AUSTRALIA

Statutory Rules 1984 No. 1

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National Health (Pharmaceutical Benefits) Regulations[2] (Amendment)

WHEREAS it is provided by sub-section 101 (4) of the *National Health Act 1953* that a drug or medicinal preparation that was not a pharmaceutical benefit under that Act immediately before the commencement of that sub-section shall not be prescribed as a pharmaceutical benefit in accordance with section 85 of that Act unless the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that it be so prescribed:

AND WHEREAS the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that each of the following drugs or medicinal preparations be prescribed as a pharmaceutical benefit under section 85 of that Act:

(a) Benzoyl Metronidazole;
(b) Bumetanide;
(c) Diclofenac Sodium;
(d) Ipratropium Bromide;
(e) "ODORTROL"; and
(f) Sodium Hypochlorite Solution 5.25%:

AND WHEREAS it is desirable, amongst other things, to prescribe each of those drugs or medicinal preparations as a pharmaceutical benefit under that section:

NOW THEREFORE I, the Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, hereby make the following Regulations under the *National Health Act 1953*.

Dated 27 November 1984.

N. M. STEPHEN

Governor-General

By His Excellency's Command,

Minister of State for Health

S.R. 334/84 Cat. No. Recommended retail price 60c 10/30.10.1984

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Commencement

1. These Regulations shall come into operation on 1 December 1984.

Principal Regulations

2. In these Regulations, "Principal Regulations" means the National Health (Pharmaceutical Benefits) Regulations.

Schedule 1

3. Schedule 1 to the Principal Regulations is amended as set out in Schedule 1.

Schedule 2

4. Schedule 2 to the Principal Regulations is amended as set out in Schedule 2.

Schedule 3

5. Schedule 3 to the Principal Regulations is amended as set out in Schedule 3.

Schedule 5

6. Schedule 5 to the Principal Regulations is amended as set out in Schedule 4.

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SCHEDULE 1

Regulation 3

AMENDMENTS OF SCHEDULE 1 TO THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) REGULATIONS

1. After item 109 insert the following item:
"109A Bethanidine Tablets".

2. Omit item 236A.

3. After item 278 insert the following item:
"278A Cyclizine Tablets".

4. Omit item 290.

5. Omit item 291.

6. After item 343 insert the following item:
"343A Digoxin".

7. Omit item 584A.

8. Omit item 605, substitute the following item:
"605 Lithium Carbonate Tablets, Slow".

9. After item 699 insert the following item:
"699A Nalorphine Injection".

10. After item 772 insert the following item:
"772A Paraldehyde Injection".

11. After item 781 insert the following item:
"781A Pentazocine Lactate Injection".

12. After item 817 insert the following items:
"817A Phenylbutazone
817B Phenylbutazone Suppositories
817C Phenylbutazone Tablets".

13. After item 1130 insert the following item:
"1130A Triprolidine Hydrochloride".

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SCHEDULE 2

Regulation 4

AMENDMENTS OF SCHEDULE 2 TO THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) REGULATIONS

1. After item 32 insert the following item:

"32A Benzoyl Metronidazole	—".

2. Omit item 65A.

3. Omit item 77, substitute the following item:

"77 Dexamethasone Sodium Metasulphobenzoate	Framycetin Sulphate, B.P., with Gramicidin and Dexamethasone Sodium Metasulphobenzoate".

4. Omit item 92, substitute the following item:

"92 Dipivefrine Hydrochloride	—".

5. Omit item 116, substitute the following item:

"116 Framycetin Sulphate, B.P.	Dexamethasone, B.P., with Gramicidin and Framycetin Sulphate, B.P. Gramicidin with Dexamethasone Sodium Metasulphobenzoate and Framycetin Sulphate, B.P.".

6. Omit item 127, substitute the following item:

"127 Glycerophosphate Syrup, Compound	—".

7. Omit item 129, substitute the following item:

"129 Gramicidin	Framycetin Sulphate, B.P., with Dexamethasone, B.P., and Gramicidin Framycetin Sulphate, B.P., with Dexamethasone Sodium Metasulphobenzoate and Gramicidin Neomycin Sulphate, B.P., with Nystatin, B.P., Triamcinolone Acetonide, B.P., and Gramicidin Polymyxin B Sulphate, B.P., with Neomycin Sulphate, B.P., and Gramicidin".

8. After item 144 insert the following item:

"144A Ipratropium Bromide	—".

9. After item 182 insert the following item:

"182A 'ODORTROL'	—".

10. Omit item 224.

11. Omit item 227, substitute the following item:

"227 Tacrine Hydrochloride	Morphine Sulphate, B.P., with Tacrine Hydrochloride".

