- Of those that answered, most respondents agreed with having a statement for pollen, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 20: Pollen responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	64	24.6	38	19.5	14	48.3	12	60.0	0	0.0
	No	2	0.8	0	0.0	0	0.0	1	5.0	1	6.3
	Not answered	194	74.6	157	80.5	15	51.7	7	35.0	15	93.8
Agree with conditions	Yes	61	23.5	36	18.5	14	48.3	10	50.0	1	6.3
	No	4	1.5	1	0.5	0	0.0	3	15.0	0	0.0
	Not answered	195	75.0	158	81.0	15	51.7	7	35.0	15	93.8
Proposed statement	Yes	52	20.0	37	19.0	13	44.8	2	10.0	0	0.0
	No	13	5.0	0	0.0	1	3.4	11	55.0	1	6.3
	Not answered	195	75.0	158	81.0	15	51.7	7	35.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include pollen warning statement

- No. This should refer to bee pollen? (Other)

Agree with conditions

- No. Where pollen is the primary ingredient (Industry)
- No. Needs to include skin and mucus membrane applications. (Public)

Agree with statement

- No. More specific – bee pollen. (HCP)
- No. "Allergen warning: contains bee products". (Industry)
- No. Is the intention to mean bee pollen is so this should refer to bee pollen? (Other)

Medsafe response/outcome

- This statement likely refers to the use of pollen in complementary medicines and includes bee and plant pollen. Unlike Australia, complementary medicines are not regulated in New Zealand. We are including this statement to align with Australian labelling requirements.
- The Australian guidance document[6] says:

  *There is no cut-off for pollen specified in Schedule 1, but it is **not** intended that pollen at background levels in the environment, to which consumers may be exposed in their everyday lives, be declared on medicine labels. The intention is to ensure consumers with pollen allergies are aware of medicines for which there is reasonable cause to suspect pollen may be present. Examples include, bee pollen products or herbal materials in medicines that include flowers.*
- Active ingredients must already be declared on package labels. For example, there is a medicine that contains grass pollen extract as the active ingredient, and this is declared on the label.
- In order to align with Australia, there is no requirement for sponsors to add 'allergen warning' to the New Zealand label. However, sponsors may choose to add this information at their discretion.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The pollen statement will be:

Medicine/Group/Class	Conditions	Statement
Pollen	For all classifications, including prescription, when for oral use	Contains pollen

6 Therapeutic Goods Administration. 2019. *Medicine labels. Guidance on TGO 91 and TGO 92*. Version 2.1, July 2019. URL: tga.gov.au/sites/default/files/medicine-labels-guidance-tgo-91-and-tgo-92.pdf (accessed 3 September 2019).

Potassium salts

Proposed warning statement for potassium salts.

Medicine/Group/Class	Conditions	Statement
Potassium salts Includes: Potassium bicarbonate Potassium chloride	For all classifications, including prescription, and for oral use – where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1 mmol) elemental potassium	Caution: contains [mg quantity of elemental potassium per dosage unit or in a stated weight or volume of the medicine]

Potassium salts responses

- Of those that answered, most respondents agreed with having a statement for potassium salts, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 21: Potassium salts responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	59	22.7	34	17.4	13	44.8	11	55.0	1	6.3
	No	3	1.2	0	0.0	1	3.4	1	5.0	1	6.3
	Not answered	198	76.2	161	82.6	15	51.7	8	40.0	14	87.5
Agree with inclusions	Yes	57	21.9	33	16.9	12	41.4	11	55.0	1	6.3
	No	4	1.5	0	0	2	6.9	1	5.0	1	6.3
	Not answered	199	76.5	162	83.1	15	51.7	8	40.0	14	87.5
Agree with conditions	Yes	55	21.2	33	16.9	12	41.4	9	45.0	1	6.3
	No	5	1.9	0	0	2	6.9	3	15.0	0	0.0
	Not answered	200	76.9	162	83.1	15	51.7	8	40.0	15	93.8
Proposed statement	Yes	49	18.8	32	16.4	13	44.8	3	15.0	1	6.3
	No	11	4.2	1	0.5	1	3.4	9	45.0	0	0.0
	Not answered	200	76.9	162	83.1	15	51.7	8	40.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include warning statement

- No. Too specific. If patient needs to decrease potassium intake can look at data sheet. (HCP)
- What is the medical reason for this? (Other)

Agree with inclusions

- No. Include all potassium salts/other forms of potassium. (HCP, Other)

Agree with conditions

- No. Quantity too low – should only apply to products containing sufficient potassium to impact potassium levels in a patient. (HCP)
- No. Should IV use also be specifically included to facilitate use of low potassium intake regimens where needed? (Industry)
- Yes. However, differs from TGO 92. The conditions for inclusion differ, with the Medsafe proposal applying when the total potassium content of the maximum recommended daily dose is greater than 39 mg (1 mmol), whereas the TGO 92 requirement applies when the total potassium content of the dose is greater than 39 mg (1 mmol) elemental potassium. In addition, the proposed statement refers to the mg quantity of elemental potassium per dosage unit or in a stated weight or volume of the medicine, whereas the TGO 92 requirement is to state the quantity of elemental potassium per dose of the medicine. (Industry)

Agree with statement

- No. "Caution:" to be excluded from the statement and "potassium" to be added statement to align with Australian labelling requirements, i.e. "Contains [quantity of elemental potassium (in mg) per dosage unit or in a stated weight or volume of the medicine] potassium" or equivalent statement e.g. "Contains potassium ([quantity of elemental potassium (in mg) per dosage unit or in a stated weight or volume of the medicine]. (Industry)
- No. It would be helpful to know what percentage over the recommended daily dose the product contains. (Public)

Medsafe response/outcome

- The medical need for this statement is for patients who need to monitor potassium intake due to certain conditions (those at risk of hyperkalaemia such as diabetics, those with chronic kidney disease, adrenal insufficiency or liver disease).
- If potassium is the active ingredient in an IV preparation, then this will already be declared on the package label.
- The intention is to align with Australia so that package labels can harmonised in both countries, where applicable. The wording proposed in the consultation was the same as in the Australian TGOs, except for the accidental omission of the word “potassium” from the statement text. This has been corrected. Therefore, if a medicine contains 15 mg of elemental potassium as an excipient, and the medicine is taken three times daily so that the total daily dose of potassium is 45 mg, then the label will be required to say, “Contains 15 mg potassium”.
- For clarity, we have modified the Conditions column from “and for oral use” to “when for oral use”.

The potassium statement will be:

Medicine/Group/Class	Conditions	Statement
Potassium salts Examples include: Potassium bicarbonate Potassium chloride	For all classifications, including prescription, when for oral use – where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1 mmol) elemental potassium	Contains [quantity [in mg] of elemental potassium per dosage unit or in a stated weight or volume of the medicine] potassium

Propolis

Proposed warning statement for propolis.

