EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2019 (No. 12)

PB 104 of 2019

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Subsection 88(1) provides that a medical practitioner is authorised to prescribe a pharmaceutical benefit. Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Variation and revocation

Unless there is an express power to revoke or vary PB 71 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 71 of 2012.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Changes to PB 71 of 2012 made by this Instrument

Schedule 1 to this Instrument provides for additions, deletions and changes to drugs, forms, brands, responsible person codes, and the circumstances for prescribing various pharmaceutical benefits (including authority requirements) and equivalent brands. These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

General

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 January 2020.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2019 (No. 12)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 12)* and may also be cited as PB 104 of 2019.

Section 2 Commencement

This section provides that this Instrument commences on 1 January 2020.

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

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

Schedule 1 Amendments

The amendments in Schedule 1 involve additions, deletions and changes to drugs, forms, brands, responsible person codes, the circumstances for prescribing various pharmaceutical benefits (including authority requirements) and equivalent brands. These changes are summarised below.

SUMMARY OF CHANGES

Listed Drugs Added

Listed Drug
Abemaciclib

Listed Drugs Deleted

Listed Drug
Verteporfin

Forms Added

Listed Drug	*Form*
Primidone	Tablet 250 mg (USP)

Forms Deleted

Listed Drug	*Form*
Fluconazole	Solution for I.V. infusion 100 mg in 50 mL
Follitropin alfa with lutropin alfa	Powder for injection 150 I.U.-75 I.U. with solvent
Morphine	Injection containing morphine tartrate 120 mg in 1.5 mL

Brands Added

Listed Drug	*Form and Brand*
Azacitidine	Powder for injection 100 mg (*Azacitidine-Teva*)

Ezetimibe with simvastatin	Tablet 10 mg-10 mg (*EzSimva GH 10/10*)
	Tablet 10 mg-20 mg (*EzSimva GH 10/20*)
	Tablet 10 mg-40 mg (*EzSimva GH 10/40*)
	Tablet 10 mg-80 mg (*EzSimva GH 10/80*)
Insulin glargine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 (*Optisulin*; *Optisulin SoloStar*)
Metformin	Tablet containing metformin hydrochloride 500 mg (*Metformin GH*)
Rituximab	Solution for I.V. infusion 100 mg in 10 mL (*Truxima*)
	Solution for I.V. infusion 500 mg in 50 mL (*Truxima*)
Teriflunomide	Tablet 14 mg (*Pharmacor Teriflunomide*; *Teriflunomide GH*)
Trastuzumab	Powder for I.V. infusion 150 mg (*Ontruzant*)

Brands Deleted

Listed Drug	***Form and Brand***
Abacavir with lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg (*Abacavir/Lamivudine 600/300 APOTEX*)
Atorvastatin	Tablet 10 mg (as calcium) (*Atorvastatin Sandoz*)
	Tablet 20 mg (as calcium) (*Atorvastatin Sandoz*)
	Tablet 40 mg (as calcium) (*Atorvastatin Sandoz*)
	Tablet 80 mg (as calcium) (*Atorvastatin Sandoz*)
Capecitabine	Tablet 500 mg (*Capecitabine Apotex*)
Nevirapine	Tablet 200 mg (*Viramune*)

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***
Methylprednisolone	Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g	***From:*** Advantan ***To:*** Advantan (Fatty)

Addition of Responsible Person Code

Dr Falk Pharma Australia Pty Ltd (*FD*)

Deletion of Responsible Person Code

Fawns and McAllan Proprietary Limited (*FM*)

Orphan Australia Pty Ltd (*OA*)

