PB 52 of 2014

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 8)

National Health Act 1953

I, PAUL CREECH, First Assistant Secretary (Acting), Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 14 JULY 2014

PAUL CREECH
First Assistant Secretary (Acting)
Pharmaceutical Benefits Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 8)*.

(2) This Instrument may also be cited as PB 52 of 2014.

2 Commencement

This Instrument commences on 1 August 2014.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

[1] Schedule 1, after entry for Acitretin in the form Capsule 25 mg *[Brand: Novatin]*

insert:

Aclidinium	Powder for oral inhalation in breath actuated device containing aclidinium bromide 400 micrograms per dose, 60 doses	Inhalation by mouth	Bretaris Genuair	FK	MP NP	C4516	1	5	1

[2] Schedule 1, entry for Alprazolam in each of the forms: Tablet 250 micrograms; and Tablet 500 micrograms

omit:

			Alprazolam Sandoz	SZ	MP NP	C1975	50	0	50

[3] Schedule 1, entry for Alprazolam in each of the forms: Tablet 1 mg; and Tablet 2 mg

omit:

			Alprazolam Sandoz	SZ	MP NP	C1975	50	2	50

[4] Schedule 1, entry for Amiodarone in the form Tablet containing amiodarone hydrochloride 100 mg

omit:

			Amiodarone Sandoz	SZ	MP NP	C1350	30	5	30

[5] Schedule 1, entry for Atomoxetine in each of the forms: Capsule 10 mg (as hydrochloride); Capsule 18 mg (as hydrochloride); Capsule 25 mg (as hydrochloride); Capsule 40 mg (as hydrochloride); Capsule 60 mg (as hydrochloride); Capsule 80 mg (as hydrochloride); and Capsule 100 mg (as hydrochloride)

omit from the column headed "Circumstances": **C3025 C3026 C3027 C3028** *substitute:* **C4578 C4591**

[6] Schedule 1, after entry for Benzylpenicillin in the form Powder for injection 3 g (as sodium)

insert:

Betaine	Oral powder 180 g	Oral	Cystadane	EU	MP	C4599	1	5	1

[7] Schedule 1, entry for Bevacizumab in each of the forms: Solution for I.V. infusion 100 mg in 4 mL; and Solution for I.V. infusion 400 mg in 16 mL

omit from the column headed "Circumstances": **C3430 C3431 C3894 C3896**

substitute: **C4584 C4585 C4587 C4588 C4589 C4594 C4597 C4598**

[8] Schedule 1, entry for Calcium in the form Tablet, chewable, 500 mg (as carbonate)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Cal-500	PP	MP NP	C4586	240	1	60

(b) *omit from the column headed "Circumstances" for the brand "Cal-Sup":* **C2212** *substitute:* **C4586**

[9] Schedule 1, entry for Calcium in the form Tablet 600 mg (as carbonate)

omit from the column headed "Circumstances": **C2212** *substitute:* **C4586**

[10] Schedule 1, entry for Capecitabine

substitute:

Capecitabine	Tablet 150 mg	Oral	Capecitabine Actavis	GN	MP	C1522 C1614 C1738 C1739 C3509 C3942	60	2	60
			Capecitabine Alphapharm	AF	MP	C1522 C1614 C1738 C1739 C3509 C3942	60	2	60
			Capecitabine-DRLA	RZ	MP	C1522 C1614 C1738 C1739 C3509 C3942	60	2	60
			Capecitabine Sandoz	SZ	MP	C1522 C1614 C1738 C1739 C3509 C3942	60	2	60
			Xeloda	RO	MP	C1522 C1614 C1738 C1739 C3509 C3942	60	2	60
	Tablet 500 mg	Oral	Capecitabine Actavis	GN	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120
			Capecitabine Alphapharm	AF	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120
			Capecitabine Apotex	TX	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120
			Capecitabine-DRLA	RZ	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120
			Capecitabine GH	GQ	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120
			Capecitabine Sandoz	SZ	MP	C1522 C1614 C1738 C1739 C3509 C3942	120	2	120

			Xeloda	RO	MP	C1522 C1614 C1738 C1739 C3509 C3942		120	2	120	

[11] Schedule 1, entry for Captopril in each of the forms: Tablet 12.5 mg; Tablet 25 mg; and Tablet 50 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			APO-Captopril	TX	MP NP			90	5	90	