Medicine/Group/Class	Conditions	Statement
Propolis	For all classifications, including prescription, and for oral use	Caution: contains propolis

Propolis responses

- Of those that answered, most respondents agreed with having a statement for propolis, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 22: Propolis responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	61	23.5	35	17.9	14	48.3	11	55.0	1	6.3
	No	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not answered	199	76.5	160	82.1	15	51.7	9	45.0	15	93.8
Agree with conditions	Yes	57	21.9	33	16.9	14	48.3	9	45.0	1	6.3
	No	4	1.5	1	0.5	0	0.0	3	15.0	0	0.0
	Not answered	199	76.5	161	82.6	15	51.7	8	40.0	15	93.8
Proposed statement	Yes	48	18.5	32	16.4	13	44.8	2	10.0	1	6.3
	No	12	4.6	2	1.0	1	3.4	9	45.0	0	0.0
	Not answered	200	76.9	161	82.6	15	51.7	9	45.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include propolis warning statement

- Yes. But combine with bee products. (HCP)

Agree with conditions

- No. Needs explanation of allergy to bees. (Public)
- No. Where propolis is one of the main active ingredients in a preparation. (Industry)

Agree with proposed statement

- No. Caution: contains propolis (Bee glue). (Public)
- Combine with royal jelly under a general title of bee products. (HCP)
- No. Allergen warning needed, eg, 'Allergen warning: contains bee products". (Public, Industry)

Medsafe response/outcome

- If propolis is used an active ingredient in a medicine, then it must already be declared on package labels.
- This statement likely refers to the use of propolis as an excipient in complementary medicines. Unlike Australia, complementary medicines are not regulated in New Zealand. We are including this statement to align with Australian labelling requirements – but it is unlikely that propolis would be an excipient in a medicine regulated under the New Zealand Medicines Act 1981.
- Sponsors can combine statements, providing that the intent isn't changed. See the General comments section, point 4.
- There is no requirement for sponsors to add 'allergen warning' or have an explanation of bee allergy on the label. See the General comments section, point 9.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The propolis statement will be:

Medicine/Group/Class	Conditions	Statement
Propolis	For all classifications, including prescription, when for oral use	Contains propolis

Royal jelly

Proposed warning statement for royal jelly.

Medicine/Group/Class	Conditions	Statement
Royal jelly	For all classifications, including prescription, and for oral use	Caution: contains royal jelly

Royal jelly responses

- Of those that answered, most respondents agreed with having a statement for royal jelly and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 23: Royal jelly responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	61	23.5	34	17.4	15	51.7	11	55.0	1	6.3
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	198	76.2	161	82.6	14	48.3	8	40.0	15	93.8
Agree with conditions	Yes	57	21.9	32	16.4	15	51.7	9	45.0	1	6.3
	No	3	1.2	0	0.0	0	0.0	3	15.0	0	0.0
	Not answered	200	76.9	163	83.6	14	48.3	8	40.0	15	93.8
Proposed statement	Yes	48	18.5	31	15.9	14	48.3	2	10.0	1	6.3
	No	13	5.0	2	1.0	1	3.4	10	50.0	0	0.0
	Not answered	199	76.5	162	83.1	14	48.3	8	40.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with conditions

- No. Where royal jelly is one of the main active ingredients in the preparation. (Industry)

Agree with proposed statement

- No. **"**Caution: contains royal jelly (Bee secretion)" or "Caution: contains royal jelly (Bee product)". (Public)
- No. Combine with propolis and say derived from bee products. (HCP)
- No. "Allergen warning: contains bee products" (Industry)
- No. As per the Food Code, the statement should read: "This product includes royal jelly which has been reported to cause severe allergic reactions, especially in asthma and allergy sufferers". (Public)

Medsafe response/outcome

- If royal jelly is used an active ingredient in a medicine, then it must already be declared on package labels. There are currently no medicines approved in New Zealand with royal jelly as an active ingredient.
- This statement likely refers to the use of royal jelly as an excipient in complementary medicines. Unlike Australia, complementary medicines are not regulated in New Zealand. We are including this statement to align with Australian labelling requirements – but it is unlikely that royal jelly would be an excipient in a medicine regulated under the New Zealand Medicines Act 1981.
- Sponsors can combine statements, providing that the intent isn't changed. See the General comments section, point 4.
- There is no requirement for sponsors to have an allergen warning or an explanation of royal jelly allergy. See the General comments section, point 9.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The royal jelly statement will be:

Medicine/Group/Class	Conditions	Statement
Royal jelly	For all classifications, including prescription, when for oral use	Contains royal jelly

Saccharin

Proposed warning statement for saccharin.

Medicine/Group/Class	Conditions	Statement
Saccharin Includes: Saccharin calcium Saccharin sodium	For all classifications, including prescription, and for oral use	Caution: contains saccharin

Saccharin responses

- Of those that answered, most respondents agreed with having a statement for saccharin, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 24: Saccharin responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	61	23.5	36	18.5	14	48.3	11	55.0	0	0.0
	No	2	0.8	0	0.0	0	0.0	1	5.0	1	6.3
	Not answered	197	75.8	159	81.5	15	51.7	8	40.0	15	93.8
Agree with inclusions	Yes	60	23.1	35	17.9	13	44.8	12	60.0	0	0.0
	No	2	0.8	0	0.0	1	3.4	0	0.0	1	6.3
	Not answered	198	76.2	160	82.1	15	51.7	8	40.0	15	93.8
Agree with conditions	Yes	59	22.7	35	17.9	13	44.8	10	50.0	1	6.3
	No	2	0.8	0	0.0	0	0.0	2	10.0	0	0.0
	Not answered	199	76.5	160	82.1	16	55.2	8	40.0	15	93.8
Proposed statement	Yes	52	20.0	35	17.9	14	48.3	2	10.0	1	6.3
	No	10	3.8	0	0.0	0	0.0	10	50.0	0	0.0
	Not answered	198	76.2	160	82.1	15	51.7	8	40.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include saccharin warning statement

- No. Is there a safety reason for requiring this sweetener to be declared? (Other)

Agree with inclusions

- Add saccharin to the list. (Other)

Medsafe response/outcome

- Saccharin is a sulfonamide so could possibly cause allergic reactions in some people.

- Saccharin is the main Medicine/Group/Class entry and does not need to be included as an example. As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The saccharin statement will be:

Medicine/Group/Class	Conditions	Statement
Saccharin Examples include: Saccharin calcium Saccharin sodium	For all classifications, including prescription, when for oral use	Contains saccharin

Sesame and sesame seed products

Proposed warning statement for sesame and sesame seed products.

