

## EXPLANATORY STATEMENT

*National Health Act 1953*

### ***National Health (Listed Drugs of F1 or F2) Determination 2021***

**PB 33 of 2021**

#### **Authority**

This legislative instrument is made pursuant to subsection 85AB(1) of the *National Health Act 1953* (the Act), which gives the Minister the power to determine that a Pharmaceutical Benefit Scheme (PBS) listed drug may be assigned to formularies identified as F1 and F2.

#### **Purpose**

The Purpose of the *National Health (Listed Drugs of F1 or F2) Determination 2021* (the Determination) is to determine the formulary allocation, identified as F1 and F2, of a PBS listed drug. The Determination repeals and replaces the *National Health (Listed drugs on F1 or F2) Determination 2010* (93 of 2010) (sunsetting Determination), which sunsets on 1 April 2021.

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 F1 are subject to provisions of the Act relating to anniversary price reductions. 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).

#### **Consultation**

This instrument affects responsible persons with drugs listed on the PBS.

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).

Members of the PBAC are appointed following nomination by prescribed organisations and associations. PBAC membership consists of consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists. In addition, an industry nominee has been appointed to the PBAC. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC that would enable them to contribute meaningfully to the deliberations of the PBAC.

Any PBAC recommendation is made following receipt of a submission made by the affected responsible person.

The majority of items listed in the Determination were listed in the *sunsetting Determination*, which sunsets on 1 April 2021. Responsible persons were consulted about changes to their items as they occurred from time to time.

The Determination differs from the *sunsetting Determination*, by adding two drugs to F1, fulvestrant and romosozumab. Fulvestrant and romosozumab meet the criteria for F1 under subsection 85AB(4) of the Act. Responsible persons of these drugs are aware these drugs meet the criteria for F1.

The Determination also differs from the *sunsetting Determination*, by moving five drugs, adalimumab, cabazitaxel, cinacalcet, erlotinib and ganirelix from F1 to F2, upon entry of bioequivalent or biosimilar brands of pharmaceutical items on 1 April 2021. All five drugs no longer meet the criteria for F1 under subsection 85AB(3) of the Act, so are required to be moved to F2. Affected responsible persons were consulted on these amendments.

One administrative correction was made to amended “Poly-L-Lactic acid” to “Poly-l-lactic acid”, consistent with the description of the drug in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)*.

No additional consultation with experts was undertaken regarding the Determination because consultation with the affected responsible persons and the PBAC, which informed the making of the Determination, drew on the knowledge of persons with relevant expertise. A provision-by-provision description of the Determination is contained in the Attachment.

The Determination commences on 1 April 2021.

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

**DETAILS OF THE *NATIONAL HEALTH (LISTED DRUGS OF F1 OR F2) DETERMINATION 2021***

**Section 1 Name**

This section provides that the name of the Determination is the *National Health (Listed Drugs of F1 or F2) Determination 2021*.

This section also provides that the instrument may be cited as PB 33 of 2021.

**Section 2 Commencement**

This section provides that the Determination commences on 1 April 2021.

**Section 3 Authority**

This section provides that the Determination is made under section 85AB of the *National Health Act 1953*.

**Section 4 Schedule 3**

This section provides that the *National Health (Listed Drugs of F1 or F2) Determination 2020* is repealed.

**Section 5 Definitions**

This section provides that the definition of Act means the *National Health Act 1953*.

**Section 6 Drugs on F1**

This section provides that for the purposes of subsection 85AB(1) of the Act, the drugs mentioned in Schedule 1 are on F1.

**Section 7 Drugs on F2**

This section provides that for the purposes of subsection 85AB(1) of the Act, the drugs mentioned in Schedule 2 are on F2.

**Schedule 1 - Drugs on F1**

This schedule lists drugs that meet the criteria for F1 under subsection 85AB(4) of the Act.

**Schedule 2 - Drugs on F2**

This schedule lists drugs that no longer meet the criteria for F1 under subsection 85AB(4) of the Act and therefore are assigned to F2 under subsection 85AB(3) of the Act.

**Schedule 3 Repeals**

This schedule repeals the *National Health (Listed Drugs on F1 or F2) Determination 2010*.

## **Statement of Compatibility with Human Rights**

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

### ***National Health (Listed Drugs of F1 or F2) Determination 2021 (PB 33 of 2021)***

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. The *National Health (Listed Drugs of F1 or F2) Determination 2021* (PB 33 of 2021) (the Determination) provides for the allocation of Pharmaceutical Benefits Scheme (PBS) listed drugs to the F1 and F2 formularies.

#### **Human rights implications**

The Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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. Efficient operational arrangements for the PBS support effective administration of the scheme. The allocation of medicines to the F1 and F2 formularies improves the operation of the PBS by applying different price reductions to different groups of medicines. This assists consumers by reducing out-of-pocket costs for some PBS medicines.

#### **Conclusion**

The Determination is compatible with human rights as it promotes the protection of human rights.

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