**EXPLANATORY STATEMENT**

**INSTRUMENT NUMBER PB 80 OF 2016**

***NATIONAL HEALTH ACT 1953***

***National Health (Weighted average disclosed price – October 2016 reduction day)
Amendment Determination 2016 (No.1)***

**Authority**

This legislative instrument is made pursuant to subsection 99ADB(4) of the *National Health Act 1953* (the Act), which provides that the Minister may, by legislative instrument, determine the weighted average disclosed price (WADP) of a brand of a pharmaceutical item (listed brand) in accordance with the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations).

Subsection 99ADB(7) of the Act further provides that a subsection 99ADB(4) determination for a listed brand may include the adjusted approved ex-manufacturer price (AAEMP) for the listed brand.

**Purpose**

This legislative instrument amends the *National Health (Weighted average disclosed price – October 2016 reduction day) Determination 2016* (PB 39 of 2016) (the Principal Instrument) by:

* amending the WADP determinations for all brands of pharmaceutical items containing the drugs dorzolamide for application to the eye (dorzolamide) and dorzolamide with timolol for application to the eye (dorzolamide with timolol) and amending the AAEMP for brands of dorzolamide with timolol;
* revoking the WADP determinations for all brands containing:
	+ cisplatin for administration by injection (cisplatin);
	+ epirubicin for administration by injection/intravesical (epirubicin); and
	+ irinotecan for administration by injection (irinotecan);
* revoking the WADP determinations for all brands of the following two pharmaceutical items:
	+ ‘Ceftriaxone, Powder for injection 500 mg (as sodium), Injection’;
	+ ‘Doxycycline, Capsule 50 mg (as hydrochloride) containing enteric coated pellets, Oral’;
* inserting WADP determinations for all brands of the following four pharmaceutical items that no longer meet Regulation 37SA;
	+ ‘Citalopram, Tablet 10 mg (as hydrobromide), Oral’;
	+ ‘Flucloxacillin, Powder for injection 500 mg (as sodium), Injection’;
	+ ‘Fluorouracil, Injection 5000 mg in 100 ml, Injection’; and
	+ ‘Tamoxifen, Tablet 10 mg (as citrate), Oral’.
* inserting WADP determinations for all brands of the following new pharmaceutical items:
	+ ‘Morphine, Injection containing morphine hydrochloride 10 mg in 1 mL, Injection’;
	+ ‘Morphine, Injection containing morphine hydrochloride 20 mg in 1 mL, Injection’;
	+ ‘Morphine, Injection containing morphine hydrochloride 50 mg in 5 mL, Injection’;
	+ ‘Morphine, Injection containing morphine hydrochloride 100 mg in 5 mL, Injection’;
	+ ‘Tacrolimus, Capsule 0.75 mg, Oral; and
	+ ‘Tacrolimus, Capsule 2 mg, Oral’.

The Principal Instrument was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for brands of pharmaceutical items with a data collection period ending 31 March 2016 (2016 October cycle).

**Amendments**

*Dorzolamide and Dorzolamide with Timolol*

Amendments are being made following consideration of matters raised by certain Responsible Persons concerning the determinations in the Principal Instrument for brands containing dorzolamide and dorzolamide with timolol. A review of determinations in response to matters raised by Responsible Persons revealed that incorrect data had been submitted by some Responsible Persons. Corrected data was submitted by some Responsible Persons for dorzolamide and dorzolamide with timolol brands for the 2016 October cycle and new calculation for the WADPs set out in this amending determination were completed under the Act and Regulations.

Schedule 1 of the Principal Instrument includes a WADP/AAEMP for brands of the dorzolamide with timolol pharmaceutical items. This amending instrument removes the previous WADPs for brands of dorzolamide and dorzolamide with timolol and inserts the revised WADPs for brands of dorzolamide with timolol in the appropriate column in Schedule 1 and for dorzolamide in Schedule 2.

Listed brands of dorzolamide are included in Schedule 2 of the Principal Instrument because their unadjusted price reduction following determination of the amended WADP is less than 10%. Listed brands of dorzolamide with timolol are included in Schedule 1 because they have an unadjusted price reduction of at least 10%.

For those brands with a WADP re-inserted in Schedule 1, the same amount is also determined as the AAEMP for the brands due to the operation of section 7 of the Principal instrument.

A Responsible Person for a listed brand appearing in Schedule 1 of the Principal Instrument will receive a price disclosure reduction on and from 1 October 2015, provided that, on that date, the ‘approved ex-manufacturer price’ for the listed brand is more than the determined ‘AAEMP’ for that brand.

