



COMMONWEALTH OF AUSTRALIA

Instrument number PB 74 of 2007

Amendment special arrangements under subsection 100(1) of the
National Health Act 1953

I, STEPHEN DELLAR, Assistant Secretary, Pharmaceutical Evaluation Branch, Department
of Health and Ageing, make this instrument under subsection 100(1) of the *National Health
Act 1953*.

Dated 6 Sept 2007

STEPHEN DELLAR

Assistant Secretary
Pharmaceutical Evaluation Branch
Department of Health and Ageing

Amendment Special Arrangements — Chemotherapy Pharmaceuticals Access Program

1 Commencement

This instrument commences on 1 October 2007.

2 Amendment of PB 54 of 2007

Schedule 1 amends PB 54 of 2007.

Schedule 1 Amendments

(section 2)

[1] Schedule 1, omit item dealing with Calcium Folate

[2] Schedule 1, omit item dealing with Cetuximab

and substitute:

Cetuximab	<p>In compliance with authority procedures set out in paragraph 14:</p> <p>Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the Therapeutic Goods Administration-approved Product Information</p> <p>Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated</p> <p>Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated</p>
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[3] Schedule 1, after item dealing with Fluorouracil

insert in the columns in the order indicated:

Folinic acid	<p>In respect of the tablet containing calcium folinate equivalent to 15 mg folinic acid: Antidote to folic acid antagonists</p> <p>In respect of the injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL, injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL and injection containing calcium folinate equivalent to 300 mg folinic acid in 30 mL: —</p>
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[4] Schedule 2, omit items dealing with Calcium Folate

[5] Schedule 2, after item dealing with Fluorouracil

insert in the columns in the order indicated:

Folinic acid	Tablet containing calcium folinate equivalent to 15 mg folinic acid	Oral	10	..	Leucovorin Calcium (Mayne Pharma Pty Ltd)
	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL	Injection	5	5	Calcium Folate Ebewe Leucovorin Calcium (Mayne Pharma Pty Ltd) Leucovorin Calcium (Pfizer Pty Limited)
	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL	Injection	10	1	Calcium Folate Ebewe Leucovorin Calcium (Pfizer Pty Limited)
	Injection containing calcium folinate equivalent to 300 mg folinic acid in 30 mL	Injection	4	1	Leucovorin Calcium (Mayne Pharma Pty Ltd)

[6] Schedule 2, after item dealing with Oxaliplatin in the form Powder for I.V. infusion 100 mg

insert in the columns in the order indicated:

	Solution concentrate for I.V. infusion 200 mg in 40 mL	Injection	1	2	Eloxatin
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[7] Schedule 4, omit item dealing with Calcium Folate

and substitute:

Folinic acid	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL	Leucovorin Calcium (Mayne Pharma Pty Ltd)	1	25.59	25.60
		Leucovorin Calcium (Pfizer Pty Limited)	10	205.31	205.51
	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL	Calcium Folate Ebewe	1	23.62	23.63