

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2010 No. 295**

#### *National Health Act 1953*

#### *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 4)*

Section 140 of the *National Health Act 1953* (the Act) provides, in part, that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted by the Act to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Regulations make changes to the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to amend the provisions relevant to one drug on the Schedule which lists brands of pharmaceutical items scheduled for staged statutory price reductions.

Section 99ACK of the Act, together with section 99ACF, provides for a 25 per cent statutory price reduction staged over time for prescribed brands of pharmaceutical items in the F2T formulary. Regulation 37B, together with Schedule 5 to the Principal Regulations, prescribes these brands of pharmaceutical items, the reduction days for these brands and the percentage reductions for each reduction day.

The Explanatory Memorandum of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2008 (No. 2)* sets out the Government's intentions that a new bioequivalent brand listing of any of the drugs contained in Schedule 5 will trigger the application of any outstanding amount of the staged 25 per cent reduction for all brands of the drug that are specified in Schedule 5 (the new brand will be offered Pharmaceutical Benefits Scheme (PBS)-listing at the new lower price). The reduction will be applied on the date of listing of the new brand. This process reflects the Government policy of applying price reductions to medicines operating in a competitive market while protecting single-brand medicines from unsustainable price reductions. The Regulations are intended to give effect to this policy.

New brands of pharmaceutical items that contain the drug lercanidipine which is used to treat hypertension, are listed on the PBS on 1 December 2010. The Regulations amend the reduction days and the amount of the percentage reductions for the existing PBS-listed brands of lercanidipine currently contained in Schedule 5. This has the effect of applying the remainder of the 25 per cent staged price reduction to the currently listed brands of lercanidipine on 1 December 2010.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations commence the day after registration on the Federal Register of Legislative Instruments.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

## Consultation

These amendments stem from the PBS Reform Policy 2007. During the implementation phase of the Government's PBS Reform Policy in 2007, all affected pharmaceutical companies and key industry bodies were consulted with regard to the changes effected by the PBS Reform Policy in 2007. The amendments to Schedule 5 of the *National Health (Pharmaceutical Benefits) Regulations 1960* were also made after consultation with affected pharmaceutical companies and key industry bodies in late 2009 and early 2010.