12. Omit item 245.

SCHEDULE 3

Regulation 5

AMENDMENTS OF SCHEDULE 3 TO THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) REGULATIONS

1. After item 34 insert the following item:
   "34A Benzoyl Metronidazole".
2. After item 42 insert the following item:
   "42A Bumetanide".
3. Omit item 69.
4. Omit item 76, substitute the following item:
   "76 Dexamethasone Sodium Metasulphobenzoate".
5. After item 78 insert the following item:
   "78A Diclofenac Sodium".
6. Omit item 87, substitute the following item:
   "87 Dipivefrine Hydrochloride".
7. Omit item 111, substitute the following item:
   "111 Glycerophosphate Syrup, Compound".
8. After item 134 insert the following item:
   "134A Ipratropium Bromide".
9. After item 175 insert the following item:
   "175A 'ODORTROL' ".
10. Omit item 218, substitute the following item:
    "218 Prednisolone Stearoylglycolate".
11. After item 236 insert the following item:
    "236A Sodium Hypochlorite Solution 5.25%".
12. Omit item 256, substitute the following item:
    "256 Ticarcillin Sodium".

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SCHEDULE 4

Regulation 6

AMENDMENTS OF SCHEDULE 5 TO THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) REGULATIONS

1. Omit item 25, substitute the following item:

"25 Captropril	With the written authority of the Secretary— Severe refractory hypertensive disease For the continuing treatment of severe refractory cardiac failure where treatment with captopril was initiated in a hospital".

2. Omit item 31, substitute the following item:

"31 Cephalothin Sodium, B.P.	Infections where positive bacteriological evidence confirms that cephalothin sodium is the most appropriate therapeutic agent Septicaemia, suspected or proven".

3. Omit item 32, substitute the following item:

"32 Cephazolin Sodium	Infections where positive bacteriological evidence confirms that cephazolin sodium is the most appropriate therapeutic agent Septicaemia, suspected or proven".

4. Omit item 34, substitute the following item:

"34 Cephradine, B.P., for Injection	Infections where positive bacteriological evidence confirms that cephradine is the most appropriate therapeutic agent Septicaemia, suspected or proven".

5. Omit item 58A.

6. Omit item 72A, substitute the following item:

"72A Etretinate	With the written authority of the Secretary— Treatment initiated in a hospital of— Darier's disease Erythrokeratoderma Pityriasis rubra pilaris Severe congenital ichthyosis (lamellar, bullous and sex linked) Severe intractable psoriasis Severe palmo-plantar keratoderma For the continuing treatment of a patient who has already received, for more than 6 months, therapy with etretinate for a condition listed above".

7. Omit item 83.

8. Omit item 84, substitute the following item:

"84 Griseofulvin Tablets, B.P.	Recalcitrant tinea infections Kerion".

9. Omit item 114.

10. Omit item 117, substitute the following item:

"117 Mexiletine Hydrochloride	Ventricular arrhythmias".

11. Omit item 118A, substitute the following item:

"118A Minoxidil	With the written authority of the Secretary—

SCHEDULE 4—continued

	For the continuing treatment of severe refractory hypertensive disease where treatment with minoxidil was initiated in a hospital For the continuing treatment of a patient who has already received, for more than 6 months, therapy with minoxidil for severe refractory hypertension".
12. Omit item 120A, substitute the following item:	
"120A (1) Nalidixic Acid Mixture, B.P. (2) Nalidixic Acid Tablets, B.P.	With the written authority of the Secretary— For use as a urinary antiseptic in patients with neurogenic bladder Urinary tract infections where current clinical and bacteriological evidence confirms that nalidixic acid is the most appropriate therapeutic agent".
13. Omit item 124, substitute the following item:	
"124 Nifedipine	With the written authority of the Secretary— Angina".
14. After item 128 insert the following item:	
"128A 'ODORTROL'	Ileostomy or colostomy conditions".
15. Omit item 135, substitute the following item:	
"135 (1) Penicillamine, B.P. (2) Penicillamine Tablets, B.P.	With the written authority of the Secretary— Acute heavy metal intoxication Cystinosis Cystinuria with calculus formation For the continuing treatment of rheumatoid arthritis where penicillamine therapy was initiated in a hospital Haemoglobinuria, paroxysmal cold Patients with rheumatoid arthritis who have already received, for more than 6 months, therapy with penicillamine Wilson's disease (hepatolenticular degeneration)".
16. Omit item 136.	
17. Omit item 137, substitute the following item:	
"137 Perhexiline Maleate	With the written authority of the Secretary— Angina not responding to other therapy".
18. Omit item 141A.	
19. Omit item 180, substitute the following item:	
"180 Ticarcillin Sodium	With the written authority of the Secretary— Infections where positive bacteriological evidence confirms that ticarcillin sodium is the most appropriate therapeutic agent Septicaemia, suspected or proven".

NOTES

1. Notified in the *Commonwealth of Australia Gazette* on 30 November 1984.
2. Statutory Rules 1960 No. 17 as amended to date. For previous amendments *see* Note 2 to Statutory Rules 1984 No. 50 and *see also* Statutory Rules 1984 Nos. 50, 148 and 169.

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