Medicine/Group/Class	Conditions	Statement
Sesame and sesame seed products Includes: Sesame seed Sesame oil *Sesamum indicum*	For all classifications, including prescription, and all uses	Caution: contains sesame seeds [or] sesame seed products

Sesame responses

- Of those that answered, most respondents agreed with having a statement for sesame products, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 25: Sesame and sesame seed product responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	66	25.4	39	20.0	15	51.7	10	50.0	2	12.5
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	193	74.2	156	80.0	14	48.3	9	45.0	14	87.5
Agree with inclusions	Yes	65	25.0	38	19.5	14	48.3	11	55.0	2	12.5
	No	1	0.4	0	0.0	1	3.4	0	0.0	0	0.0
	Not answered	194	74.6	157	80.5	14	48.3	9	45.0	14	87.5
Agree with conditions	Yes	64	24.6	38	19.5	15	51.7	9	45.0	2	12.5
	No	2	0.8	0	0.0	0	0.0	2	10.0	0	0.0
	Not answered	194	74.6	157	80.5	14	48.3	9	45.0	14	87.5
Proposed statement	Yes	57	21.9	38	19.5	15	51.7	2	10.0	2	12.5
	No	8	3.1	0	0.0	0	0.0	8	40.0	0	0.0
	Not answered	195	75.0	157	80.5	14	48.3	10	50.0	14	87.5

* See Table 3 for a description of respondent categories.

Summary of comments

See the General comments section.

Medsafe comments/outcome

The sesame and sesame seed products statement will be:

Medicine/Group/Class	Conditions	Statement
Sesame and sesame seed products Examples include: Sesame seed Sesame oil *Sesamum indicum*	For all classifications, including prescription, and all uses	Contains sesame seeds [or] sesame seed products

Sodium salts

Proposed warning statement for sodium salts.

Medicine/Group/Class	Conditions	Statement
Sodium salts Includes: Sodium bicarbonate Sodium chloride	For all classifications, including prescription, and for oral use – where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium	Caution: contains [mg quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine]

Sodium salts responses

- Of those that answered, most respondents agreed with having a statement for sodium salts, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 26: Sodium salts responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	54	20.8	31	15.9	12	41.4	11	55.0	0	0.0
	No	3	1.2	0	0.0	0	0.0	2	10.0	1	6.3
	Not answered	203	78.1	164	84.1	17	58.6	7	35.0	15	93.8
Agree with inclusions	Yes	53	20.4	30	15.4	11	37.9	12	60.0	0	0.0
	No	3	1.2	0	0.0	1	3.4	1	5.0	1	6.3
	Not answered	204	78.5	165	84.6	17	58.6	7	35.0	15	93.8
Agree with conditions	Yes	51	19.6	30	15.4	10	34.5	11	55.0	0	0.0
	No	4	1.5	0	0.0	2	6.9	2	10.0	0	0.0
	Not answered	205	78.8	165	84.6	17	58.6	7	35.0	16	100.0
Proposed statement	Yes	44	16.9	29	14.9	12	41.4	3	15.0	0	0.0
	No	11	4.2	1	0.5	0	0.0	10	50.0	0	0.0
	Not answered	205	78.8	165	84.6	17	58.6	7	35.0	16	100.0

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include sodium salts warning statement

- No. Unless there is a medical reason to include this. (Other)

Agree with inclusions

- No. What about other forms of sodium? (Other)

Agree with conditions

- No. Why does it not also refer to mmols as for potassium 1mmol sodium - 23mg. (HCP)

- No. Would increase the maximum daily dose condition to 250mg. (HCP)
- No. Should IV use also be specifically included to facilitate low sodium intake regimens where needed? (Industry)
- No. Sodium: Similarly, to the proposed statement for potassium, TGO 92 requires a sodium declaration when the total sodium content of the maximum recommended daily dose of the formulation is greater than 120 mg of elemental sodium per dose. The Medsafe proposal however applies when the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium. In addition, the TGO 92 requires a sodium declaration as mg elemental sodium per dose, whereas Medsafe proposes a sodium declaration as mg quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine. (Industry)

Agree with proposed statement

- No. It would be helpful to know what percentage over the recommended daily dose of sodium the product contains. (Public)
- No. This could be better phrased as "contains [mg quantity] of elemental sodium per [dosage unit or in a stated weight or volume of the medicine]". (Industry)

Medsafe comments/outcome

- There is evidence to suggest that medicines containing high sodium content might be associated with an increased risk of hypertension (high blood pressure)[7].
- If sodium is the active ingredient in an IV preparation, then this will already be declared on the package label.
- The intention is to align with Australia so that package labels can harmonised in both countries, where applicable. The wording proposed in the consultation was the same as in the Australian TGOs, except for the accidental omission of the word "sodium" from the statement text. This has been corrected.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The sodium salts statement will be:

Medicine/Group/Class	Conditions	Statement
Sodium salts Examples include: Sodium bicarbonate Sodium chloride	For all classifications, including prescription, when for oral use – where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium	Contains [mg quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine] sodium

[7] European Medicines Agency. 2017. *Questions and answers on sodium used as an excipient in medicinal products for human use* 9 October 2017. URL: ema.europa.eu/en/documents/scientific-guideline/questions-answers-sodium-used-excipient-medicinal-products-human-use_en.pdf (accessed 2 December 2019).

Sorbic acid and sorbic acid salts

Proposed warning statement for sorbic acid and sorbic acid salts.

Medicine/Group/Class	Conditions	Statement
Sorbic acid and sorbic acid salts Includes: Potassium sorbate	For all classifications, including prescription, and all uses	Caution: contains sorbates

Sorbic acid responses

- Of those that answered, most respondents agreed with having a statement for sorbic acid, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 27: Sorbic acid and sorbic acid salts responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	51	19.6	29	14.9	11	37.9	10	50.0	1	6.3
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	208	80.0	166	85.1	18	62.1	9	45.0	15	93.8
Agree with inclusions	Yes	49	18.8	28	14.4	10	34.5	11	55.0	0	0.0
	No	2	0.8	0	0.0	1	3.4	0	0.0	1	6.3
	Not answered	209	80.4	167	85.6	18	62.1	9	45.0	15	93.8
Agree with conditions	Yes	48	18.5	28	14.4	11	37.9	8	40.0	1	6.3
	No	3	1.2	0	0.0	0	0.0	3	15.0	0	0.0
	Not answered	209	80.4	167	85.6	18	62.1	9	45.0	15	93.8
Proposed statement	Yes	42	16.2	28	14.4	11	37.9	2	10.0	1	6.3
	No	8	3.1	0	0.0	0	0.0	8	40.0	0	0.0
	Not answered	210	80.8	167	85.6	18	62.1	10	50.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Add other sorbates. "Sorbic acid and sorbic acid salts. Includes: Sorbic acid, calcium, sodium, potassium sorbate". (Other)

Agree with conditions

- No. Consistent with TGA guidelines on TGO 91 and TGO 92 the warning statement should only apply to preservatives and not other sorbates such as polysorbates. Where an ingredient contains sorbate as a preservative, but it is at very low levels in the final product then a sorbate warning statement should not be required. (Industry)

Medsafe response/outcome

- As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only.
- The Australian guidance document includes an explanation of sorbates, copied below. We have added '(preservatives)' to the Medicines/Group/Class column and made polysorbates an exclusion in the Conditions column.