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*
Alprazolam	Tablet 500 micrograms	Alprax 0.5	***From:*** QA ***To:*** AS
	Tablet 1 mg	Alprax 1	***From:*** QA ***To:*** AS
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Moxiclav Duo 500/125	***From:*** QA ***To:*** LN
	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Moxiclav Duo Forte 875/125	***From:*** QA ***To:*** LN
Amphotericin B	Lozenge 10 mg	Fungilin	***From:*** QA ***To:*** AS
Anastrozole	Tablet 1 mg	Anastrol	***From:*** QA ***To:*** AS
Atropine	Eye drops containing atropine sulfate monohydrate 10 mg per mL, 15 mL	Atropt	***From:*** QA ***To:*** AS
Betamethasone	Cream 200 micrograms (as valerate) per g, 100 g	Betnovate 1/5	***From:*** QA ***To:*** AS
		Cortival 1/5	***From:*** FM ***To:*** LN
	Cream 500 micrograms (as valerate) per g, 15 g	Betnovate 1/2	***From:*** QA ***To:*** AS
		Cortival 1/2	***From:*** FM ***To:*** LN
Bicalutamide	Tablet 50 mg	Calutex	***From:*** QA ***To:*** AS
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Bimtop	***From:*** QA ***To:*** AS
Budesonide	Rectal foam 2 mg per application, 14 applications, aerosol 16.8 g, 2	Budenofalk	***From:*** OA ***To:*** FD
Capecitabine	Tablet 500 mg	Xelabine	***From:*** QA ***To:*** AS
Chloramphenicol	Eye drops 5 mg per mL, 10 mL	Chlorsig	***From:*** QA ***To:*** AS
Cladribine	Injection 10 mg in 5 mL	Litak	***From:*** OA ***To:*** AS
Codeine	Tablet containing codeine phosphate hemihydrate 30 mg	Aspen Pharma Pty Ltd	***From:*** QA ***To:*** AS

Cyproterone	Tablet containing cyproterone acetate 50 mg	Cyprocur 50	***From:*** QA ***To:*** AS
	Tablet containing cyproterone acetate 100 mg	Cyprocur 100	***From:*** QA ***To:*** AS
Dexamfetamine	Tablet containing dexamfetamine sulfate 5 mg	Aspen Pharma Pty Ltd	***From:*** QA ***To:*** AS
Digoxin	Paediatric oral solution 50 micrograms per mL, 60 mL	Lanoxin	***From:*** QA ***To:*** AS
	Tablet 62.5 micrograms	Lanoxin-PG	***From:*** QA ***To:*** AS
		Sigmaxin-PG	***From:*** FM ***To:*** LN
	Tablet 250 micrograms	Lanoxin	***From:*** QA ***To:*** AS
		Sigmaxin	***From:*** FM ***To:*** LN
Dorzolamide	Eye drops 20 mg (as hydrochloride) per mL, 5 mL	Trusamide	***From:*** QA ***To:*** AS
Dorzolamide with timolol	Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL	Cosdor	***From:*** QA ***To:*** AS
Fludrocortisone	Tablet containing fludrocortisone acetate 100 micrograms	Florinef	***From:*** QA ***To:*** AS
Griseofulvin	Tablet 125 mg	Grisovin	***From:*** QA ***To:*** AS
	Tablet 500 mg	Grisovin 500	***From:*** QA ***To:*** AS
Haloperidol	Injection 5 mg in 1 mL	Serenace	***From:*** QA ***To:*** AS
	Oral solution 2 mg per mL, 100 mL	Serenace	***From:*** QA ***To:*** AS
	Tablet 500 micrograms	Serenace	***From:*** QA ***To:*** AS
	Tablet 1.5 mg	Serenace	***From:*** QA ***To:*** AS
	Tablet 5 mg	Serenace	***From:*** QA ***To:*** AS
Hydrocortisone	Cream containing hydrocortisone acetate 10 mg per g, 50 g	Cortic-DS 1%	***From:*** FM ***To:*** LN
		Sigmacort	***From:*** QA ***To:*** AS
	Eye ointment containing hydrocortisone acetate 10 mg per g, 5 g	Hycor	***From:*** QA ***To:*** AS

