POISONS AND THERAPEUTIC GOODS ACT 1966

Section 10(4)(d) of the Poisons and Therapeutic Goods Act 1966

Clauses 53, 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008

AUTHORITY

I, Dr Kerry Chant, Chief Health Officer, a duly appointed delegate of the Secretary, NSW Health, pursuant to clauses 53, 170, and 171 of the Poisons and Therapeutic Goods Regulation 2008 for the purpose of section 10(4)(d) of the Poisons and Therapeutic Goods Act 1966, hereby:

1. Cancel the Instrument of Authority – Supply of restricted substances by pharmacists dated 9 December 2024.

2. Make this instrument.

Dr Kerry Chant

Chief Health Officer

(Delegation Numbers PH380 and PH427)

Dated:28/02/2025

Authority – Supply of restricted substances by pharmacists.

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1) Authorisation

This instrument authorises an 'approved pharmacist' to supply from an approved pharmacy to an 'applicable patient' a restricted substance listed in clause 2 of this Authority other than on prescription subject to the conditions in clause 3 of this instrument for the purposes of the 'clinical trial'.

2) Restricted substance to which this instrument applies

This instrument applies to the following substances:

- mupirocin*
- dicloxacillin
- flucloxacillin
- cefalexin
- trimethoprim and sulfamethoxazole
- valaciclovir
- famciclovir

- aciclovir
- hydrocortisone
- methylprednisolone
- triamcinolone
- mometasone
- betamethasone
- desonide
- pimecrolimus
- crisaborole
- calcipotriol

3) . Conditions — Limitation on supply

a. The approved pharmacist must only supply the substance for the indication, and in the formulation and strength listed in Appendix 1.

b. The approved pharmacist must only supply the restricted substances from an 'approved pharmacy'.

c. The approved pharmacist must comply with the 'Guidelines and Protocols' approved for the Clinical trial conducted in NSW on dermatological conditions.

d. The approved pharmacist must make a record in MedAdvisor pharmacy software, or an approved system by the Ministry of Health, regarding the supply.

e. The approved pharmacist must make and keep a clinical record of the consultation required to be conducted under the 'Guidelines and Protocols' for 7 years (at the pharmacy where the patient consultation occurred) that contains:

    - the patient's name, street address and date of birth.
    - the date of the treatment.
    - the name of the pharmacist who undertook the consultation.
    - any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history).
    - any clinical opinion reached by the pharmacist.
    - actions taken by the pharmacist.
    - particulars of any medication supplied for the patient (such as form, strength and quantity).
    - notes as to information or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient.
    - any consent given by a patient to the treatment proposed.

f. The pharmacist shares a record of the supply with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient.

g. The pharmacist must consent to participate in the clinical trial and its evaluation, including by sharing records of applicable patients with the University of Newcastle and The George Institute for Global Health.

h. The pharmacist must comply with the Australian Health Practitioner Regulation Agency (AHPRA) & National Boards Code of Conduct; and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.

4) Publication

This instrument will be published on the NSW Health website.

5) Definitions

In this instrument:

- An 'applicable patient' means a patient who for:
    - Mild to moderate atopic dermatitis, is over 6 months of age to 65 years.
    - Herpes zoster (Shingles), is over 18 years.
    - Impetigo, is 12 month or above.
    - Acute exacerbation of mild plaque psoriasis, is over 18 years.
    - An 'approved pharmacist' means a pharmacist holding general registration with the AHPRA, with no conditions on their registration, and who is employed or engaged in an 'approved pharmacy' who has successfully completed:
        - Australasian College of Pharmacy education on Dermatological Conditions; or
        - Pharmaceutical Society of Australia NSW education on Dermatological Conditions; and
        - Modules developed by the University of Newcastle for the clinical trial; and
        - Any other training module(s) that have been approved by the Chief Health Officer for the purposes of the clinical trial.
- An 'approved pharmacy' means a pharmacy or class of pharmacies approved in writing by the Chief Health Officer which:
    - offers applicable patients the services specified in this authorisation at all opening hours of the pharmacy; and
    - has a service room, consulting room, or area consistent with the following:
        - the room or area is not to be used as a dispensary, storeroom, staff room or retail area,
        - is fully enclosed and provides adequate privacy (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
        - has adequate lighting,
        - is maintained at a comfortable ambient temperature,
        - has a hand sanitisation facility,
        - has ready access to a hand washing facility, and
        - has sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the consultation and an

accompanying person, and to allow the pharmacist adequate space to manoeuvre.

