

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021

Authority

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act 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.

Subsection 99ADC(1) of the Act provides that the regulations may prescribe price disclosure requirements to provide information in relation to the supply of a brand of a pharmaceutical item.

Subsection 99ADB(6) of the Act provides that the regulations may prescribe a method or formula for determining the weighted average disclosed price of a brand of pharmaceutical item. Subsection 99ADB(6A) of the Act provides that the regulations may prescribe information that the method or formula must not take into account.

From 1 July 2022, the Act will be amended by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021* (the Enhancing the PBS Amendment Act) so that:

- Subsection 99ACC(2) of the Act provides that the regulations may prescribe a method for price reduction to the approved ex-manufacturer price of a single brand of combination item when a component drug in the combination item is subject to a statutory price reduction.
- Subsection 99ADHB(2) of the Act provides that the regulations may prescribe a method for price reduction to the approved ex-manufacturer price of an existing brand of combination item when a brand of pharmaceutical item that is not a combination item that has a common drug that is in the combination item is subject to a price reduction under section 99ADH of the Act.

From 1 July 2023, the Act will be amended by the Enhancing the PBS Amendment Act so that:

- Subsection 99AEKC(5) of the Act provides that **usual demand** for a brand of a pharmaceutical item is to be ascertained in accordance with the regulations.
- Subsection 99AEKF(1) of the Act provides that the regulations may prescribe stockholding disclosure requirements.

Subsection 33(3) of the *Acts Interpretation Act 1901* (Acts Interpretation Act) provides that where an Act confers a power to make an instrument of a legislative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to amend or vary any such instrument. Subsection 4(2) of the Acts Interpretation Act provides that where an amendment to an Act will confer a power to make an instrument, the power may be exercised before commencement of the amendments as if

the relevant commencement had occurred. The provisions of the instrument take effect at the commencement date (or later time specified in the instrument) (subsection 4(5) of the Acts Interpretation Act).

Purpose

The *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021* (the proposed Regulations) would make amendments to the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) relating to price reductions, price disclosure and stockholding requirements agreed in new Strategic Agreements with Medicines Australia (MA) and the Generic and Biosimilar Medicines Association (GBMA).

Background

Part VII of the *National Health Act 1953* (the Act) establishes the Pharmaceutical Benefits Scheme (PBS), which provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits.

On 6 September 2021 the Commonwealth entered into new 5-year Strategic Agreements with MA and the Generic and GBMA commencing on 1 July 2022. The new agreements included agreement from MA and the GBMA to improved statutory price reductions under Division 3A of the Act and to the introduction of new price protections and stockholding requirements under the Act and the Principal Regulations.

Consultation

The Regulations impact pharmaceutical companies that supply medicines that are subsidised through the PBS. The measures implemented by the Regulations have been agreed by MA and the GBMA who acted on behalf of the pharmaceutical industry in Australia in the negotiation of the new Strategic Agreements. MA and the GBMA have been consulted on the specific amendments in the Regulations.

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

The Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations would commence as set out in the Attachment.

Details of the Regulations are set out in the Attachment.

The Minute recommends that the Regulations be made in the form proposed.

Authority: Section 140 of the
National Health Act 1953

Details of the proposed *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*

Section 1 – Name

This section would provide that the title of the Regulations is the *Error! Use the Home tab to apply ShortT to the text that you want to appear here.*

Section 2 – Commencement

This section would provide that the Regulations commence as follows:

Sections 1 to 4 would commence on the day after the proposed Regulations are registered.

Schedule 1, Part 1, which would provide formulas for flow-on reductions to combination items under sections 99ACC and 99ADHB of the Act, would commence on 1 July 2022. This would be at the same time as amendments made by the Enhancing the PBS Amendment Act to sections 99ACC and 99ADHB of the Act, that provide for combination flow-on price reductions to be given effect using a method prescribed by the regulations, would take effect.

Schedule 1, Part 2, which would amend the circumstances for removal of originator brands from calculation of the weighted average disclosed price so that originator brands would be removed 18 months after a drug moved to F2 if there had been no price reduction, would commence on 1 October 2022. This would give effect to the commitments in the Strategic Agreements that this occur from 1 July 2022. These amendments would apply to the first weighted average disclosed price calculation to occur after 1 July 2022 based on information about supplies from 1 April 2022 to 31 September 2022 reported in the 1 October 2022 to 11 November 2022 reporting period.

Schedule 1, Part 3, which would introduce a new step to adjust net revenue in the weighted average disclosed price calculation and remove the requirement that responsible persons exclude information in relation to supplies to public hospitals after the drug has been on F2 for at least 42 months, will commence on 1 April 2023. These amendments will apply in relation to data collection periods and supplies occurring on or after 1 October 2022 to support new price protections in the Act commencing on 1 October 2022.

Schedule 1, Part 4, which would provide for stockholding disclosure requirements for the purposes of new section 99AEKF(1) of the Act and calculation of usual demand for the purposes of new section 99AEKC(5) of the Act, would commence on 1 April 2023. This would be at the same time as amendments made by the Enhancing the PBS Amendment Act which insert new sections 99AEKF and 99AEKC into the Act, would take effect.

Section 3 – Authority

This section would provide that the Regulations are made under the *National Health Act 1953*.

Section 4 – Schedules

This section would provide that each instrument that is specified in a Schedule to the Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

Schedule 1 – Amendments

Part 1 – Amendments commencing on 1 July 2022

This part introduces formulas for the flow-on of statutory price reductions under section 99ACC of the Act and price disclosure reductions under section 99ADHB of the Act to combination items. Amendments to the Act that commence on 1 July 2022 provide for reductions under these sections to be given effect through a method prescribed by the regulations. Under current provisions, flow-on price reductions to combination items are to be given effect through new price agreements between the responsible person (pharmaceutical company) and the Minister under section 85AD of the Act. The amendments are to reduce the administrative burden and uncertainty with the current arrangements and ensure that they occur automatically.