	Ointment containing hydrocortisone acetate 10 mg per g, 50 g	Cortic-DS 1%	***From:*** FM ***To:*** LN
		Sigmacort	***From:*** QA ***To:*** AS
Hypromellose	Eye drops 5 mg per mL, 15 mL	Methopt	***From:*** QA ***To:*** AS
Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30	Aeron 250	***From:*** QA ***To:*** AS
	Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30	Aeron 500	***From:*** QA ***To:*** AS
Labetalol	Tablet containing labetalol hydrochloride 100 mg	Trandate	***From:*** QA ***To:*** AS
	Tablet containing labetalol hydrochloride 200 mg	Trandate	***From:*** QA ***To:*** AS
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL	Xalaprost	***From:*** QA ***To:*** AS
Latanoprost with timolol	Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL	Xalamol 50/5	***From:*** QA ***To:*** AS
Letrozole	Tablet 2.5 mg	Fera	***From:*** QA ***To:*** AS
Levothyroxine	Tablet containing 50 micrograms anhydrous levothyroxine sodium	Eutroxsig	***From:*** FM ***To:*** LN
		Oroxine	***From:*** QA ***To:*** AS
	Tablet containing 75 micrograms anhydrous levothyroxine sodium	Eutroxsig	***From:*** FM ***To:*** LN
		Oroxine	***From:*** QA ***To:*** AS
	Tablet containing 100 micrograms anhydrous levothyroxine sodium	Eutroxsig	***From:*** FM ***To:*** LN
		Oroxine	***From:*** QA ***To:*** AS
	Tablet containing 200 micrograms anhydrous levothyroxine sodium	Eutroxsig	***From:*** FM ***To:*** LN
		Oroxine	***From:*** QA ***To:*** AS
Liothyronine	Tablet containing liothyronine sodium 20 micrograms	Tertroxin	***From:*** QA ***To:*** AS

Mesalazine	Enemas 2 g in 60 mL, 7	Salofalk	***From:*** OA ***To:*** FD
	Enemas 4 g in 60 mL, 7	Salofalk	***From:*** OA ***To:*** FD
	Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g	Salofalk	***From:*** OA ***To:*** FD
	Sachet containing granules, 500 mg per sachet	Salofalk	***From:*** OA ***To:*** FD
	Sachet containing granules, 1 g per sachet	Salofalk	***From:*** OA ***To:*** FD
	Sachet containing granules, 1.5 g per sachet	Salofalk	***From:*** OA ***To:*** FD
	Sachet containing granules, 3 g per sachet	Salofalk	***From:*** OA ***To:*** FD
	Suppository (moulded) 1 g	Salofalk	***From:*** OA ***To:*** FD
	Tablet 500 mg (enteric coated)	Salofalk	***From:*** OA ***To:*** FD
	Tablet 1 g (enteric coated)	Salofalk	***From:*** OA ***To:*** FD
Methadone	Injection containing methadone hydrochloride 10 mg in 1 mL	Physeptone	***From:*** QA ***To:*** AS
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	Aspen Methadone Syrup	***From:*** QA ***To:*** AS
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	Aspen Methadone Syrup	***From:*** QA ***To:*** AS
	Tablet containing methadone hydrochloride 10 mg	Physeptone	***From:*** QA ***To:*** AS
Minocycline	Tablet 50 mg (as hydrochloride)	Minomycin-50	***From:*** QA ***To:*** AS
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Momasone	***From:*** QA ***To:*** AS
	Lotion containing mometasone furoate 1 mg per g, 30 mL	Momasone	***From:*** QA ***To:*** AS
	Ointment containing mometasone furoate 1 mg per g, 15 g	Momasone	***From:*** QA ***To:*** AS
Nicorandil	Tablets 10 mg, 60	Ikotab	***From:*** QA ***To:*** AS
	Tablets 20 mg, 60	Ikotab	***From:*** QA ***To:*** AS