[12] Schedule 1, entry for Carboplatin in the form Solution for I.V. injection 450 mg in 45 mL

omit:

			Carbaccord	GN	MP			See Note 3	See Note 3	1	D(100)

[13] Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg *[Maximum Quantity: 100; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Cyrotone	ER	MP	C1014 C1230 C1404	P1014 P1404	100	5	50	

[14] Schedule 1, entry for Enalapril in each of the forms: Tablet containing enalapril maleate 5 mg; Tablet containing enalapril maleate 10 mg; and Tablet containing enalapril maleate 20 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Malean	FM	MP NP			30	5	30	

[15] Schedule 1, entry for Epirubicin in each of the forms: Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL; Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL; Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL; and Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL

omit:

			Epiccord	GN	MP			See Note 3	See Note 3	1	D(100)

[16] Schedule 1, after entry for Epoprostenol in the form Powder for I.V. infusion, 500 micrograms (as sodium) infusion administration set

insert in the columns in the order indicated:

	Powder for I.V. infusion 500 micrograms (as sodium)	Injection	Veletri	AT	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[17] Schedule 1, after entry for Epoprostenol in the form Powder for I.V. infusion, 1.5 mg (as sodium) infusion administration set

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Powder for I.V. infusion 1.5 mg (as sodium)	Injection	Veletri	AT	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[18] Schedule 1, entry for Erlotinib in each of the forms: Tablet 25 mg (as hydrochloride); Tablet 100 mg (as hydrochloride); and Tablet 150 mg (as hydrochloride)

(a) *omit from the column headed "Circumstances":* **C4481 C4525 C4536**

(b) *insert in numerical order:* **C4600**

[19] Schedule 1, entry for Esomeprazole

substitute:

Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	Esomeprazole RBX	RA	MP NP	C1337 C1629 C2273 C3429	P2273	30	1	30
			Nexium	AP	MP NP	C1337 C1629 C2273 C3429	P2273	30	1	30
			Esomeprazole RBX	RA	MP NP	C1337 C1629 C2273 C3429	P1337 P1629 P3429	30	5	30
			Nexium	AP	MP NP	C1337 C1629 C2273 C3429	P1337 P1629 P3429	30	5	30
	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole RBX	RA	MP NP	C1337 C1628 C3429	P1628	30	1	30
			Nexium	AP	MP NP	C1337 C1628 C3429	P1628	30	1	30
			Esomeprazole RBX	RA	MP NP	C1337 C1628 C3429	P1337 P3429	30	5	30
			Nexium	AP	MP NP	C1337 C1628 C3429	P1337 P3429	30	5	30

[20] Schedule 1, entry for Fondaparinux

omit from the column headed "Responsible Person": **GK** *substitute:* **AS**

[21] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 200 mg (as hydrochloride)

(a) *omit:*

	Gemcitabine Actavis	GN	MP	See Note 3	See Note 3	1		D(100)

(b) *omit:*

	Gemplan	GN	MP	See Note 3	See Note 3	1		D(100)

[22] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 1 g (as hydrochloride)

omit:

	Gemplan	GN	MP	See Note 3	See Note 3	1		D(100)

[23] Schedule 1, entry for Irbesartan in the form Tablet 75 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Irprestan 75	ZP	MP NP		30	5	30	

[24] Schedule 1, entry for Irbesartan in the form Tablet 150 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Irprestan 150	ZP	MP NP		30	5	30	

[25] Schedule 1, entry for Irbesartan in the form Tablet 300 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Irprestan 300	ZP	MP NP		30	5	30	

[26] Schedule 1, entry for Irbesartan with Hydrochlorothiazide in the form Tablet 150 mg-12.5 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Irbesartan HCT Actavis 150/12.5	UA	MP NP	C4374	30	5	30	

[27] Schedule 1, entry for Irbesartan with Hydrochlorothiazide in the form Tablet 300 mg-25 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Irbesartan HCT Actavis 300/25	UA	MP NP	C4374	30	5	30	

[28] Schedule 1, entry for Levetiracetam in the form Tablet 250 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Levi 250	FM	MP NP	C2664	60	5	60	

[29] Schedule 1, entry for Levetiracetam in the form Tablet 500 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Levi 500	FM	MP NP	C2664	60	5	60	

