



Consent relating to Listed Medicines that Contain Whole Live Microorganisms as an Active Ingredient

I, George Vuckovic, as delegate of the Secretary of the Department of Health, Disability and Ageing under sections 14 and 14A of the *Therapeutic Goods Act 1989*, give the following consent.

Dated 30 September 2026

George Vuckovic
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health, Disability and Ageing

1 Authority

This consent is given under sections 14 and 14A of the *Therapeutic Goods Act 1989*.

2 Definitions

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

- (a) British Pharmacopoeia;
- (b) European Pharmacopoeia;
- (c) export only medicine;
- (d) medicine;
- (e) Register;
- (f) therapeutic goods;
- (g) United States Pharmacopeia-National Formulary.

In this consent:

Act means the *Therapeutic Goods Act 1989*.

TGO 92 means the *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines*.

TGO 116 means the *Therapeutic Goods (Standard for Labelling of Non- Prescription Medicines) (TGO 116) Order 2026*.

3 Particular goods or classes of goods

This consent is given in relation to the class of therapeutic goods that:

- (a) are medicines that are listed in the Register, other than export only medicines;
- (b) contain a whole live microorganism, other than *arthrospira maxima* or *arthrospira platensis*, as an active ingredient; and
- (c) comply with at least one of the following:
 - (i) the requirements in the applicable monographs of the United States Pharmacopeia-National Formulary for how the ingredients, and the formulated enumeration unit, should be presented on the label;
 - (ii) the requirements in monograph 3053 of the British Pharmacopoeia or European Pharmacopoeia for including the name of each strain, and the unit of potency of each strain, on the label;
 - (iii) paragraph 9(3)(a) of TGO 92 or subsection 11(5) of TGO 116, subject to any other consent given under sections 14 and 14A of the Act in relation to those provisions.

Note: For the avoidance of doubt, medicines specified in this section are required to comply with all other applicable requirements in the United States Pharmacopeia-National Formulary, British Pharmacopoeia, European Pharmacopoeia, TGO 92 or TGO 116 (subject to any consent given under sections 14 and 14A of the Act).

4 Consent

This consent is for the importing, supplying and exporting of medicines in the class of therapeutic goods mentioned in section 3 that do not conform with the following:

- (a) for goods that comply with subparagraph 3(c)(ii) or (iii)—the requirements in the applicable monographs of the United States Pharmacopeia-National Formulary for how the ingredients, and the formulated enumeration unit, should be presented on the label; or
- (b) for goods that comply with subparagraph 3(c)(i) or (iii)—the requirements in monograph 3053 of the British Pharmacopoeia or European Pharmacopoeia for including the name of each strain, and unit of potency of each strain, on the label; or
- (c) for goods that comply with subparagraph 3(c)(i) or (ii)—paragraph 9(3)(a) of TGO 92 or subsection 11(5) of TGO 116 only in relation to the inclusion of the strain name of an active ingredient between the Australian Approved Name and the quantity of the active ingredient.

Note 1: For medicines mentioned in section 3 that comply with the requirements in the applicable monographs of the United States Pharmacopeia-National Formulary for how the ingredients, and the formulated enumeration unit, should be presented on the label, the consent in this section relates to non-compliance with the requirements in monograph 3053 of the British Pharmacopoeia or European Pharmacopoeia for including the name of each strain, and unit of potency of each strain, on the label, or paragraph 9(3)(a) of TGO 92 or subsection 11(5) of TGO 116 only in relation to the inclusion of the strain name of an active ingredient between the Australian Approved Name and the quantity of the active ingredient e.g. *Bacillus coagulans* MTCC 5856 20 billion CFU/g.

Note 2: For medicines mentioned in section 3 that comply with the requirements in monograph 3053 of the British Pharmacopoeia or European Pharmacopoeia for including the name of each strain, and unit of potency of each strain, on the label, the consent in this section relates to non-compliance with the applicable monographs of the United States Pharmacopeia-National Formulary for how the ingredients, and the formulated enumeration unit, should be presented on the label, or paragraph 9(3)(a) of TGO 92 or subsection 11(5) of TGO 116 only in relation to the inclusion of the strain name of an active ingredient between the Australian Approved Name and the quantity of the active ingredient e.g. *Bacillus coagulans* MTCC 5856 20 billion CFU/g.

Note 3: For medicines mentioned in section 3 that comply either with paragraph 9(3)(a) of TGO 92 or with subsection 11(5) of TGO, the consent in this section relates to non-compliance with the applicable monographs of the United States Pharmacopeia-National Formulary for how the ingredients, and the formulated enumeration unit, should be presented on the label, or with monograph 3053 of the British Pharmacopoeia or European Pharmacopoeia for including the name of each strain, and unit of potency of each strain, on the label.

5 Period in force

This consent has effect from the date it is given, and until 30 September 2031.