EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 114 of 2025

NATIONAL HEALTH ACT 1953

National Health (Originator Brand) Determination 2025

Authority

This legislative instrument is made pursuant to subsection 99ADB(6B) of the *National Health Act 1953* (the Act), which provides that the Minister (or delegate) may, by legislative instrument, determine that a brand of a pharmaceutical item that has a drug on F2 is an originator brand.

Subsection 99ADB(6C) of the Act further provides that when deciding whether to determine originator brands, the Minister (or delegate) must have regard to whether the brand was on F1 or CDL when it was first determined as the brand of a pharmaceutical item under subsection 85(6) of the Act.

Subsection 33(3) of the *Act's Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(6B) for the medicines affected by this legislative instrument.

Purpose

This legislative instrument repeals the *National Health (Originator Brand) Determination 2015* (PB 100 of 2015) (the **Sunsetting Instrument**), which expires on 1 October 2025, to determine originator brand status for pharmaceutical items of drugs included on the Pharmaceutical Benefits Scheme (PBS) F2 formulary, and takes effect on 1 October 2025.

This legislative instrument, the *National Health (Originator Brand) Determination 2025* (PB 114 of 2025) (the **Originator Brand Determination**), determines originator brands of pharmaceutical items that have a drug on the F2 formulary. On meeting certain criteria, drugs move from the F1 formulary (s85AB of the Act), or the single brand Combination Drug List (CDL), to F2 formulary. All drugs on F2 are subject to price disclosure. This instrument is necessary to implement the removal of originator brand data from price disclosure calculations (originator brand removal) in certain circumstances as set out in the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations). Originator brand removal will potentially increase price disclosure reductions because originator brands tend to maintain higher prices and retain larger market shares than other generic brands.

The Originator Brand Determination differs from the Sunsetting Instrument by:

- correcting the numbering of Item column in Schedule 1
- correcting the letter capitalisation and/or spelling for the following drug names in Schedule 1:
    - Abacavir with lamivudine
    - Aluminium hydroxide with magnesium hydroxide
    - Amlodipine with atorvastatin
    - Candesartan with hydrochlorothiazide
    - Codeine with paracetamol
    - Dexamethasone with framycetin and gramicidin

  - Diphenoxylate with atropine
  - Dipyridamole with aspirin
  - Doxorubicin - pegylated liposomal
  - Electrolyte replacement, oral
  - Enalapril with hydrochlorothiazide
  - Follitropin alfa
  - Fosinopril with hydrochlorothiazide
  - Glyceryl trinitrate
  - Hydrochlorothiazide with amiloride
  - Hypromellose with carbomer 980
  - Hypromellose with dextran
  - Irbesartan with hydrochlorothiazide
  - Isosorbide dinitrate
  - Isosorbide mononitrate
  - Lamivudine with zidovudine
  - Levodopa with carbidopa
  - Levonorgestrel with ethinylestradiol
  - Mycophenolic acid
  - Pamidronic acid
  - Polyvinyl alcohol
  - Risedronic acid
  - Risedronic acid and calcium
  - Telmisartan with hydrochlorothiazide
  - Tranexamic acid
  - Triamcinolone with neomycin, gramicidin and nystatin
  - Trimethoprim with sulfamethoxazole
  - Ursodeoxycholic acid
  - Valproic acid
- correcting the letter capitalisation for the following originator brand names in Schedule 1:
  - Orencia ClickJect (abatacept)
  - Toujeo Solostar (insulin glargine)
  - Noriday 28 Day (norethisterone)

Consultation

The Responsible Persons with PBS-listed brands of the drugs moving from F1 and CDL to F2 were previously consulted on the potential originator brand determination. No comments were received from the affected Responsible Persons. No additional consultation with other experts was undertaken regarding the determination as consultation with the Responsible Persons affected drew on the knowledge of persons with relevant expertise.

To the extent that this instrument outlines the changes above, it was considered that no consultation was necessary as the corrections of names for those drugs and/or brands should not increase the risk of shortages in supply or unmet patient need.

This instrument commences on 1 October 2025.

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) Determination 2025 (PB 114 of 2025)

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 repeals the *National Health (Originator Brand) Determination 2015* (PB 100 of 2015) (the Sunsetting Instrument) to determine originator brands for pharmaceutical items of drugs on the PBS F2 formulary and takes effect on 1 October 2025. The instrument differs from the Sunsetting Instrument by a) correction of letter capitalisation and/or spelling for certain drug names in Schedule 1, and b) correction of letter capitalisation for certain originator brand names in Schedule 1.

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 *National Health Act 1953* (the Act) and the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

This legislative instrument is necessary to implement removal of originator brand data for price disclosure calculations in certain circumstances as set out in the Regulations. Originator brand removal from price disclosure calculations will potentially increase PBS price reductions, as originator brands tend to maintain higher prices than other generic brands. Originator brand removal 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.

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 necessary and cost-effective medicines for all Australians. The PBS operates under Part VII of 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

The Originator Brand Determination 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 that assists with providing subsidised access to medicines for people. This is a positive and supportive step towards attaining the highest standard of health for all Australians.

The price disclosure program progressively reduces the prices of some PBS medicines, which are subject to competition. Determining an originator brand will improve the operation of the PBS by delivering better value for money for PBS medicines through price disclosure reductions. This may assist consumers by reducing out-of-pocket costs for some PBS medicines.

Conclusion

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

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