[30] Schedule 1, entry for Levetiracetam in the form Tablet 1 g

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Levi 1000	FM	MP NP	C2664	60	5	60	

[31] Schedule 1, entry for Macrogol 3350

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

Oral liquid 13.125 g with electrolytes, 500 mL	Oral	Movicol Liquid	NE	MP NP	C4576 C4577 C4580 C4590 C4595 C4596 C4601	P4590	2	0	1
				MP NP	C4576 C4577 C4580 C4590 C4595 C4596 C4601	P4595	2	3	1
				MP NP	C4576 C4577 C4580 C4590 C4595 C4596 C4601	P4576 P4577 P4580 P4596 P4601	2	5	1

[32] Schedule 1, entry for Macrogol 3350

omit:

Sachets containing powder for oral solution 13.125 g with electrolytes, 30	Oral	APO-MACROGOL plus ELECTROLYTES	TX	MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3643 See Note 2	2 See Note 2	0 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3642 See Note 2	2 See Note 2	3 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P1263 P1613 P2693 P2823 See Note 2	1 See Note 2	5 See Note 2	1
		LaxaCon	GN	MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3643 See Note 2	2 See Note 2	0 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3642 See Note 2	2 See Note 2	3 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P1263 P1613 P2693 P2823 See Note 2	1 See Note 2	5 See Note 2	1
		lax-sachets	AE	MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3643 See Note 2	2 See Note 2	0 See Note 2	1

				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3642 See Note 2	2 See Note 2	3 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P1263 P1613 P2693 P2823 See Note 2	1 See Note 2	5 See Note 2	1
		Molaxole	HM	MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3643 See Note 2	2 See Note 2	0 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3642 See Note 2	2 See Note 2	3 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P1263 P1613 P2693 P2823 See Note 2	1 See Note 2	5 See Note 2	1
		Movicol	NE	MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3643 See Note 2	2 See Note 2	0 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P3642 See Note 2	2 See Note 2	3 See Note 2	1
				MP NP See Note 1	C1263 C1613 C2693 C2823 C3642 C3643 See Note 2	P1263 P1613 P2693 P2823 See Note 2	1 See Note 2	5 See Note 2	1

substitute:

Sachets containing powder for oral solution 13.125 g with electrolytes, 30	Oral	APO-MACROGOL plus ELECTROLYTES	TX	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4576 P4577 P4580 P4596 P4601 See Note 2	1 See Note 2	5 See Note 2	1
		LaxaCon	GN	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4576 P4577 P4580 P4596 P4601 See Note 2	1 See Note 2	5 See Note 2	1

lax-sachets	AE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4576 P4577 P4580 P4596 P4601 See Note 2	1 See Note 2	5 See Note 2	1
Molaxole	HM	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4576 P4577 P4580 P4596 P4601 See Note 2	1 See Note 2	5 See Note 2	1
Movicol	NE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4576 P4577 P4580 P4596 P4601 See Note 2	1 See Note 2	5 See Note 2	1
APO- MACROGOL plus ELECTROLYTES	TX	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4590 See Note 2	2 See Note 2	0 See Note 2	1
LaxaCon	GN	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4590 See Note 2	2 See Note 2	0 See Note 2	1
lax-sachets	AE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4590 See Note 2	2 See Note 2	0 See Note 2	1
Molaxole	HM	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4590 See Note 2	2 See Note 2	0 See Note 2	1
Movicol	NE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4590 See Note 2	2 See Note 2	0 See Note 2	1
APO- MACROGOL plus ELECTROLYTES	TX	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4595 See Note 2	2 See Note 2	3 See Note 2	1

LaxaCon	GN	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4595 See Note 2	2 See Note 2	3 See Note 2	1
lax-sachets	AE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4595 See Note 2	2 See Note 2	3 See Note 2	1
Molaxole	HM	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4595 See Note 2	2 See Note 2	3 See Note 2	1
Movicol	NE	MP NP See Note 1	C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2	P4595 See Note 2	2 See Note 2	3 See Note 2	1

[33] Schedule 1, entry for Metoprolol succinate in the form Tablet 23.75 mg (controlled release)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Metrol-XL 23.75	QA	MP NP	C3234	15	0	15

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Minax XL	AF	MP NP	C3234	15	0	15