  Sorbates *– this entry refers to preservatives and does not include polysorbates.*
- See also the General comments section, point 6, for a discussion about thresholds.

The sorbic acid and sorbic acid salts statement will be:

Medicine/Group/Class	Conditions	Statement
Sorbic acid and sorbic acid salts (preservatives) Examples include: Potassium sorbate	Excludes polysorbates For all classifications, including prescription, and all uses	Contains sorbates

Soya beans and soya bean products

Proposed warning statement for soya beans and soya bean products.

Medicine/Group/Class	Conditions	Statement
Soya beans and soya bean products Includes: *Glycine max* Soya bean Soya oil	Excludes: • soya oil that is fully refined; • d-alpha tocopherol, d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources; • vegetable oils derived phytosterols and phytosterol esters from soybean sources; • plant stanol ester produced from vegetable oil sterols from soybean sources For all classifications, including prescription, and all uses	Caution: contains [soya beans; or soya bean products]

Soya bean responses

- Of those that answered, most respondents agreed with having a statement for soya beans, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 28: Soya beans and soya bean products responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	68	26.2	41	21.0	14	48.3	10	50.0	3	18.8
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	190	73.1	154	79.0	14	48.3	9	45.0	13	81.3
Agree with inclusions	Yes	64	24.6	37	19.0	13	44.8	11	55.0	3	18.8
	No	4	1.5	2	1.0	2	6.9	0	0.0	0	0.0
	Not answered	192	73.8	156	80.0	14	48.3	9	45.0	13	81.3
Agree with conditions	Yes	59	22.7	34	17.4	14	48.3	9	45.0	2	12.5
	No	9	3.5	5	2.6	1	3.4	2	10.0	1	6.3
	Not answered	192	73.8	156	80.0	14	48.3	9	45.0	13	81.3
Proposed statement	Yes	56	21.5	36	18.5	15	51.7	2	10.0	3	18.8
	No	12	4.6	4	2.1	0	0.0	8	40.0	0	0.0
	Not answered	192	73.8	155	79.5	14	48.3	10	50.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include soya bean warning statement

- No. This is confusing. (HCP)

Agree with inclusions

- Yes. But include genetically modified soya products to be labelled as GMO. (HCP)

Agree with conditions

- No. I would want to have confidence that manufacturers are incentivised/audited to ensure they meet some kind of standard for fully refined soy oil for example. (Public)
- No. Include all soy derivatives, even if fully refined. Non Ige conditions such as FPIES require clear information of all trace allergens present in a formulation. (Public, HCP)

Agree with proposed statement

- No. Should declare the actual component/form as people have different allergies eg allergic to soy bean but can tolerate soy oil or lecithin. Eg, "Caution: contains [soya beans; or soya bean products [specify form]" (Public)

Medsafe response/outcome

- As previously stated, we are aligning with the labelling requirements in Australia – which have these inclusions and conditions.
- If the soya oil is fully refined, there should be no trace allergens in the product when manufactured to GMP and controlled to pharmacopoeial quality standards – see the General comments section, point 7.
- There is no requirement to specify the form – see the General comments section, point 9.

The soya bean and soya bean products warning statement will be:

Medicine/Group/Class	Conditions	Statement
Soya beans and soya bean products Examples include: *Glycine max* Soya bean Soya oil	Excludes: • soya oil that is fully refined • d-alpha tocopherol, d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources; • vegetable oils derived phytosterols and phytosterol esters from soybean sources; • plant stanol ester produced from vegetable oil sterols from soybean sources For all classifications, including prescription, and all uses	Contains [soya beans; or soya bean products]

Sucralose

Proposed warning statement for sucralose.

Medicine/Group/Class	Conditions	Statement
Sucralose	For all classifications, including prescription, and for oral use	Caution: contains sucralose

Sucralose responses

- Of those that answered, most respondents agreed with having a statement for sucralose, and agreed with the conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 29: Sucralose responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	52	20.0	31	15.9	11	37.9	9	45.0	1	6.3
	No	3	1.2	0	0.0	0	0.0	2	10.0	1	6.3
	Not answered	205	78.8	164	84.1	18	62.1	9	45.0	14	87.5
Agree with conditions	Yes	51	19.6	30	15.4	11	37.9	9	45.0	1	6.3
	No	2	0.8	0	0.0	0	0.0	2	10.0	0	0.0
	Not answered	207	79.6	165	84.6	18	62.1	9	45.0	15	93.8
Proposed statement	Yes	43	16.5	30	15.4	11	37.9	1	5.0	1	6.3
	No	10	3.8	0	0.0	0	0.0	10	50.0	0	0.0
	Not answered	207	79.6	165	84.6	18	62.1	9	45.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Include warning statement

- No. What the safety risk is with using this sweetener? It has been evaluated for safety by the WHO/FAO JECFA for use in food. Eg, does it interact with one or more medicines? (Other)

Medsafe response/outcome

- The TGA have advised that sucralose was added to the TGO 91 and 92 labelling requirements based on consumer requests to include this ingredient on product labels.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The sucralose statement will be:

Medicine/Group/Class	Conditions	Statement
Sucralose	For all classifications, including prescription, when for oral use	Contains sucralose

Sugar alcohols

Proposed warning statement for sugar alcohols.

Medicine/Group/Class	Conditions	Statement
Sugar alcohols Includes: Erythritol Isomalt Lactitol Maltitol Mannitol Polydextrose Sorbitol Xylitol	Excludes glycerol For all classifications, including prescription, and for oral use – where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose	Caution: contains [quantity of sugar alcohols present per recommended maximum daily dose]. Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea

Sugar alcohol responses

- Of those that answered, most respondents agreed with having a statement for sugar alcohols, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 30: Sugar alcohol responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	**Response**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Include warning statement	Yes	56	21.5	32	16.4	11	37.9	12	60.0	1	6.3
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	203	78.1	163	83.6	18	62.1	7	35.0	15	93.8
Agree with inclusions	Yes	55	21.2	31	15.9	10	34.5	13	65.0	1	6.3
	No	1	0.4	0	0.0	1	3.4	0	0.0	0	0.0
	Not answered	204	78.5	164	84.1	18	62.1	7	35.0	15	93.8
Agree with conditions	Yes	52	20.0	31	15.9	10	34.5	10	50.0	1	6.3
	No	4	1.5	0	0.0	1	3.4	3	15.0	0	0.0
	Not answered	204	78.5	164	84.1	18	62.1	7	35.0	15	93.8
Proposed statement	Yes	45	17.3	31	15.9	11	37.9	2	10.0	1	6.3
	No	10	3.8	0	0.0	0	0.0	10	50.0	0	0.0
	Not answered	205	78.8	164	84.1	18	62.1	8	40.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with conditions