Nystatin	Capsule 500,000 units	Nilstat	***From:*** QA ***To:*** AS
	Cream 100,000 units per g, 15 g	Mycostatin	***From:*** FM ***To:*** LN
	Tablet 500,000 units	Nilstat	***From:*** QA ***To:*** AS
Oxazepam	Tablet 15 mg	Serepax	***From:*** QA ***To:*** AS
	Tablet 30 mg	Serepax	***From:*** QA ***To:*** AS
Perhexiline	Tablet containing perhexiline maleate 100 mg	Pexsig	***From:*** QA ***To:*** AS
Phenobarbital	Injection 200 mg (as sodium) in 1 mL	Fawns and McAllan Proprietary Limited	***From:*** FM ***To:*** AS
Phenoxymethylpenicillin	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	Cilicaine V	***From:*** FM ***To:*** AS
Prednisolone	Suppositories 5 mg (as sodium phosphate), 10	Predsol	***From:*** QA ***To:*** AS
	Enema, retention, 20 mg (as sodium phosphate) in 100 mL	Predsol	***From:*** QA ***To:*** AS
Tamoxifen	Tablet 20 mg (as citrate)	Tamosin	***From:*** QA ***To:*** AS
Temazepam	Tablet 10 mg	Normison	***From:*** QA ***To:*** AS
		Temtabs	***From:*** FM ***To:*** LN
Temozolomide	Capsule 5 mg	Temizole 5	***From:*** QA ***To:*** AS
	Capsule 20 mg	Temizole 20	***From:*** QA ***To:*** AS
	Capsule 100 mg	Temizole 100	***From:*** QA ***To:*** AS
	Capsule 140 mg	Temizole 140	***From:*** QA ***To:*** AS
	Capsule 250 mg	Temizole 250	***From:*** QA ***To:*** AS
Triamcinolone	Cream containing triamcinolone acetonide 200 micrograms per g, 100 g	Aristocort 0.02%	***From:*** QA ***To:*** AS
		Tricortone	***From:*** FM ***To:*** LN
	Injection containing triamcinolone acetonide 10 mg in 1 mL	Kenacort-A10	***From:*** QA ***To:*** AS
	Ointment containing triamcinolone acetonide 200 micrograms per g, 100	Aristocort 0.02%	***From:*** QA ***To:*** AS

	g	Tricortone	***From:*** FM ***To:*** LN
Triamcinolone with neomycin, gramicidin and nystatin	Ear drops containing triamcinolone acetonide 0.9 mg with neomycin 2.25 mg (as sulfate), gramicidin 225 micrograms and nystatin 90,000 units per mL, 7.5 mL	Kenacomb Otic	***From:*** QA ***To:*** AS
		Otocomb Otic	***From:*** FM ***To:*** LN
	Ear ointment containing triamcinolone acetonide 1 mg with neomycin 2.5 mg (as sulfate), gramicidin 250 micrograms and nystatin 100,000 units per g, 5 g	Kenacomb Otic	***From:*** QA ***To:*** AS
		Otocomb Otic	***From:*** FM ***To:*** LN
Ursodeoxycholic acid	Capsule 250 mg	Ursofalk	***From:*** OA ***To:*** FD
	Tablet 500 mg	Ursofalk	***From:*** OA ***To:*** FD

Alteration of Circumstances

Listed Drug

Avelumab

Cobimetinib

Imatinib

Palbociclib

Ribociclib

Risperidone

Somatropin

Trametinib

Document/s incorporated by reference

Listed Drug	***Document incorporated***	***Document access***
Palbociclib	The Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003. The RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment.	The RECIST guidelines are available for download for free from the RECIST Working Group website: https://recist.eortc.org/

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 12)

(PB 104 of 2019)

This Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 12)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Principal Instrument) which determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

Schedule 1 to this Instrument provides for additions, deletions and changes to drugs, forms, brands, schedule equivalence, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities, section 100 only status and prescriber bag only status.

Human rights implications

This Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based. The pharmaceutical industry now has a nominee on the PBAC membership.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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