COMMONWEALTH OF AUSTRALIA

Instrument number PB 37 of 2008

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

I, DIANA MACDONELL, Acting Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing, delegate of the Minister for Health and Ageing, make this instrument under subsection 100(1) of the *National Health Act 1953*.

Dated 3rd March 2008

DIANA MACDONELL
Acting Assistant Secretary
Pharmaceutical Evaluation Branch
Department of Health and Ageing

Amendment Special Arrangements — Chemotherapy Pharmaceuticals Access Program

1 Commencement

This instrument commences on 1 April 2008.

2 Amendment of PB 93 of 2007

Schedule 1 amends PB 93 of 2007.

Federal Register of Legislative Instruments F2008L00702

Schedule 1 Amendments

[1] Schedule 1, item dealing with Docetaxel

omit from "Column 2":

	Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%, where the patient was receiving prior treatment with other chemotherapy for androgen independent (hormone refractory) metastatic carcinoma of the prostate at 1 November 2007, and where docetaxel is administered in three weekly cycles

[2] Schedule 1, item dealing with Pemetrexed

omit all text from "Column 2" and substitute:

	In compliance with authority procedures set out in paragraph 14: Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where the dose per treatment cycle does not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is included in the authority application Mesothelioma, in combination with cisplatin, where the dose per treatment cycle does not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is included in the authority application

[3] Schedule 2, item dealing with Cetuximab

insert as the first entry in the columns in the order indicated:

	Solution for I.V. infusion 100 mg in 20 mL	Injection	1	..	Erbitux

[4] Schedule 2, after item dealing with Cetuximab in the form Solution for I.V. infusion 100 mg in 50 mL

insert in the columns in the order indicated:

	Solution for I.V. infusion 500 mg in 100 mL	Injection	1	..	Erbitux

[5] Schedule 2, item dealing with Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL

in the column headed "Brand" insert in alphabetical order:

Irinotecan Sandoz

[6] Schedule 2, item dealing with Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

in the column headed "Brand" insert in alphabetical order:

Irinotecan Sandoz

[7] Schedule 2, item dealing with Pemetrexed in the form Powder for I.V. infusion 500 mg (as disodium heptahydrate)

(a) *omit from the column headed "Maximum quantity":*

2

and substitute:

1

(b) *omit from the column headed "Maximum number of repeats":*

2

and substitute:

3

[8] Schedule 3, item dealing with Cetuximab

insert as the first entry in the columns in the order indicated:

	Solution for I.V. infusion 100 mg in 20 mL	In compliance with authority procedures set out in paragraph 14: 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	Injection	1	6	Erbitux

[9] Schedule 3, after item dealing with Cetuximab in the form Solution for I.V. infusion 100 mg in 50 mL

insert in the columns in the order indicated:

	Solution for I.V. infusion 500 mg in 100 mL	In compliance with authority procedures set out in paragraph 14: 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	Injection	1	6	Erbitux

[10] Schedule 3, omit item dealing with Pemetrexed

[11] Schedule 4, omit item dealing with Pemetrexed