- No. Include glycerol. Important for athletes to comply with competition regulations. TGO92 does not exclude glycerol and by differing there is potential for different calculations of 2g per maximum recommended daily dose and therefore different labels. (HCP, Industry)

Agree with proposed statement

- No. The statements need to be more flexible. The first statement should allow the quantity of sugar alcohols to be declared per dosage unit or in a stated weight or volume of the product as well as per recommended maximum daily dose. It also needs to be flexible, for example if a product contains only one sugar alcohol then the statement should permit declaration of the amount of that ingredient per dosage unit or maximum daily dose and not required to declare only the amount of sugar alcohols. The second statement should be flexible as well. If a product only contains 1 sugar alcohol it should permitted to state: 'Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea'. If the product contains more than 1 sugar alcohol the use of the group name should be permitted "Products containing sugar alcohols may have a laxative effect or cause diarrhoea"" (Industry)
- No. This could be better phrased as "Maximum daily dose contains [quantity] of [name of sugar alcohol]. Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea". (Industry)

Medsafe response/outcome

- The intention is to align with Australia so that package labels can harmonised in both countries, where applicable. The wording proposed in the consultation was the same as in the Australian TGOs, however the TGOs 91 and 92 have an explanatory note (Note 5A, copied below) about glycerol. The current LSD layout doesn't allow for notes, so we made glycerol an exclusion.

  Note 5A: Sugar alcohols *– It is generally accepted that while glycerol is a sugar alcohol, it does not have a laxative effect. Therefore, glycerol is not required to be declared in relation to sugar alcohols and their associated laxative effect.*
- The need for this statement relates to the potential for sugar alcohols to cause a laxative effect. As glycerol does not have a laxative effect, it does not need to be stated on the package label when used as an excipient. Athletes or their health care providers can check the Product/Application search on the Medsafe website for the list of excipients in a medicine, including glycerol.
- Statements can be flexible and combined, providing the intent isn't changed. See the General comments section, point 4.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The sugar alcohols warning statement will be:

Medicine/Group/Class	Conditions	Statement
Sugar alcohols Examples include: Erythritol Isomalt Lactitol Maltitol Mannitol Polydextrose Sorbitol Xylitol	Excludes glycerol For all classifications, including prescription, when for oral use – where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose	Contains [quantity of sugar alcohols present per recommended maximum daily dose]. Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea

Sugars – monosaccharides and disaccharides

Proposed warning statement for sugars – monosaccharides and disaccharides.

Medicine/Group/Class	Conditions	Statement
Sugars – monosaccharides and disaccharides Includes: Fructose Glucose Honey Invert sugar Lactose Maltose Sucrose	For all classifications, including prescription, and for oral use – where the presence of sugars may have a significant glycaemic effect and the total sugar content (including: lactose which requires a separate declaration) exceeds 100 mg per maximum recommended daily dose	Caution: contains sugars

Sugars responses

- Of those that answered, most respondents agreed with having a statement for sugars, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 31: Sugars - monosaccharides and disaccharides responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	60	23.1	36	18.5	11	37.9	11	55.0	2	12.5
	No	2	0.8	0	0.0	1	3.4	1	5.0	0	0.0
	Not answered	198	76.2	159	81.5	17	58.6	8	40.0	14	87.5
Agree with inclusions	Yes	58	22.3	35	17.9	11	37.9	12	60.0	0	0.0
	No	2	0.8	0	0.0	0	0.0	0	0.0	2	12.5
	Not answered	200	76.9	160	82.1	18	62.1	8	40.0	14	87.5
Agree with conditions	Yes	56	21.5	35	17.9	11	37.9	10	50.0	0	0.0
	No	4	1.5	0	0.0	1	3.4	2	10.0	1	6.3
	Not answered	200	76.9	160	82.1	17	58.6	8	40.0	15	93.8
Proposed statement	Yes	48	18.5	34	17.4	11	37.9	2	10.0	1	6.3
	No	12	4.6	1	0.5	1	3.4	9	45.0	1	6.3
	Not answered	200	76.9	160	82.1	17	58.6	9	45.0	14	87.5

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Does not align with Food Standards Code (Std 1.1.2-2). (Other)
- Yes. Honey and fructose should have a separate statement. (HCP)

- Yes. Consider adding galactose and tagatose also. (Industry)
- No. Be more specific. (Other)
- No. We are not sure why specific examples are given for inclusion as this may exclude some sugars that fit under the same conditions in the future. (HCP)

Agree with conditions

- No. Needs to be more specific so it's clear what is in the medication. (Other)
- No. How do you determine if something is likely to have a significant glycaemic effect? Is the 100 mg above the maximum recommended dose a dose above the WHO recommended intake of sugar per day or above 100mg of sugar in the tablet? (HCP)

Agree with proposed statement

- Yes. A statement of "Contains xxx mg total sugars per tablet/capsule/etc" may be more useful especially for those patients who are monitoring sugar levels. (Industry)
- No. Be more specific. "Caution: contains sugars [specify form]". (Public, Other)

Medsafe response/outcome

- This statement is only required if, when a patient takes the recommended daily dose of the medicine, the sugar content is greater than 100 mg. For example, if a medicine contains 50 mg of sucrose as an excipient and the recommended daily dose of that medicine is 3 tablets per day, then the total sucrose content would be 150 mg and the medicine label would need to include the sugar statement.
- As stated in the General comments section, point 5, the inclusions are not an exhaustive list and are meant to be examples only. We have modified the wording in the Medicine/Group/Class column to state "Examples include:".
- There is no requirement to specify the sugar form. See the General comments section, point 9.
- For clarity, we have modified the Conditions column from "and for oral use" to "when for oral use".

The sugars warning statement will be:

Medicine/Group/Class	Conditions	Statement
Sugars – monosaccharides and disaccharides Examples include: Fructose Glucose Honey Invert sugar Lactose Maltose Sucrose	For all classifications, including prescription, when for oral use – where the presence of sugars may have a significant glycaemic effect and the total sugar content (including: lactose which requires a separate declaration) exceeds 100 mg per maximum recommended daily dose	Contains sugars

Sulfites

Proposed warning statement for sulfites.

