

## EXPLANATORY STATEMENT

### INSTRUMENT NUMBER PB 51 OF 2011

#### ***NATIONAL HEALTH ACT 1953***

#### ***National Health (Listed drugs on F1 or F2) Amendment Determination 2011 (No.8)***

##### *Purpose*

This instrument, made under subsection 85AB(1) of the *National Health Act 1953* (the Act), amends the principal determination, the *National Health (Listed drugs on F1 or F2) Determination 2010* (PB 93 of 2010) to provide for allocation of drugs to the F1 and F2 formularies for the Pharmaceutical Benefits Scheme (PBS).

##### *Background*

Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits. Drugs and medicinal preparations to which Part VII applies are declared by the Minister by legislative instrument under subsection 85(2). These are listed drugs as defined in subsection 84(1).

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 statutory price reductions, price disclosure and guarantee of supply.

Section 84AC relevantly 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) empowers the Minister 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)).

Section 85AB(5)(a) determines that if a drug is in a combination item that section 85AB does not apply. This means while there is only a single brand combination drug on the PBS, the item would remain on the combination drug list. When a second brand of the combination

drug lists on the PBS, this would move the combination drug from the combination drug list to F2.

#### *Details of this Instrument*

PB 93 of 2010 maintains a list of all F1 and F2 drugs that are currently listed on the PBS.

This instrument removes three drugs, dolasetron, exemestane and fentanyl from F1.

Dolasetron will no longer be listed on the PBS from 1 August 2011 and as such needs to be removed from F1. The other two drugs, exemestane and fentanyl will move from F1 to F2 with listings of new brands that are bioequivalent. These three changes are effective from 1 August 2011.

#### *Consultation*

The instrument affects pharmaceutical companies with medicines listed on the PBS. Before drugs are listed and allocated to formularies, there are detailed consultations about the drug with the intended responsible person, and a recommendation is received from the Pharmaceutical Benefits Advisory Committee (PBAC). Any PBAC recommendation is made following receipt of submissions by affected pharmaceutical companies. 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.

#### *General*

This instrument commences on 1 August 2011.

This instrument constitutes a legislative instrument for the purpose of the *Legislative Instruments Act 2003*.