EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 56

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 2)

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

The purpose of the regulation is to amend regulation 8 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No.5)* by creating subregulation 8(3) to specify that sales revenue and adjusted volume data is to be excluded from the weighted average disclosed price (WADP) calculations for brands of pharmaceutical items (listed brands) that are in the third transitional disclosure cycle and have a first reporting period ending on 31 January 2012.

Regulation 37G of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) sets out the method for determining the WADP for all listed brands with the same drug and manner of administration in a disclosure cycle. This method excludes the sales revenue and adjusted volume data for the first month of the first reporting period for listed brands that are newly listed on the Pharmaceutical Benefits Scheme.

The exclusion of the first month's sales revenue and adjusted volume data in regulation 37G of the Principal Regulations, does not apply to newly listed brands in the third transitional disclosure cycle that have a first reporting period ending on 31 January 2012 (the relevant listed brands). subregulation 8(3) corrects this oversight.

All responsible persons for the relevant listed brands have separately identified the first month's sales revenue and adjusted volume data in their disclosed data. The data is able to be excluded when the regulation 37G method is applied.

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

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on the day after registration on the Federal Register of Legislative Instruments.

Consultation

This instrument affects pharmaceutical companies with medicines listed on the PBS. Pharmaceutical companies were involved in the negotiations that resulted in the

requirement to identify first month's sales and volume data and the exclusion of the data from the WADP calculations, for new brands listing on the PBS. This instrument ensures that this requirement applies to all relevant brands. Information on this requirement was provided directly to pharmaceutical companies through information sessions and educational workshops.

Authority: Section 140 of the *National Health Act 1953*

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 2)

This Bill/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 Bill/Legislative Instrument

The purpose of the regulation is to amend regulation 8 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No.5)* by creating subregulation 8(3) to specify that sales revenue and adjusted volume data is to be excluded from the weighted average disclosed price calculations for brands of pharmaceutical items (listed brands) that are in the third transitional disclosure cycle and have a first reporting period ending on 31 January 2012.

Human rights implications

This Bill/Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Bill/Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Tanya Plibersek

Minister for Health