[34] Schedule 1, entry for Metoprolol succinate in the form Tablet 47.5 mg (controlled release)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Metrol-XL 47.5	QA	MP NP	C3234	30	5	30

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Minax XL	AF	MP NP	C3234	30	5	30

[35] Schedule 1, entry for Metoprolol succinate in the form Tablet 95 mg (controlled release)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Metrol-XL 95	QA	MP NP	C3234	30	5	30

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Minax XL	AF	MP NP	C3234	30	5	30

[36] Schedule 1, entry for Metoprolol succinate in the form Tablet 190 mg (controlled release)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Metrol-XL 190	QA	MP NP	C3234	30	5	30

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Minax XL	AF	MP NP	C3234	30	5	30

[37] Schedule 1, entry for Metronidazole

omit:

	I.V. infusion 500 mg in 100 mL	Injection	Baxter Healthcare Pty Ltd	BX	MP NP	C4167 C4168 C4169	10	0	1
					PDP	C4169	10	0	1
			DBL Metronidazole Intravenous Infusion	HH	MP NP	C4167 C4168 C4169	10	0	10
					PDP	C4169	10	0	10
			Metronidazole-Claris	AE	MP NP	C4167 C4168 C4169	10	0	5
					PDP	C4169	10	0	5
			Metronidazole Sandoz IV	SZ	MP NP	C4167 C4168 C4169	10	0	10
					PDP	C4169	10	0	10

substitute:

	I.V. infusion 500 mg in 100 mL	Injection	DBL Metronidazole Intravenous Infusion	HH	MP NP	C4592 C4593	10	0	5
					PDP	C4581	10	0	5
			Metronidazole-Claris	AE	MP NP	C4592 C4593	10	0	10
					PDP	C4581	10	0	10
			Metronidazole Sandoz IV	SZ	MP NP	C4592 C4593	10	0	10
					PDP	C4581	10	0	10

[38] Schedule 1, entry for Norethisterone in the form Tablets 350 micrograms, 28

omit:

			Locilan 28 Day	FZ	MP NP			4	2	4	

[39] Schedule 1, entry for Omalizumab

substitute:

Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Xolair	NV	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Xolair	NV	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
	Powder for injection 150 mg with diluent	Injection	Xolair	NV	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[40] Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50 mg

omit:

			Xalox	GN	MP			See Note 3	See Note 3	1	D(100)

[41] Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100 mg

omit:

			Xalox	GN	MP			See Note 3	S See Note 3	1	D(100)

[42] Schedule 1, after entry for Panitumumab in the form Solution concentrate for I.V. infusion 100 mg in 5 mL

insert in the columns in the order indicated:

	Solution concentrate for I.V. infusion 400 mg in 20 mL	Injection	Vectibix	AN	MP	C4462 C4498 C4530 C4543	See Note 3	See Note 3	See Note 3	1	D(100)

[43] Schedule 1, after entry for Progesterone in the form Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator

insert in the columns in the order indicated:

	Vaginal tablet 100 mg	Vaginal	Endometrin	FP	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[44] Schedule 1, entry for Quetiapine in the form Tablet 25 mg (as fumarate)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Quetia 25	FM	MP NP	C4385 C4391 C4396		60	0	60	

[45] Schedule 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Quetia 100	FM	MP NP	C1589 C2044 C2765		90	5	90	

[46] Schedule 1, entry for Quetiapine in the form Tablet 200 mg (as fumarate)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Quetia 200	FM	MP NP	C1589 C2044 C2765		60	5	60	

[47] Schedule 1, entry for Quetiapine in the form Tablet 300 mg (as fumarate)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Quetia 300	FM	MP NP	C1589 C2044 C2765		60	5	60	

[48] Schedule 1, entry for Saxagliptin

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

Tablet 2.5 mg (as hydrochloride)	Oral	Onglyza	AP	MP NP	C4520		28	5	28	

[49] Schedule 1, entry for Sildenafil

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

		APO-Sildenafil PHT	TX	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	90	D(100)

(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

		Sildenafil Sandoz PHT 20	SZ	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	90	D(100)

[50] Schedule 1, entry for Tacrolimus in the form Capsule 0.5 mg *[Maximum Quantity: 100; Number of Repeats: 3]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Pharmacor Tacrolimus 0.5	CR	MP	C3080		100	3	100	

