EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listed drugs on F1 or F2) Amendment Determination 2020 (No. 7)

PB 73 of 2020

Authority

This instrument, made under subsection 85AB(1) and section 99AEJ of the *National Health Act 1953* (the Act), amends the *National Health (Listed drugs on F1 or F2) Determination 2010* (PB 93 of 2010) (the Principal Determination).

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

This instrument makes amendments to the Principal Determination.

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

Background

The Act provides that listed drugs may be assigned to formularies identified as F1 and F2. F1 is intended for single brand 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.

This instrument removes one drug from F2, mercaptopurine and places it back on F1 under section 99AEJ of the Act . Under section 99AEH of the Act, on 1 August 2020 the Minister's delegate revoked the determination under subsection 85(6) of the Act in relation to MERCAPTOPURINE-LINK (the ***delisted brand***) of a pharmaceutical item, mercaptopurine, tablet containing mercaptopurine monohydrate 50 mg, oral (the ***existing item***). Before the revocation came into force, subsection 99AEC(2) applied to the delisted brand of the existing item. From 1 August 2020, there is only one listed brand of mercaptopurine, tablet containing mercaptopurine monohydrate 50 mg, oral (the ***remaining item***) that is bioequivalent or biosimilar to the delisted brand of the existing item. Apart from paragraph 85AB(4)(c) of the Act, mercaptopurine satisfies the criteria for F1 referred to in subsection 85AB(4) of the Act. Further, mercaptopurine was on F1 the day before subsection 99AEC(2) began to apply to the delisted brand of the existing item (on 31 March 2020).

This Instrument also amends the Principal Determination by adding to F1 three new drugs entrectinib, lorlatinib and stiripentol. It also moves two currently listed drugs, lurasidone and nitrofurantoin from F1 to F2 in addition to moving one currently listed drug, levodopda with carbidopa and entacapone from the single brand Combination Drug List (CDL) to F2.

Consultation

This Instrument affects pharmaceutical companies with new medicines listing on the PBS. Entrectinib, lorlatinib and stiripentol all meet the criteria for F1 set out in section 85AB(4) of the Act.

Lurasidone, nitrofurantoin and levodopa with carbidopa and entacapone no longer meet the criteria for F1 set out in section 85AB(4) of the Act so are required to be moved to F2.

Before the drugs were listed and allocated to formularies, there were detailed consultations about the drugs with the responsible persons, and a recommendation was received 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.

The responsible persons (manufacturers) for the delisted brand and the existing item were consulted about mercaptopurine moving from F2 to F1.

No additional consultations 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.

Commencement

This Instrument commences on 1 August 2020.

This Instrument constitutes a legislative instrument for the purpose 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 2020 (No. 7) (PB 73 of 2020)

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) and section 99AEJ 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 2010* (PB 93 of 2010) (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 three new drugs entrectinib, lorlatinib and stiripentol. It also moves two currently listed drugs, lurasidone and nitrofurantoin from F1 to F2 in addition to moving one currently listed drug, levodopda with carbidopa and entacapone from the single brand Combination Drug List (CDL) to F2. In addition, it also removes one drug from F2, mercaptopurine and places it back on F1 under section 99AEJ of the Act.

Human rights implications

This Legislative Instrument engages Article 2 and 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 benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

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

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