

THERAPEUTIC GOODS ACT 1989

THERAPEUTIC GOODS ORDER NO. 46

I, GARRY JAMES, delegate of the Minister for Family Services for the purposes of the exercise of the Minister's powers under section 10 of the Therapeutic Goods Act 1989 and acting under section 10, HEREBY:

- (a) REVOKE Therapeutic Goods Order Number 4 titled "Modification to the Monograph of the British Pharmacopoeia for Potassium Chloride" made on 2 March 1981 and gazetted in Gazette No. S128 on 30 June 1981;
- (b) REVOKE Therapeutic goods Order Number 23 titled "Standard for hydrocortisone Acetate Creams" made on 10 April 1986 and gazetted on 12 August 1986 in Gazette No. G32;
- (c) REVOKE Therapeutic Goods Order Number 24 titled "Standard for Hydrocortisone Acetate Ointments" made on 10 April 1986 and gazetted on 12 August 1986 in Gazette No, G32;
- (d) DETERMINE that the monograph for Potassium Chloride in the British Pharmacopoeia shall constitute the standard for potassium chloride subject to the following modification that will include an arsenic limit test for potassium chloride -

"It contains not more than 1 part per million of arsenic, determined in accordance with Test A of the Limit Tests for Arsenic specified in the British Pharmacopoeia.";

- (e) DETERMINE that the monograph for Hydrocortisone Acetate Cream in the British Pharmacopoeia shall constitute the standard for hydrocortisone acetate creams subject to the following modification;

"96% ethanol may be used, instead of water, as the diluent in cases where the final extract in the assay method is turbid or shows phase separation or precipitation.";

- (f) DETERMINE that the monograph for Hydrocortisone ACETATE Ointment in the British Pharmacopoeia shall constitute the standard for hydrocortisone acetate ointments subject to the following modification:

"96% ethanol may be used, instead of water, as the diluent in cases where the final extract in the assay method is turbid or shows phase separation or precipitation.".

Dated 29 October 1993

GARRY JAMES
(Delegate of the Minister for Family Services)