[51] Schedule 1, entry for Tacrolimus in the form Capsule 0.5 mg *[Maximum Quantity: 200; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Pharmacor Tacrolimus 0.5	CR	MP See Note 1	C1654 C3328		200	5	100	C(100)

[52] Schedule 1, entry for Tacrolimus in the form Capsule 1 mg *[Maximum Quantity: 100; Number of Repeats: 3]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Tacrolimus 1	CR	MP	C3080	100	3	100	

[53] Schedule 1, entry for Tacrolimus in the form Capsule 1 mg *[Maximum Quantity: 200; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Tacrolimus 1	CR	MP See Note 1	C1654 C3328	200	5	100	C(100)

[54] Schedule 1, entry for Tacrolimus in the form Capsule 5 mg *[Maximum Quantity: 50; Number of Repeats: 3]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Tacrolimus 5	CR	MP	C3080	50	3	50	

[55] Schedule 1, entry for Tacrolimus in the form Capsule 5 mg *[Maximum Quantity: 100; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Tacrolimus 5	CR	MP See Note 1	C1654 C3328	100	5	50	C(100)

[56] Schedule 1, entry for Ticarcillin with Clavulanic Acid

omit from the column headed "Pack Quantity" (twice occurring): **10** *substitute:* **1**

[57] Schedule 1, entry for Tirofiban

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Tirofiban AC	GN	MP NP	C1275 C1729 C1730	1	2	1	

[58] Schedule 1, entry for Vancomycin in the form Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)

(a) *omit:*

	Vycin IV	GN	MP	C1091 C1302 C1464	P1302	2	0	1
			PDP	C1302		2	0	1

(b) *omit:*

	Vycin IV	GN	MP	C1091 C1302 C1464	P1091 P1464	5	0	1

[59] Schedule 3, after details relevant to Responsible Person code ER

insert:

EU	Emerge Health Pty Ltd	72 145 180 865

[60] Schedule 4, Part 1, after entry for Acitretin

insert:

Aclidinium	C4516			Chronic obstructive pulmonary disease (COPD)	

[61] Schedule 4, Part 1, entry for Atomoxetine

substitute:

Atomoxetine	C4578			Attention deficit hyperactivity disorder Continuing treatment Patient must have previously been issued with an authority prescription for this drug	Compliance with Authority Required procedures - Streamlined Authority Code 4578
	C4591			Attention deficit hyperactivity disorder Initial treatment The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria; AND Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously) Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive	Compliance with Authority Required procedures - Streamlined Authority Code 4591

[62] Schedule 4, Part 1, after entry for Benzydamine

insert:

Betaine	C4599			Homocystinuria The treatment must be as adjunctive therapy to current standard care; AND The condition must be treated by or in consultation with a metabolic physician The name of the specialist must be included in the authority application	Compliance with Authority Required procedures

[63] Schedule 4, Part 1, entry for Bevacizumab

substitute:

Bevacizumab	C4584			Where the patient is receiving treatment at/from a Public Hospital Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition; AND Patient must not have progressive disease; AND	Compliance with Authority Required procedures - Streamlined Authority Code 4584

				The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks; AND The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer	
	C4585			Where the patient is receiving treatment in the community setting or at/from a Private Hospital Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition; AND Patient must not have progressive disease; AND The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks; AND The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer	Compliance with Authority Required procedures
	C4587			Where the patient is receiving treatment at/from a Public Hospital Metastatic colorectal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks The patient's body weight must be documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 4587
	C4588			Where the patient is receiving treatment in the community setting or at/from a Private Hospital Metastatic colorectal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks	Compliance with Authority Required procedures
	C4589			Where the patient is receiving treatment in the community setting or at/from a Private Hospital Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm); AND Patient must have a WHO performance status of 2 or less; AND The condition must be previously untreated; AND The treatment must be commenced in combination with platinum-based chemotherapy; AND The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks; AND The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures
	C4594			Where the patient is receiving treatment at/from a Public Hospital Metastatic colorectal cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND	Compliance with Authority Required procedures - Streamlined Authority Code 4594