- 'Guidelines and Protocols' means the guidelines and protocols established for use by approved pharmacists in the clinical trial.
- The 'clinical trial' means the trial put in place by the University of Newcastle on behalf of the Ministry of Health regarding the supply of specified medications for the dermatological conditions without a prescription.
- A 'pharmacy' has the same meaning as in the Health Practitioner Regulation National Law.

6) Commencement

This authority commences on publication.

7) Cancellation

This authority is cancelled on 31st August 2025 unless earlier cancelled.

Appendix 1:

Generic Name	Indication	Formulation	Strength	Maximum quantity per consultation
Mupirocin	Impetigo	Cream/Ointment*	2%	15g tube
	* Nasal ointment is excluded			
Dicloxacillin	Impetigo	Capsule	500 mg	2 x 24 caps
Flucloxacillin	Impetigo	Capsule	500 mg	2 x 24 caps
		Oral Liquid	25 mg/mL 50 mg/mL	3 x 100mL bottles
Cefalexin	Impetigo	Capsule	500 mg	2 x 20 caps
		Oral Liquid	25 mg/mL 50 mg/mL	3 x 100mL bottles
Trimethoprim + Sulfamethoxazole	Impetigo	Tablet	160 mg + 800 mg	1 x 10 tabs
		Oral Liquid	8 mg/mL + 40 mg/mL	2 x 100mL bottles

Valaciclovir	Herpes Zoster (Shingles)	Tablet	500 mg	1 x 42 tabs
Famciclovir	Herpes Zoster (Shingles)	Tablet	250 mg	1 x 21 tabs for patients with known reduced renal function
			500 mg	1 x 30 tabs
Aciclovir	Herpes Zoster (Shingles)	Tablet	800 mg	1 x 35 tabs
Hydrocortisone	Atopic dermatitis	Cream/ Ointment	1%	50g tube
Methylprednisolone aceponate	Atopic dermatitis and plaque psoriasis	Cream/ Ointment/ Fatty Ointment/ Lotion	0.1%	15g tube – cream/ ointment/ fatty ointment/ lotion 20g – lotion Amount dispensed should be that required to cover surface area of rash until medical practitioner review
Triamcinolone acetonide	Atopic dermatitis	Ointment	0.02%	100g tube ointment
Mometasone furoate	Atopic dermatitis and plaque psoriasis	Cream/ Ointment/ Lotion/ Hydrogel	0.1%	15g tube – cream/ ointment/ hydrogel 50g tube – cream/ ointment 30mL – lotion 45g tube – hydrogel Amount dispensed should be that required to cover surface area of rash until medical practitioner review
Betamethasone dipropionate	Atopic dermatitis and	Cream/ ointment/ lotion	0.05%	15g tube – cream/ ointment

	plaque psoriasis			50g tube – cream/ ointment 30mL – lotion Amount dispensed should be that required to cover surface area of rash until medical practitioner review
Betamethasone valerate	Atopic dermatitis	Ointment	0.1%	30g tube
Desonide	Atopic dermatitis	Lotion	0.05%	60mL bottle
Pimecrolimus	Atopic dermatitis	Cream	1%	15g tube
Crisborole	Atopic dermatitis	Ointment	2%	60g tube
Calcipotriol with betamethasone	Plaque psoriasis	Ointment	0.005% / 0.05%	30g tube
Calcipotriol with betamethasone	Plaque psoriasis	Foam	0.005% / 0.05%	60g bottle