



COMMONWEALTH OF AUSTRALIA

Instrument number PB 65 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 14 August 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 September 2007.

2 Amendment of PB 54 of 2007

Schedule 1 amends PB 54 of 2007.

Schedule 1 Amendments

(section 2)

[1] Schedule 1, after item dealing with Carboplatin

insert in the columns in the order indicated

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 either contraindicated or 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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[2] Schedule 2, after item dealing with Carboplatin

insert in the columns in the order indicated

Cetuximab	Solution for I.V. infusion 100 mg in 50 mL	Injection	6	..	Erbitux
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[3] Schedule 2, items dealing with Ondansetron, I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL and I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL

in the column headed "Brand" insert brand:

Onsetron

after brand:

Ondaz

[4] Schedule 3, before item dealing with Interferon Alfa-2a

insert in the columns in the order indicated

Cetuximab	Solution for I.V. infusion 100 mg in 50 mL	<p>In compliance with authority procedures set out in paragraph 14:</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>	Injection	4	6	Erbitux
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