

## **EXPLANATORY STATEMENT**

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

#### ***NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 2)***

#### **PB 18 of 2012**

#### **Authority**

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits. Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

#### **Purpose**

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the Act, is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement), to make changes to the special arrangement relating to the efficient funding of chemotherapy.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines (“chemotherapy pharmaceutical benefits”) to eligible patients being treated for cancer, to reflect the 2010 budget measure titled ‘Revised arrangements for the efficient funding of chemotherapy drugs’. This special arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment (“related pharmaceutical benefits”) at certain public hospitals.

This instrument makes changes to the pharmaceutical benefits available under the section 100 special arrangement for the efficient funding of chemotherapy. These changes reflect changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument* made under sections 84AF, 85, 85A, 88 and 101 of the Act, which commence on the same day.

This Instrument:

- adds 11 new listed brands with the listed drugs ‘Bleomycin’, ‘Doxorubicin’, ‘Epirubicin’ and ‘Methotrexate’; and
- reflects that the listed drug ‘Bortezomib’ will only be available for supply under this Special Arrangement from 1 April 2012.

This instrument also amends the figures relevant to the special patient contribution for a listed brand with the listed drug ‘Bleomycin’.

This instrument also makes changes to the Special Arrangement to reflect the commencement of section 98AC of the Act on 1 April 2012 and the rules made under subsection 98AC(4). Section 98AC was included in the amendments to the Act made by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010*. Section 98AC of the Act requires the provision of under co-payment data by approved suppliers. This instrument makes

modifications to the operation of the rules under subsection 98AC(4) to reflect other modifications made to Part VII of the Act by this Special Arrangement.

### **Consultations**

An ongoing and formal process of consultation in relation to matters relevant to this instrument includes the involvement of interested parties through the membership of the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits.

PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

This Instrument commences on 1 April 2012.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

A provision by provision description of this Instrument is contained in the [Attachment](#).

## ATTACHMENT

**PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH  
(EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT  
AMENDMENT INSTRUMENT 2012 (No. 2)**

**Section 1 Name of Instrument**

This section provides that this Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 2)* and that it may also be cited as PB 18 of 2012.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 April 2012.

**Section 3 Amendments to PB 79 of 2011**

This section provides that Schedule 1 amends the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement).

**Schedule 1**

**Item 1** amends the definition of ‘dose’ in section 3 of the Special Arrangement to expressly provide for the avoidance of doubt that the quantity of a dose includes its unit of use.

**Item 2** amends the definitions in section 3 of the Special Arrangement to add a new definition for ‘under co-payment data’.

**Item 3** amends the headings for Part 4 Division 1 of the Special Arrangement to reflect the addition of provisions for the supply of under co-payment data.

**Item 4** modifies the operation of the rules made under subsections 99AAA(8) and 98AC(4) of the Act to adjust to the Special Arrangement.

**Item 5** modifies the operation of the rules made under sections 99AAA(8) and 98AC(4) of the Act to adjust to the Special Arrangement.

**Item 6** amends the entry in Schedule 1 Part 1 of the Special Arrangement for ‘Bleomycin’ by adding a new pharmaceutical benefit, which is the listed drug ‘Bleomycin’ in the form ‘Powder for injection containing bleomycin sulfate 15,000 I.U.’ with manner of administration ‘Injection’ and brand ‘Bleo 15K’.

**Item 7** amends the entry in Schedule 1 Part 1 of the Special Arrangement for ‘Bortezomib’ to add a ‘D’ to the column headed ‘Section 100 only’ to reflect that the listed drug ‘Bortezomib’ will only be available under a section 100 special arrangement.

**Item 8** amends the entry in Schedule 1 Part 1 of the Special Arrangement for ‘Doxorubicin’ by adding a new pharmaceutical benefit, which is the listed drug ‘Doxorubicin’ in the form ‘Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial’ with manner of administration ‘Injection/intravesical’ and brand ‘Accord Doxorubicin’.

**Item 9** amends the entry in Schedule 1 Part 1 of the Special Arrangement for ‘Doxorubicin’ by adding a new pharmaceutical benefit, which is the listed drug ‘Doxorubicin’ in the form ‘Solution for I.V. injection or intravesical administration containing doxorubicin

hydrochloride 200 mg in 100 mL single dose vial' with manner of administration 'Injection/intravesical' and brand 'Accord Doxorubicin'.

**Item 10** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL' with manner of administration 'Injection/intravesical' and brand 'Epiccord'.

**Item 11** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL' with manner of administration 'Injection/intravesical' and brand 'Epiccord'.

**Item 12** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL' with manner of administration 'Injection/intravesical' and brand 'Epiccord'.

**Item 13** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL' with manner of administration 'Injection/intravesical' and brand 'Epirubicin Kabi'.

**Item 14** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL' with manner of administration 'Injection/intravesical' and brand 'Epiccord'.

**Item 15** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Epirubicin' by adding a new pharmaceutical benefit, which is the listed drug 'Epirubicin' in the form 'Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL' with manner of administration 'Injection/intravesical' and brand 'Epirubicin Kabi'.

**Item 16** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Methotrexate' by adding a new pharmaceutical benefit, which is the listed drug 'Methotrexate' in the form 'Injection 50 mg in 2 mL vial' with manner of administration 'Injection' and brand 'Methaccord'.

**Item 17** amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Methotrexate' by adding a new pharmaceutical benefit, which is the listed drug 'Methotrexate' in the form 'Solution concentrate for I.V. infusion 1000 mg in 10 mL vial' with manner of administration 'Injection' and brand 'Methaccord'.

**Items 18 and 19** amend Schedule 5 of the Special Arrangement by adjusting the special patient contribution for the listed brand 'Hospira Pty Ltd' with the listed drug 'Bleomycin'.

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

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*  
***National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 2)***

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**

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the Act, is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement), to make changes to the special arrangement relating to the efficient funding of chemotherapy.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines (“chemotherapy pharmaceutical benefits”) to eligible patients being treated for cancer, to reflect the 2010 budget measure titled ‘Revised arrangements for the efficient funding of chemotherapy drugs’. This Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment (“related pharmaceutical benefits”) at certain public hospitals.

This instrument inserts 11 new listed brands and reflects that the listed drug ‘Bortezomib’ will only be available for supply under this Special Arrangement from 1 April 2012.

This instrument also makes changes to the Special Arrangement to reflect the commencement of section 98AC of the Act on 1 April 2012 and the rules made under subsection 98AC(4). Section 98AC was included in the amendments to the Act made by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010*. Section 98AC of the Act requires the provision of under co-payment data by approved suppliers. This instrument makes modifications to the operation of the rules under subsection 98AC(4) to reflect other modifications made to Part VII of the Act by this Special Arrangement.

### **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 because it advances the protection of human rights.

**Felicity McNeill**  
**First Assistant Secretary, Pharmaceutical Benefits Division**  
**Department of Health and Ageing**