Medicine/Group/Class	Conditions	Statement
Sulfites Includes: Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulphite Sulfur dioxide (including residues)	For all classifications, including prescription, and all uses	Caution: contains sulfites

Sulfites responses

- Of those that answered, most respondents agreed with having a statement for sulfites, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 32: Sulfites responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	72	27.7	45	23.1	16	55.2	10	50.0	1	6.3
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	187	71.9	150	76.9	13	44.8	9	45.0	15	93.8
Agree with inclusions	Yes	69	26.5	44	22.6	15	51.7	10	50.0	0	0.0
	No	3	1.2	0	0.0	1	3.4	1	5.0	1	6.3
	Not answered	188	72.3	151	77.4	13	44.8	9	45.0	15	93.8
Agree with conditions	Yes	68	26.2	44	22.6	16	55.2	8	40.0	0	0.0
	No	4	1.5	0	0.0	0	0.0	3	15.0	1	6.3
	Not answered	188	72.3	151	77.4	13	44.8	9	45.0	15	93.8
Proposed statement	Yes	59	22.7	43	22.1	15	51.7	1	5.0	0	0.0
	No	11	4.2	1	0.5	0	0.0	9	45.0	1	6.3
	Not answered	190	73.1	151	77.4	14	48.3	10	50.0	15	93.8

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Should align with food labelling. FSCode Std 1.2.3-4 the declaration should be for added sulphites in concentrations of 10mg/kg. The list should also include potassium sulphite, and potassium bisulphite. (Public, Other).

- No. Use the "ph" spelling of sulphite and sulphur, hence "sulphur dioxide", "sodium bisulphite" etc. (Industry, Other)

Agree with conditions

- No. Be consistent with Food Code, which only requires labelling for food products when the concentration is 10 mg/kg or more. (Industry, Other)

Agree with proposed statement

- No. Specify form. "Caution: contains sulfites [specify form]". (Public)

Medsafe response/outcome

- The intention is to align with Australia so that package labels can harmonised in both countries, where applicable. There is no threshold for sulfites in the TGOs, and there is no requirement to specify the form – see the General comments section, points 6 and 9.
- The wording proposed in the consultation was the same as in the Australian TGOs, however, the TGOs 91 and 92 have an explanatory note for sulfur dioxide (Note 7, copied below). The current LSD layout doesn't allow for notes, so we have included gelatin in the Medicines/Group/Class column.

  Note 7: Sulfur dioxide *– some formulations of medicines may contain sulfur dioxide as a residue, for example, gelatin, but must be identified.*

- Spelling 'sulfites' with an 'f' instead of 'ph' aligns with the International nonproprietary name (INN) guidelines[8]. INNs identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. However, sponsors may use 'sulphites' instead of 'sulfites' on medicine labels as these would be considered words of a similar meaning – see the General comments section, point 4.

The sulfites statement will be:

Medicine/Group/Class	Conditions	Statement
Sulfites Examples include: Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulfite Sulfur dioxide (including when present as a residue, such as in gelatin)	For all classifications, including prescription, and all uses	Contains sulfites

[8] World Health Organization. 2017. *Guidance on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*. URL: who.int/medicines/services/inn/FINAL_WHO_PHARM_S_NOM_1570_web.pdf?ua=1 (accessed 31 January 2020).

Tartrazine

The following questions relate to the proposed warning statement for tartrazine. There is already a warning statement for tartrazine (see 'Current tartrazine warning statement'). However, to align with the Australian labelling requirements, we are proposing to amend the conditions so that the warning statement applies to all classifications and uses (see 'Proposed tartrazine warning statement').

Current tartrazine warning statement

Medicine/Group/Class	Conditions	Statement
Tartrazine	For oral use	Caution: contains tartrazine

Proposed tartrazine warning statement

Medicine/Group/Class	Conditions	Statement
Tartrazine	For all classifications, including prescription, and all uses	Caution: contains tartrazine

Tartrazine responses

- Of those that answered, most respondents agreed with the revised condition.

Table 33: Tartrazine responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Agree with conditions	Yes	55	21.2	33	16.9	12	41.4	10	50.0	0	0
	No	3	1.2	0	0.0	1	3.4	2	10.0	0	0
	Not answered	202	77.7	162	83.1	16	55.2	8	40.0	16	100.0

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with tartrazine conditions

- No. There is no need for a caution statement highlighting that the product contains Tartrazine since this presence would be evident from the ingredient label. There is no credible evidence that Tartrazine actually causes allergenic reactions which requires the need for any special warning statement such as this. There is always a small sub-population of people who may be sensitive to many components in drug products. However, that sensitive sub-population can select products based on the ingredient labels for any component that they may be sensitive to. (Industry)

Medsafe response/outcome

- As stated in the consultation, this is an existing warning statement, and non-prescription products marketed in New Zealand are already required to include the presence of tartrazine on the package label. We are changing the conditions to align with Australian requirements, so that the tartrazine statement applies to all classifications and all uses.

- Medsafe disagrees that the presence of tartrazine should only be declared in the ingredient label (in New Zealand, this is the data sheet). See the General comments section, points 2 and 3.
- Based on feedback to all statements, we have also removed the word 'Caution'.

The tartrazine statement will be:

Medicine/Group/Class	Conditions	Statement
Tartrazine	For all classifications, including prescription, and all uses	Contains tartrazine

Tree nuts and tree nut products

Proposed warning statement for tree nuts and tree nut products.

Medicine/Group/Class	Conditions	Statement
Tree nuts and tree nut products Includes: Almond oil Brazil nut Cashew Chestnut *Juglans nigra* Macadamia nut oil *Macadamia ternifolia* *Prunus dulcis* Walnut	For all classifications, including prescription, and all uses	Caution: contains tree nuts [or] tree nut products

Tree nut responses

- Of those that answered, most respondents agreed with having a statement for tree nuts, and agreed with the inclusions, conditions and the statement.
- Industry did not agree with the statement text – this related to the use of the word 'Caution' in the statement (see the General comments section, point 8).

Table 34: Tree nuts and tree nut products responses

		Respondent category*									
		All (n=260)		Public (n=195)		HCP (n=29)		Industry (n=20)		Other (n=16)	
Question	Response	No.	%	No.	%	No.	%	No.	%	No.	%
Include warning statement	Yes	86	33.1	55	28.2	18	62.1	10	50.0	3	18.8
	No	1	0.4	0	0.0	0	0.0	1	5.0	0	0.0
	Not answered	173	66.5	140	71.8	11	37.9	9	45.0	13	81.3
Agree with inclusions	Yes	75	28.8	49	25.1	14	48.3	10	50.0	2	12.5
	No	11	4.2	5	2.6	4	13.8	1	5.0	1	6.3
	Not answered	174	66.9	141	72.3	11	37.9	9	45.0	13	81.3
Agree with conditions	Yes	81	31.2	54	27.7	18	62.1	7	35.0	2	12.5
	No	5	1.9	0	0.0	0	0.0	4	20.0	1	6.3
	Not answered	174	66.9	141	72.3	11	37.9	9	45.0	13	81.3
Proposed statement	Yes	72	27.7	51	26.2	18	62.1	2	10.0	1	6.3
	No	14	5.4	3	1.5	0	0.0	9	45.0	2	12.5
	Not answered	174	66.9	141	72.3	11	37.9	9	45.0	13	81.3

* See Table 3 for a description of respondent categories.

