Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019

I, Cheryl McRae, as delegate of the Minister for Health, make the following determination.

Dated 27/8/19

Cheryl McRae
Assistant Secretary
Complementary and Over the Counter Medicines Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	2 September 2019.	2 September 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 26BC of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2019

1 Schedule 1 (after table item 187)

Insert:

187A	3,7-DIMETHYL-1-OCTEN-3-OL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.

2 Schedule 1 (after table item 730)

Insert:

730A	BACILLUS COAGULANS	A	Only to be used in a medicine where Pathway International Pty Ltd (Client ID 23355), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 2 September 2021. Only permitted for use in medicines: - limited to oral routes of administration; and - when the strain of Bacillus coagulans is confirmed to be Microbial Type Culture Collection (MTCC) accession number 5260. The strain of Bacillus coagulans must be declared on the label.

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			The maximum recommended daily dose of the medicine must not provide more than 6 billion CFU of Bacillus coagulans. The following warning statements are required on the medicine label: - (CHILD2) ‘Not suitable for children’. - (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'

3 Schedule 1 (table item 938)

Repeal the item, substitute:

938	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.

4 Schedule 1 (table item 939)

Repeal the item, substitute:

939	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.

5 Schedule 1 (table item 1029)

Repeal the item, substitute:

1029	CAFFEINE	A, E	When used as an excipient, only for use in topical medicines for dermal application. Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more

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	designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine). When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg of caffeine from this ingredient. When for internal use or oral application, the following warning statement is required on the medicine label: - (ADULT) 'Adults only' (or words to that effect). When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a)

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to (d) below.

a) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

b) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

c) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’

d) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) ‘Caffeine

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			interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

6 Schedule 1 (table item 1106)

Repeal the item, substitute:

1106	CAMELLIA SINENSIS	A, E, H	Caffeine is a mandatory component of Camellia sinensis. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum

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recommended daily dose of the medicine must provide no more than 400mg of total caffeine.

b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’

e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

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			- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

7 Schedule 1 (table item 1495)

Repeal the item, substitute:

1495	COFFEA ARABICA	A, E, H	Caffeine is a mandatory component of Coffea arabica. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the

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requirements in paragraphs (a) to (e) below.

a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.

b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’

e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the

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			medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

8 Schedule 1 (table item 1496)

Repeal the item, substitute:

1496	COFFEA CANEPHORA	A, E, H	Caffeine is a mandatory component of Coffea canephora. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register

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before 2 September 2019; and

- is supplied before 2 March 2021;

may comply with the requirements in paragraphs (a) to (e) below.

a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.

b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during

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			pregnancy or breastfeeding.' e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

9 Schedule 1 (table item 1497)

Repeal the item, substitute:

1497	COFFEE	E, H	Caffeine is a mandatory component of coffee. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March

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	2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of

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			caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).

10 Schedule 1 (table item 1504)

Repeal the item, substitute:

1504	COLA ACUMINATA	A, E, H	Caffeine is a mandatory component of Cola acuminata. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient

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	that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product]

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			total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

11 Schedule 1 (table item 1505)

Repeal the item, substitute:

1505	COLA NITIDA	A, E, H	Caffeine is a mandatory component of Cola nitida. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.

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	The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or

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			words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).

12 Schedule 1 (table item 2649)

Repeal the item, substitute:

2649	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of Ilex paraguariensis. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a

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divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.

The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:

- is listed in the Register on or after 2 September 2019; or

- is supplied after 2 March 2021.

A medicine that contains the ingredient and that:

- was listed in the Register before 2 September 2019; and

- is supplied before 2 March 2021;

may comply with the requirements in paragraphs (a) to (e) below.

a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.

b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the

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			medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).

13 Schedule 1 (table item 2935)

Repeal the item, substitute:

2935	LAVANDULA ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

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			In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.

14 Schedule 1 (table item 2936)

Repeal the item, substitute:

2936	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.

15 Schedule 1 (table item 2937)

Repeal the item, substitute:

2937	LAVANDULA X INTERMEDIA	A, E, H	Camphor is a mandatory component of Lavandula x intermedia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

16 Schedule 1 (table item 2938)

Repeal the item, substitute:

2938	LAVENDER OIL	A, E, H	

17 Schedule 1 (table item 3575)

Repeal the item, substitute:

3575	ORIGANUM MAJORANA	A, H	Arbutin is a mandatory component of Origanum majorana. The concentration of arbutin in the medicine must be no more

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			than 25mg/Kg or 25mg/L or 0.0025% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74%. When the plant preparation is oil or distillate and the concentration of Origanum majoranum oil or distillate within the medicine is greater than 50%: a) the nominal capacity of the container must be no more than 50 millilitre; b) a restricted flow insert must be fitted on the container; and c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).

18 Schedule 1 (table item 3686)

Repeal the item, substitute:

3686	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine

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that contains the ingredient that:

- is listed in the Register on or after 2 September 2019; or

- is supplied after 2 March 2021.

A medicine that contains the ingredient and that:

- was listed in the Register before 2 September 2019; and

- is supplied before 2 March 2021;

may comply with the requirements in paragraphs (a) to (e) below.

a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.

b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per

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			mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

19 Schedule 1 (after table item 3967)

Insert:

3967A	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3%.

20 Schedule 1 (table item 4864)

Repeal the item, substitute:

4864	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma

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	cacao.
	When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.
	When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.
	The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below.
	a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.
	b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.
	c) When the medicine is for

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internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’

e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).

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21 Schedule 1 (table item 4877)

Repeal the item, substitute:

4877	THYMOL	A, E	When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges. When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.

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