*Revocation of WADPs*

This amending instrument revokes the WADP determination in the Principal Instrument for all brands of cisplatin, epirubicin, irinotecan, the ‘Ceftriaxone, Powder for injection 500 mg (as sodium), Injection’ pharmaceutical item and the ‘Doxycycline, Capsule 50 mg (as hydrochloride) containing enteric coated pellets, Oral’ pharmaceutical item to support the Act and the National Medicines Policy objective to provide continued affordable access to medicines needed by Australians. As a result of the amending instrument no price disclosure reduction would apply to any brand of cisplatin, epirubicin, irinotecan, the ‘Ceftriaxone, Powder for injection 500 mg (as sodium), Injection’ pharmaceutical item or the ‘Doxycycline, Capsule 50 mg (as hydrochloride) containing enteric coated pellets, Oral’ pharmaceutical item on 1 October 2016.

*Insertion of WADP determination for brands that no longer meet Regulation 37SA*

WADPs/AAEMPs are being determined for all brands of four pharmaceutical items that no longer meet the criteria under Regulation 37SA. The applicable PBS price that was determined as the WADP for these brands is being omitted from Schedule 2 and a new reduced price for each brand is being inserted into Schedule 1 because the unadjusted price reduction for these brands is now 10% or greater.

*Insertion of WADP determinations for New Brands of New Pharmaceutical Items*

A WADP is required to be determined for new brands of pharmaceutical items listing between 1 July 2016 and 1 September 2016 that have no other existing brand of the same pharmaceutical item (including a single brand pharmaceutical item where the brand or pharmaceutical item changes, or where all existing brands change).

There are six brands of six new pharmaceutical items that have been included in this amending instrument, as follows:

* the Morphine Juno® brand of ‘Morphine, Injection containing morphine hydrochloride 10 mg in 1 mL, Injection’;
* the Morphine Juno® brand of ‘Morphine, Injection containing morphine hydrochloride 20 mg in 1 mL, Injection’;
* the Morphine Juno® brand of ‘Morphine, Injection containing morphine hydrochloride 50 mg in 5 mL, Injection’;
* the Morphine Juno® brand of ‘Morphine, Injection containing morphine hydrochloride 100 mg in 5 mL, Injection’;
* the Tacrolimus Sandoz® brand of ‘Tacrolimus, Capsule 0.75 mg, Oral; and
* the Tacrolimus Sandoz® brand of ‘Tacrolimus, Capsule 2 mg, Oral’.

*Basis for amendments*

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(4) for the medicines affected by this amending instrument.

**Consultation**

This instrument affects companies that are a Responsible Person for brands of pharmaceutical items containing dorzolamide, dorzolamide with timolol, cisplatin, epirubicin, irinotecan and the following pharmaceutical items:

* ‘Ceftriaxone, Powder for injection 500 mg (as sodium), Injection’
* ‘Doxycycline, Capsule 50 mg (as hydrochloride) containing enteric coated pellets, Oral’
* ‘Citalopram, Tablet 10 mg (as hydrobromide), Oral’;
* ‘Flucloxacillin, Powder for injection 500 mg (as sodium), Injection’;
* ‘Fluorouracil, Injection 5000 mg in 100 ml, Injection’; and
* ‘Tamoxifen, Tablet 10 mg (as citrate), Oral’.

Each of the affected companies were consulted concerning the amendments. No concerns were expressed.

The Responsible Persons of the six new brands of new pharmaceutical items were not consulted because the determination of a WADP for these brands will not result in a price disclosure price reduction to these brands.

This instrument commences on the day after it is registered on the Federal Register of Legislation. This instrument is a legislative instrument for the purposes of the *Legislation Act 2003.*

**Statement of Compatibility with Human Rights**

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

***National Health (Weighted average disclosed price – October 2016 reduction day)
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This Legislative 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 Legislative Instrument**

This instrument amends the *National Health (Weighted average disclosed price – October 2016 reduction day) Determination 2016* (the Principal Instrument) to: a) amend the price disclosure determination for brands of dorzolamide and dorzolamide with timolol due to corrected data provided by companies, b) revoke price reduction determinations to support the *National Health Act 1953* (the Act) and the National Medicines Policy objective to provide continued affordable access to medicines needed by Australians, c) insert new reduced prices for all brands of four pharmaceutical items that no longer meet the criteria under Regulation 37SA of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) and d) insert prices for six new brands of six new pharmaceutical items.

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Part VII, Division 3B of the Act deals with price disclosure. Price disclosure provides for the ‘approved ex-manufacturer price’ of a ‘brand of a pharmaceutical item’ to be reduced on a reduction day in certain specified circumstances. The reduction is based on sales revenue, incentives and volume data collected from Responsible Persons (drug companies) and occurs in accordance with the Act and the Regulations.

The amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 October 2016 under the statutory provisions for price disclosure.

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 price disclosure program progressively reduces the price of some PBS medicines which are subject to competition, ensuring better value for money from these medicines. These reductions may also result in patients accessing these medicines at lower prices.

**Conclusion**

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

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