Summary of comments

See also the General comments section.

Agree with inclusions

- No. Include: hazelnuts and hazelnut oil, pecan, pistachio, pink peppercorn. (HCP, Public).

- No. Use tree nuts associated with allergies in Australia and NZ. Includes: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut, excluding coconut. This would enable individuals with allergies only to certain tree nuts to safely choose from a broader range of foods. (Public, Other)
- No. Why do some plants have their Latin names and others their common name? (Public)

Agree with conditions

- No. Add a condition or explanatory note that coconuts are excluded (as per TGOs). (Sponsor)

Agree with proposed statement

- No. Specify the nut. This would enable individuals with allergies only to certain tree nuts to safely choose products with tree nuts they are not allergic to. "Caution: contains tree nuts [specify nut] [or] tree nut [specify] products." (Public, Industry, Other)

Medsafe response/outcome

- The Australian TGO 91 and 92 entry for tree nuts includes almond oil, *Julgans nigra*, macadamia nut oil, *Macadamia ternifolia*, *Prunus dulcis* and walnut. There is also an explanatory note for tree nuts which includes additional examples of tree nuts, and states that coconuts are not considered to be tree nuts (Note 8, copied below). The current LSD layout doesn't allow for notes, so we included the examples in the Medicines/Group/Class column. We have also made coconuts an exclusion in the Conditions column.

  Note 8: Tree nuts *– are the seeds of a variety of trees and shrubs which are characterised by a hard inedible shell enclosing an oily seed. Tree nuts include almond, Brazil, cashew, chestnut, and walnut. Coconut is the fruit of the palm* (Cocos nucifera*) and is not considered to be a tree nut.*

- Also, the inclusions are examples only and should not be considered a complete list (see the General comments section, point 5). We have modified the text in the Medicine/Group/Class column to say, "Examples include:". We have also added: almond, hazelnut, macadamia, pecan, pine nut and pistachio to the list.
- There is no requirement to specify the tree nut (see the General comments section, point 9), although sponsors may choose to include the specific tree nut on the label.

The tree nuts and tree nuts products statement will be:

Medicine/Group/Class	Conditions	Statement
Tree nuts and tree nut products Examples include: Almond Almond oil Brazil nut Cashew Chestnut Hazelnut *Juglans nigra* Macadamia Macadamia nut oil *Macadamia ternifolia* Pecan Pine nut Pistachio *Prunus dulcis* Walnut	Excludes coconut For all classifications, including prescription, and all uses	Contains tree nuts [or] tree nut products

Other comments

Summary

See also the General comments section.

Similar comments have been combined into the same bullet point.

General

- Think it's a good idea highlight these ingredients. Consumers have a right to know what they are consuming. Thank you. (Public)
- Delighted that prescription medicines will be labelled. Especially important for coeliacs. (Public)
- Suggest providing some education to the public around what constitutes an allergy verses an intolerance. Whatever the changes, it needs to be clear to both the patient and the pharmacist what the labels mean and the risk attached with taking the medicine if you are allergic. (HCP + Public)
- Important to ensure manufacturers don't take an overly conservative stance and include an allergen statement when the specific product doesn't in fact contain it. (Public)
- Include a mandatory review in the legislation 5 years post-implementation, to ensure that this labelling actually does meet consumers' needs. (Public)

Medsafe comment

- Medsafe will produce information for consumers about these new statements, likely in the form of a Consumer information leaflet that will be published on the Medsafe website.
- Medsafe expects manufacturers to only include a warning statement when the excipient is present. If it is unlikely that a substance is present, declarations should not be made simply as disclaimers. See the General comments section, point 6.
- The Label Statements Database is reviewed and updated just as per this current consultation.

Other allergens

- All food derivatives should be labelled. Very important for FPIES patients who can have unusual triggers (eg, oats, corn, rice). (HCP)
- Include a warning for the following excipients (Public, HCP):
  - Stevia
  - Allium
  - Salicylates – Vegetable sterrate is a binder in tablets that ups my level of salicylate, too
  - Sodium Starch Glycolate Type A (potato starch)
  - Chlorhexidine
  - Latex
  - Lanoline and wool fat derivatives
  - Castor oil derivatives
- Should state on the label if genetically modified organisms are used. (HCP)

- Full ingredient list should be on the label. Eg, if it includes citrus. (Public)
- How was this list derived? (HCP)

Medsafe comment

- As previously stated, these warning statements align with those required in Australia. However, we have noted these requests for future consideration and discussion with the Australian Therapeutic Goods Administration.
- The full ingredient list for a medicine is available in the Product/Application search on the Medsafe website. Medsafe also publishes data sheets and consumer medicine information (CMI) documents. Pharmaceutical companies are responsible for the content of data sheets and CMIs, including keeping the information up-to-date.

Labels

- Will these allergens also be required on the product? As the packaging is often discarded. This information needs to be on all labels, include pharmacy-supplied bottles and/or labels. (Public, HCP).
- Is there a minimum type size and type style for these warnings? (HCP)
- These statements should be included on all medicine labels, whether topical or oral, inhaled etc. (Public)
- It would be very useful if this data could be made available in a way for automatic extraction/download for use by vendors. (HCP)

Medsafe comment

- Medsafe is not responsible for pharmacy-generated labels. However, any allergen statement on the product package label should be a prompt for the pharmacist to discuss potential allergens with patients.
- Medsafe has published guidelines for industry for labelling of medicines and related products[9]. This information includes links to international best practice recommendations for labelling.
- As previously stated, these warning statements align with those required in Australia. Not all routes of administration of a medicine (topical, inhaled, etc) may cause a reaction.
- The full ingredient list for a medicine is available in the Product/Application search on the Medsafe website.

Other

- Is makeup/cosmetics included? The same standards also need to apply to health supplements/dietary supplements/complementary medicines. (Public)
- Can we please have a gluten free folic acid option in NZ? (Public)
- Please ban tartrazine from all food and medicines in NZ. (Public)

Medsafe comment

- These warning statements only apply to medicines and related products regulated under the Medicines Act 1981 and the Medicines Regulations 1984. They do not apply to food, cosmetics, herbal preparations or dietary supplements.

- PHARMAC is responsible for the funding of medicines. Please contact PHARMAC regarding the request for a gluten-free folic acid option in New Zealand.
- Medsafe does not have the regulatory authority to ban tartrazine. However, we encourage manufacturers to carefully consider which excipients are appropriate for their medicines.

