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

I, Avinash Clarke, as delegate of the Secretary of the Department of Health and Aged Care under sections 14 and 14A of the *Therapeutic Goods Act 1989*, give the following consent.

Dated 12 December 2024

Avinash Clarke
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

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.*

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.

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, or TGO 92 (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.

Note: 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 with paragraph 9(3)(a) of TGO 92.

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 with paragraph 9(3)(a) of TGO 92.

For medicines mentioned in section 3 that comply with paragraph 9(3)(a) of TGO 92, 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 1 October 2026.