EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listed Drugs on F1 or F2) Amendment Determination 2022 (No. 8)

PB 95 of 2022

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 four new drugs, decitabine with cedazuridine, mecasermin, somatrogon and trientine and removes two drugs enfuvirtide from F1 and alendronic acid with colecalciferol and calcium from F2 as these drugs will no longer be PBS listed from 1 October 2022. In addition, it also moves two currently listed F1 drugs, pomalidomide and plerixafor to F2.

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. Decitabine with cedazuridine, mecasermin, somatrogon and trientine meet the criteria for F1 under subsection 85AB(4). Enfuvirtide and alendronic acid with colecalciferol and calcium are being removed from the PBS at the request of the pharmaceutical company that sponsors the PBS listing. Pomalidomide and plerixafor no longer meet the criteria for F1 under subsection 85AB(4), so are 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 person and the PBAC drew on the knowledge of persons with relevant expertise.

Commencement

This instrument commences on 1 October 2022.

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 (Listed Drugs on F1 or F2) Amendment Determination 2022 (No.8) (PB 95 of 2022)

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 four new drugs, decitabine with cedazuridine, mecasermin, somatrogon and trientine and removes two drugs, enfuvirtide from F1 and alendronic acid with colecalciferol and calcium from F2 as these drugs will no longer be PBS listed from 1 October 2022. In addition, it also moves two currently listed F1 drugs, pomalidomide and plerixafor 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 Pharmaceutical Benefits Advisory Committee 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.

It is noted that this amending instrument requests the delisting of two drugs – enfuvirtide and alendronic acid with colecalciferol and calcium, which will result in these drugs being no longer available at subsidised prices.

The delisting of enfuvirtide from the PBS occurred at the request of the company responsible for its supply in Australia (the sponsor), Roche Products Pty Ltd due to it being discontinued from manufacture. The PBAC advised that the delisting of both forms from the PBS may result in an unmet clinical need. The Department contacted the sponsor and sought to retain the product in line with this advice, however the sponsor indicated retention was not possible due to the product being discontinued from manufacture and that it wished to proceed with the delisting. Efforts have been made to ensure continued subsidised access to this medicine.

Sponsors are private entities that make their own decisions regarding their products, and cannot be compelled by the Government to continue to list a product on the PBS.

The delisting of alendronic acid with colecalciferol and calcium from the PBS occurred at the request of the company responsible for its supply in Australia (the sponsor), Dr Reddy's Laboratories (Australia) Pty Ltd. The PBAC considered that although this is the last combination product of alendronate, vitamin D and calcium, there are suitable alternatives in separate forms available. The PBAC advised the delisting of alendronate with colecalciferol and calcium would not result in an unmet clinical need. The delisting of this item will not affect access to treatment as affected patients will be able to access alternate medicines through the PBS.

Patients accessing PBS subsidised medicines are usually required to pay a co-payment towards their cost. From 1 January 2022, these fees are up to $42.50 for general patients and up to $6.80 for concession card holders. These co-payments are payable for accessing all PBS subsidised medicines. The deletion of enfuvirtide and alendronic acid with colecalciferol and calcium is therefore unlikely to result in a negative financial impact for patients. This is due to the same maximum co-payments applying to all PBS listed medicines

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.

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.

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