[9] Medsafe. 2018. *Guideline on the Regulation of Therapeutic Products in New Zealand. Part 5: Labelling of medicines and related products*. Edition 1.6 February 2018. URL: medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part5.pdf

Appendix 1: Final statements

Note: The 'Statements or requirements column" is the information that will appear on the package label. However, words of a similar meaning to the statements may be used and individual statements may be combined provided the intent is not changed.

Medicine/Group/Class	Conditions	Statements or requirements	Required by
Antibiotics	For all classifications, including prescription, and all uses – when the antibiotic is not an active ingredient and is present only as a residual impurity	Contains residual [antibiotic name]	1/03/2024
Aspartame	For all classifications, including prescription, when for oral use	Contains aspartame	1/03/2024
Benzoates Examples include: Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate	For all classifications, including prescription, and uses	Contains benzoates	1/03/2024
Crustacea and crustacean products (aquatic animals which have an inedible chitinous outer shell) Examples include**:** Crab Crayfish Lobster Prawn Shrimp	For all classifications, including prescription, and uses	Contains crustacea [or] crustacean products	1/03/2024
Egg, egg products and products manufactured in eggs Examples include: Dried egg yolk Egg lecithin Influenza vaccine	For all classifications, including prescription, and all uses	Contains egg [or] egg products [or] manufactured in eggs	1/03/2024
Ethanol	For all classifications, including prescription, and for all uses – when ethanol is present in a concentration of 3% v/v or more	Contains [quantity of ethanol as % v/v] alcohol	1/03/2024
Fish and fish products (freshwater fish, diadromous fish and marine fish) Examples include: Cod Cod liver oil Halibut Tuna Shark	For all classifications, including prescription, and all uses	Contains fish [or] fish products	1/03/2024
Galactose	For all classifications, including prescription, when for oral use	Contains galactose	1/03/2024

Medicine/Group/Class	Conditions	Statements or requirements	Required by
Gluten Examples include: Wheat Barley Rye Oats Spelt Derivatives of the above that may contain gluten	For all classifications, including prescription, and all uses – where gluten is present in a concentration of 3 parts per million or more	Contains gluten from [specify source]	1/03/2024
Hydroxybenzoic acid esters (parabens with hydroxybenzoate in the substance name) Examples include: Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate	Excludes salicylates For all classifications, including prescription, and all uses	Contains hydroxybenzoates	1/03/2024
Lactose	For all classifications, including prescription, when for oral use When lactose is obtained from milk, the label does not require the 'contains milk product' statement	Contains lactose	1/03/2024
Milk and milk products Examples include: Casein Hydrolysed milk protein Non-fat dry milk Whey powder Whole dry milk	For all classifications, including prescription, and all uses	Contains milk [or] milk products	1/03/2024
Peanuts and peanut products Examples include: *Arachis hypogaea* Arachis (peanut) oil	For all classifications, including prescription, and all uses	Contains peanuts [or] peanut products	1/03/2024
Phenylalanine	For all classifications, including prescription, and all uses other than skin and mucous membrane applications	Contains phenylalanine	1/03/2024
Pollen	For all classifications, including prescription, when for oral use	Contains pollen	1/03/2024
Potassium salts Examples include: Potassium bicarbonate Potassium chloride	For all classifications, including prescription, when for oral use – where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1 mmol) elemental potassium	Contains [quantity [in mg] of elemental potassium per dosage unit or in a stated weight or volume of the medicine] potassium	1/03/2024

Medicine/Group/Class	Conditions	Statements or requirements	Required by
Propolis	For all classifications, including prescription, when for oral use	Contains propolis	1/03/2024
Royal jelly	For all classifications, including prescription, when for oral use	Contains royal jelly	1/03/2024
Saccharin Examples include: Saccharin calcium Saccharin sodium	For all classifications, including prescription, when for oral use	Contains saccharin	1/03/2024
Sesame and sesame seed products Examples include: Sesame seed Sesame oil *Sesamum indicum*	For all classifications, including prescription, and all uses	Contains sesame seeds [or] sesame seed products	1/03/2024
Sodium salts Examples include: Sodium bicarbonate Sodium chloride	For all classifications, including prescription, when for oral use – where the total sodium content of the maximum recommended daily dose is greater than 120 mg of elemental sodium	Contains [mg quantity of elemental sodium per dosage unit or in a stated weight or volume of the medicine] sodium	1/03/2024
Sorbic acid and sorbic acid salts (preservatives) Examples include: Potassium sorbate	Excludes polysorbates For all classifications, including prescription, and all uses	Contains sorbates	1/03/2024
Soya beans and soya bean products Examples include: *Glycine max* Soya bean Soya oil	Excludes: • soya oil that is fully refined; • d-alpha tocopherol, d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources; • vegetable oils derived phytosterols and phytosterol esters from soybean sources; • plant stanol ester produced from vegetable oil sterols from soybean sources For all classifications, including prescription, and all uses	Contains [soya beans; or soya bean products]	1/03/2024
Sucralose	For all classifications, including prescription, when for oral use	Contains sucralose	1/03/2024

Medicine/Group/Class	Conditions	Statements or requirements	Required by
Sugar alcohols Examples include: Erythritol Isomalt Lactitol Maltitol Mannitol Polydextrose Sorbitol Xylitol	Excludes glycerol For all classifications, including prescription, when for oral use – where the total sugar alcohol content of the formulation exceeds 2 g per maximum recommended daily dose	Contains [quantity of sugar alcohols present per recommended maximum daily dose]. Products containing [name of sugar alcohol] may have a laxative effect or cause diarrhoea	1/03/2024
Sugars – monosaccharides and disaccharides Examples include: Fructose Glucose Honey Invert sugar Lactose Maltose Sucrose	For all classifications, including prescription, when for oral use – where the presence of sugars may have a significant glycaemic effect and the total sugar content (including: lactose which requires a separate declaration) exceeds 100 mg per maximum recommended daily dose	Contains sugars	1/03/2024
Sulfites Examples include: Potassium metabisulfite Sodium bisulfite Sodium metabisulfite Sodium sulphite Sulfur dioxide (including when present as a residue, such as in gelatin)	For all classifications, including prescription, and all uses	Contains sulfites	1/03/2024
Tartrazine	For all classifications, including prescription, and all uses	Contains tartrazine	1/03/2024
Tree nuts and tree nut products Examples include: Almond Almond oil Brazil nut Cashew Chestnut Hazelnut *Juglans nigra* Macadamia Macadamia nut oil *Macadamia ternifolia* Pecan Pine nut Pistachio *Prunus dulcis* Walnut	Excludes coconut For all classifications, including prescription, and all uses	Contains tree nuts [or] tree nut products	1/03/2024