				The treatment must be in combination with first-line chemotherapy; AND The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR *The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated	
	C4597			Where the patient is receiving treatment in the community setting or at/from a Private Hospital Metastatic colorectal cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks	Compliance with Authority Required procedures
	C4598			Where the patient is receiving treatment at/from a Public Hospital Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm); AND Patient must have a WHO performance status of 2 or less; AND The condition must be previously untreated; AND The treatment must be commenced in combination with platinum-based chemotherapy; AND The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks; AND The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 4598

[64] Schedule 4, Part 1, entry for Calcium

substitute:

Calcium	C4586			Hyperphosphataemia The condition must be associated with chronic renal failure	Compliance with Authority Required procedures - Streamlined Authority Code 4586

[65] Schedule 4, Part 1, entry for Erlotinib

(a) *omit:*

	C4481			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be as monotherapy; AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal; AND Patient must have failed prior therapy which included a platinum compound; AND Patient must have a WHO performance status of 3 or less; AND The condition must have progressed following treatment with docetaxel or pemetrexed; OR	Compliance with Written Authority Required procedures

				Patient must have a contraindication or intolerance to treatment with docetaxel and pemetrexed; AND Patient must not be able to receive further chemotherapy subsidised by the PBS or from other sources following treatment with erlotinib Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Non-Small Cell Lung Cancer Erlotinib Authority Application - Supporting Information Form, which includes: (i) evidence that the patient has been treated with platinum-based chemotherapy; AND (ii) evidence that disease progression has occurred following treatment with docetaxel or pemetrexed. In patients in whom docetaxel or pemetrexed is contraindicated or cannot be tolerated the prescriber must state the reasons for intolerance or the contraindication; AND (iii) a declaration from the prescriber that the patient has exhausted all opportunities for treatment with chemotherapy either on the PBS, through special access schemes or in a clinical trial; and (3) a signed patient acknowledgement	
	C4525			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have progressive disease Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Non-Small Cell Lung Cancer Erlotinib Authority Application - Supporting Information Form, which includes: (i) evidence that the patient has been treated with platinum-based chemotherapy; AND (ii) evidence that disease progression has occurred following treatment with docetaxel or pemetrexed. In patients in whom docetaxel or pemetrexed is contraindicated or cannot be tolerated the prescriber must state the reasons for intolerance or the contraindication; AND (iii) a declaration from the prescriber that the patient has exhausted all opportunities for treatment with chemotherapy either on the PBS, through special access schemes or in a clinical trial; and (3) a signed patient acknowledgement	Compliance with Written Authority Required procedures
	C4536			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug prior to 1 January 2014; AND Patient must not have progressive disease Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type	Compliance with Authority Required procedures

(b) *insert in numerical order following existing text:*

	C4600			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014; AND Patient must not have progressive disease Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type	Compliance with Authority Required procedures

[66] Schedule 4, Part 1, entry for Macrogol 3350

(a) *omit:*

	C1263	P1263		Patients receiving palliative care	
	C1613	P1613		Constipation in patients with malignant neoplasia	
	C2693	P2693		Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies	
	C2823	P2823		Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents	
	C3642	P3642		Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem	Compliance with Authority Required procedures – Streamlined Authority Code 3642
	C3643	P3643		Continuing supply for a palliative care patient where constipation is a problem	Compliance with Authority Required procedures – Streamlined Authority Code 3643

(b) *insert in numerical order following existing text:*

	C4576	P4576		Constipation Patient must have malignant neoplasia	
	C4577	P4577		Constipation Patient must be receiving palliative care	
	C4580	P4580		Constipation Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies	
	C4590	P4590		Constipation Continuing treatment Patient must be receiving palliative care	Compliance with Authority Required procedures - Streamlined Authority Code 4590
	C4595	P4595		Constipation Initial treatment Patient must be receiving palliative care; AND Patient must not receive more than 4 months treatment under this restriction	Compliance with Authority Required procedures - Streamlined Authority Code 4595
	C4596	P4596		Chronic constipation The condition must be inadequately controlled with first line interventions such as bulk-forming agents	
	C4601	P4601		Faecal impaction The condition must be inadequately controlled with first line interventions such as bulk-forming agents	

[67] Schedule 4, Part 1, entry for Metronidazole

(a) *omit from the column headed "Circumstances Code":* **C4167** *substitute:* **C4581**

(b) *omit from the column headed "Circumstances Code":* **C4168** *substitute:* **C4592**

(c) *omit from the column headed "Circumstances Code":* **C4169** *substitute:* **C4593**