Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022

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

Dated 13 December 2022

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

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1 Name

This instrument is the *Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022*.

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	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 28(2) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) batch;
(b) export only medicine;
(c) manufacture;
(d) medicine;
(e) Register;
(f) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Regulations means the *Therapeutic Goods Regulations 1990.*

relevant person, in relation to a medicine, means the person in relation to whom the medicine is listed in the Register.

specified listed medicines means medicines that are listed in the Register under section 26A or 26AE of the Act.

Note: Specified listed medicines do not include export only medicines, which are listed under section 26 of the Act.

Therapeutic Goods Administration, or ***TGA,*** means that part of the Department known as the Therapeutic Goods Administration.

5 Conditions of listing

Specified listed medicines

(1) For the purposes of subsection 28(1) of the Act, the conditions set out in the table in Part 1 of Schedule 1 are determined to be conditions to which the listing of the following goods is subject:

(a) specified listed medicines.

Specified listed medicines that are sunscreen preparations

(2) For the purposes of subsection 28(1) of the Act, the conditions set out in the table in Part 2 of Schedule 1 are determined to be conditions to which the listing of the following goods is subject:

(a) specified listed medicines mentioned in item 7 of the table in Schedule 4 to the Regulations.

Specified listed medicines that may contain aristolochic acids

(3) For the purposes of subsection 28(1) of the Act, the conditions set out in the table in Part 3 of Schedule 1 are determined to be conditions to which the listing of the following goods is subject:

(a) specified listed medicines that contain, or may contain, one or more of the following ingredients:

(i) *Anamirta cocculus;*
(ii) *Asarum europaeum;*
(iii) *Asarum heterotropoides;*
(iv) asarum oil;
(v) *Asarum sieboldii;*
(vi) *Clematis armandii;*
(vii) *Clematis chinensis*;
(viii) *Clematis recta*;
(ix) *Clematis vitalba*;
(x) *Cocculus orbiculatus*;
(xi) costus root oil;
(xii) *Menispermum canadense*;
(xiii) *Saussurea costus*;
(xiv) *Sinomenium actutum*;
(xv) *Stephania tetranda*.

Schedule 1—Conditions of listing

Note: See section 5

Part 1—Specified listed medicines

Conditions applicable to specified listed medicines	
Column 1	**Column 2**
Item	**Conditions**
1	The relevant person must keep records relating to the medicine that are necessary to: (a) expedite recall, if necessary, of a batch of the medicine; and (b) identify the manufacturer of each batch of the medicine.
2	Where any step in the manufacture of the medicine in Australia is sub-contracted to a third party, the relevant person must keep copies of relevant Good Manufacturing Practice agreements in relation to that manufacture.
3	The relevant person must: (a) retain records of the distribution of the medicine for a period of five years; and (b) upon request, provide the records (or copies of the records) to the TGA.
4	The relevant person must notify the TGA of any product recall or other regulatory action taken in relation to the medicine outside Australia, which is or may be relevant to the quality, safety or efficacy of the medicine supplied in Australia, as soon as reasonably practicable after the relevant person becomes aware of the product recall or other regulatory action.

Part 2—Specified listed medicines that are sunscreens

Conditions applicable to sunscreens	
Column 1	**Column 2**
Item	**Conditions**
1	Where testing conducted by AMA Laboratories Inc. is used to substantiate compliance of the medicine with paragraphs (a) and (b) of item 7 of the table in Schedule 4 to the Regulations, the relevant person must: (a) hold one of the following to scientifically justify the validity and accuracy of the SPF, broad spectrum and water resistance claims for the medicine: (i) adequate supplementary in-vitro testing data; or (ii) relevant testing data from an independent testing laboratory on a comparable formulation; or (iii) other justification acceptable to the TGA; and (b) provide the information mentioned in paragraph (a) to the TGA within 10 working days of a request by the TGA, or within such other longer period as is agreed with the TGA.

Part 3—Specified listed medicines that may contain aristolochic acids

Conditions applicable to specified listed medicines that may contain aristolochic acid	
Column 1	**Column 2**
Item	**Conditions**
1	The relevant person must: (a) confirm the absence of aristolochic acids in each batch of the medicine by undertaking chemical analysis of either the raw material or the final medicine, using Liquid Chromatography Mass Spectrometry (LC-MS), where the chemical analysis (the ***confirmatory evidence***): (i) adheres to best practice according to contemporary scientific literature; and (ii) is traceable to the batch of the medicine; and (iii) includes all relevant details of the methodology used, such as analytical method validation data; and (iv) includes the raw results, such as data for a reference standard, the sample and a sample spiked with aristolochic acid at the reporting level; and (b) provide the confirmatory evidence, or a copy of the confirmatory evidence, to the TGA; and (c) not supply a batch of the medicine in Australia until the confirmatory evidence for that batch is approved in writing by the TGA.