EXPLANATORY STATEMENT

National Health Act 1953

National Health (Originator Brand) Amendment Determination 2016 (No. 2)

Authority

This legislative instrument is made pursuant to subsection 99ADB(6B) of the *National Health Act 1953* (the Act).

Purpose

This legislative instrument amends the *National Health (Originator Brand) Determination 2015* (PB 100 of 2015) (the Principal Instrument) to:

- determine the originator brand of a pharmaceutical item for one drug new to the Pharmaceutical Benefits Scheme (PBS) F2 formulary on 1 April 2016;
- determine an originator brand of a pharmaceutical item of an existing F2 formulary drug on 1 April 2016 because its pharmaceutical item is no longer exempt under section 84AH of the Act.

The Principal Instrument determined originator brands of pharmaceutical items that have a drug on the F2 formulary. On meeting certain criteria drugs move from the F1 formulary (see s 85AB of the Act), or the single brand Combination Drug List, to F2. All drugs on F2 are subject to price disclosure. The instrument is necessary to implement removal of originator brand data from price disclosure calculations in certain circumstances as set out in the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations). Removal of originator data will potentially increase price disclosure related price reductions because originator brands tend to maintain higher prices than other brands.

Amendments

An originator brand determination is set out in Schedule 1 of this amending instrument for one drug that is moving from F1 to F2 (modafinil) and for the addition of a brand of pharmaceutical item of an existing F2 listed drug (baclofen) because its pharmaceutical item is no longer exempt on 1 April 2016.

The main criteria used for the determination were:

- The brand determined as an originator was already PBS listed when the drug was on the F1 formulary, before the move to F2 (supported by any available PBS listing history, including whether the brand was the first brand of the drug available on the PBS);
- There are existing determined originator brands with a similar brand name.

  With respect to the determination of the Lioresal Intrathecal brand of the drug baclofen, two brands of the drug were previously determined as originator brands (Lioresal 10 and Lioresal 25). Those existing originator brands are similar to the brand Lioresal Intrathecal which is determined by this amendment as a result of its pharmaceutical item no longer being exempt under *Section 84AH of the National Health Act 1953.*

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(6B) for the medicines affected by this amending instrument.

Consultation

The companies with a PBS listed brand of the drug for which an originator brand has been determined were asked for comments in relation to potential originator brand determination. No comments were received.

This instrument commences on 1 April 2016.

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 (Originator Brand) Amendment Determination 2016 (No. 2)

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 legislative instrument amends the *National Health (Originator Brand) Determination 2015* (PB 100 of 2015) (the Principal Instrument) to determine an originator brand of a pharmaceutical item for one drug new to the Pharmaceutical Benefits Scheme (PBS) F2 formulary and to determine the originator brand of a pharmaceutical item of an existing F2 formulary drug because its pharmaceutical item is no longer exempt under *Section 84AH of the National Health Act 1953* on 1 April 2016.

The instrument is necessary to implement removal of originator brand data for price disclosure calculations in certain circumstances as set out in the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations). The removal of originator brand data during price disclosure calculations will potentially increase PBS price reductions as originator brands tend to maintain higher prices than other brands. Removal of originator brand data means that the Government price would more closely reflect the prices at which generic brands of the medicine are being sold in the market, not the prices of all brands.

The PBS provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the *National Health Act 1953* (the Act) which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Regulations prescribe matters and set out details in relation to the operation of the PBS.

Human rights implications
This legislative instrument is compatible with 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 assists with advancement of this human right by providing subsidised access to medicines for Australians.

The removal of the originator brand disclosed data from price disclosure calculations will improve the operation of the PBS by delivering better value for money for PBS medicines through price reductions. This will assist consumers by reducing out-of-pocket costs for some PBS medicines.

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

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