EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listed Drugs on F1 or F2) Amendment Determination (No. 8) 2026

PB 119 of 2026

Authority

This instrument, made under subsection 85AB(1) of the *National Health Act 1953* (the Act), amends the *National Health (Listed Drugs on F1 or F2) Determination 2021* (PB 33 of 2021) (the Principal Determination).

The Principal Determination provides for the allocation of drugs to the F1 and F2 formularies of the Pharmaceutical Benefits Scheme (PBS).

Purpose

This instrument makes amendments to the Principal Determination.

The Act provides that PBS listed drugs may be assigned to formularies identified as F1 and F2. F1 is intended for single branded drugs and F2 for drugs that have multiple brands, or are in a therapeutic group with other drugs with multiple brands. Drugs on F2 are subject to the provisions of the Act relating to price disclosure and guarantee of supply.

Section 84AC of the Act provides that a drug is on F1 or F2 if there is a determination in force under section 85AB that the drug is on F1 or F2.

Subsection 85AB(1) of the Act empowers the Minister (or delegate) to determine by legislative instrument that a listed drug is on F1 or F2. For a drug to be on F1, it must satisfy the criteria in subsection 85AB(4). This requires that there are no listed brands of pharmaceutical items that have the drug that are bioequivalent or biosimilar, and no listed brands of pharmaceutical items that have another drug in the same therapeutic group as the first drug that are bioequivalent or biosimilar. It also requires that the drug was not on F2 the day before the determination comes into effect. A drug may only be determined to be on F2 if it does not satisfy one or more of the criteria for F1 (subsection 85AB(3)).

When subsection 85AB(5) of the Act applies, which relates to listed drugs with a single brand combination item on the PBS, the listed drug is not placed on F1 or F2, but on the administrative combination drug list (CDL).

This instrument amends the Principal Determination by adding to F1 one new drug, tofersen on 1 October 2026. In addition, it moves another currently listed drug, nilotinib from F1 to F2.

Authorised Version Explanatory Statement registered 30/09/2026 to F2026L01328

Variation and revocation

Unless there is an express power to revoke or vary PB 33 of 2021 cited in this instrument, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 33 of 2021.

Consultation

This instrument affects pharmaceutical companies with new medicines listing on the PBS. One new drug, tofersen meets the criteria for F1 under subsection 85AB(4). Nilotinib no longer meets the criteria for F1 set out in section 85AB(4) of the Act so is required to be moved to F2 under subsection 85AB(3).

Before a drug is PBS listed and allocated to a formulary, there are detailed consultations about the drug with the responsible person and recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC). Any PBAC recommendation is made following receipt of a submission made by the affected pharmaceutical company. Two-thirds of the PBAC membership is from the following interests or professions: consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and medical specialists.

No additional consultation with experts was undertaken regarding this determination because consultation with the affected responsible persons and the PBAC drew on the knowledge of persons with relevant expertise. Where relevant, affected responsible persons were consulted on the amendments to this determination.

Commencement

This instrument commences on 1 October 2026.

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

Authorised Version Explanatory Statement registered 30/09/2026 to F2026L01328

Statement of Compatibility with Human Rights

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

National Health (Listed Drugs on F1 or F2) Amendment Determination (No. 8) 2026 (PB 119 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 is made pursuant to subsection 85AB(1) of the *National Health Act 1953* (the Act), which relates to listed drugs on F1 or F2. This instrument amends the *National Health (Listed Drugs on F1 or F2) Determination 2021* (PB 33 of 2021) (the Principal Determination) which provides for the allocation of drugs to the F1 and F2 formularies of the Pharmaceutical Benefits Scheme (PBS).

This instrument amends the Principal Determination by adding to F1 one new drug, tofersen on 1 October 2026. In addition, it moves another currently listed drug, nilotinib from F1 to F2.

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 assists with the advancement of this human right by providing for subsidised access of medicines to patients. The recommendatory role of the PBAC ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (ICESCR). It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Authorised Version Explanatory Statement registered 30/09/2026 to F2026L01328

Conclusion

This legislative instrument is compatible with human rights. Human rights continue to be protected by retaining clinically important medicines on the PBS and placing them in formularies that ensure the most cost-effective pricing for supply of each medicine to Australians.

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

Authorised Version Explanatory Statement registered 30/09/2026 to F2026L01328