EXPLANATORY STATEMENT

National Health Act 1953
National Health (Originator Brand) Amendment Determination (October Update) 2026
PB 120 of 2026

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 2025* (PB 114 of 2025) (the Principal Instrument) to determine originator brand status for pharmaceutical items of one drug included on the Pharmaceutical Benefits Scheme (PBS) F2 formulary on 1 October 2026.

The Principal Instrument 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. 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 removal) in certain circumstances as set out in the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations). Originator removal will potentially increase price disclosure related price reductions because originator brands tend to maintain higher prices than other brands.

Amendment

An amendment to the originator brand determination is set out in Schedule 1 of this amending instrument for the drug that is moving from F1 to F2 (nilotinib on 1 October 2026). Subsection 99ADB(6C) of the Act 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 a brand of pharmaceutical item under subsection 85(6) of the Act.

Basis for amendments

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 amending instrument.

Consultation

The company with a PBS listed brand of the drug moving from F1 to F2 was consulted on the potential originator brand determination. No comments were received from the affected company. No additional consultation with experts was undertaken regarding this determination because consultation with the affected company drew on the knowledge of persons with relevant expertise.

This instrument commences on 1 October 2026.

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

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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 (October Update) 2026 (PB 120 of 2026)

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 2025* (PB 114 of 2025) (the Principal Instrument) to determine originator brands of pharmaceutical items for one drug new to the PBS F2 formulary on 1 October 2026.

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 2017* (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 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.

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*, 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 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 benefits 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.

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 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.

Mike Pope
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division
Department of Health, Disability and Ageing

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