Item [1] new section 65A

Item 1 would insert a new section 65A before section 66 of the Principal Regulations which would prescribe a formula in subsection 65A(2) for price reductions to brands of combination items for the purposes of subsection 99ACC(2) of the Act. Section 99ACC applies where there is only one listed brand of the combination item (single brand). Combination items are pharmaceutical items with a drug that is a combination of two or more other drugs or medicinal preparations, at least one of which is a listed drug. For example, a pharmaceutical item with the drug “Netupitant with Palonosetron” is a combination item because the drug contains two component drugs – the listed drug Palonosetron and the non-listed drug Netupitant.

From 1 July 2022, section 99ACC will specify that the price of a single brand of combination item is to be reduced in accordance with the formula prescribed in the regulations when one or more of the listed drugs contained in the drug in the combination item (listed component drug) becomes subject to a statutory price reduction under Division 3A of the Act or price disclosure reduction under Division 3B (as defined in subsection 99ACC(6)).

New section 65A would apply in relation to reduction days occurring on or after 1 July 2022 (see new section 103 of the Principal Regulations, inserted by item 10) and this amendment is sought in anticipation of amendments to the Act by the Enhancing the PBS Amendment Act which commence on 1 July 2022.

The formula in subsection 65A(2) is:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

The effect of the formula would be that the approved ex-manufacturer price of the single brand of combination item would be reduced by an amount that reflects the price reduction to the listed component drug or drugs in the combination item.

For example, for a single brand of combination item that has a drug containing Drug A and Drug B with a *day before combination item AEMP* of \$150, and where a brand of the listed component item that has Drug A has been reduced by 5% from an approved ex-manufacturer price of \$100 to \$95 on the reduction day, and the approved ex-manufacturer price of the brand of component item that has Drug B has an approved ex-manufacturer price of \$50 that is not reduced on the reduction day, the reduced approved ex-manufacturer price will be worked out as follows: (*reduction day component AEMPs* \$95 + \$50) x ((*day before combination item AEMP* \$150) / (*day before component AEMPs* \$100 + \$50)) = \$145.

The *day before combination item AEMP* is the approved ex-manufacturer price of the brand of the combination item on the day before the reduction day.

The *day before component AEMPs* are the sum of:

- (a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item; and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

Listed component drug is defined in subsection 99ACA(1) of the Act.

For example, if the combination item contains Drug A and Drug B and a brand of the listed component item that has Drug A has an approved ex-manufacturer price (adjusted in accordance with subsection 65A(3)) of \$100 and a brand of the listed component item that has Drug B has an approved ex-manufacturer price (adjusted in accordance with section 65A(3)) of \$50, then the *day before component AEMPs* will be \$100 + \$50 = \$150.

The *listed component item*, for each listed component drug contained in the combination item, is the pharmaceutical item that has:

- (a) the listed component drug; and
- (b) the same manner of administration as the combination item as referred to in subsection 99ACC(7) of the Act; and
- (c) subject to subsection (4) of new section 65A, the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

For example, if the combination item contains 125mg of Drug C and has a pricing quantity of 5 tablets and there are three pharmaceutical items that have 50mg, 100mg, and 200mg of Drug C respectively all with a pricing quantity of 5 tablets, the *listed component item* will be the pharmaceutical item that has 100mg of Drug C x pricing quantity of 5 = 500mg, as this is the closest quantity of Drug C to the amount of Drug C in the combination item (125 mg x pricing quantity of 5 = 600mg).

The **non-listed component price** is the day before combination item AEMP reduced (but not below zero) by the sum of the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item.

For example, if a brand of combination item that has an approved ex-manufacturer price of \$200 on the day before the reduction day has a drug that contains Drug A, Drug B and Drug N, and Drug N is not a listed drug, and the sum of the approved ex-manufacturer prices (adjusted in accordance with subsection 65A(3)) for any one brand of the listed component item for Drug A and any one brand of the listed component item for Drug B are $\$100 + \$50 = \$150$. The non-listed component price for Drug N will be $\$200 - \$150 = \$50$.

The **reduction day component AEMPs** means the sum of:

- (a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item; and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

Component drug is defined in subsection 99ACA(1) of the Act.

Example 1: if the combination item contains Drug A and Drug B and the brand of the listed component item that has Drug A has been reduced by 5% from an approved ex-manufacturer price (adjusted in accordance with subsection 65A(3)) of \$100 to \$95 on the reduction day, and the brand of listed component item that has Drug B has an approved ex-manufacturer price (adjusted in accordance with subsection 65A(3)) of \$50 on the reduction day, then the **reduction day component AEMPs** will be $\$95 + \$50 = \$145$.

Example 2: if the combination item contains Drug A, Drug B, and Drug N, and Drug N is not a listed drug, and the brand of the listed component item that has Drug A has been reduced by 5% from an approved ex-manufacturer price (adjusted in accordance with subsection 65A(3)) of \$100 to \$95 on the reduction day, and the brand of the listed component item that has Drug B has an approved ex-manufacturer price that is not reduced on the reduction day, and the non-listed component price of Drug N, after being multiplied by the differential reduction percentage of 95%, is \$47.50, then the **reduction day component AEMPs** will be $\$95 + \$50 + \$47.50 = \192.50 .

The **differential reduction percentage** is to be determined as follows:

- (a) if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day, the difference between 100% and the percentage by which the approved ex-manufacturer price has been reduced; or
- (b) if there are two or more listed component items for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision mentioned in subsection 99ACC(6) of the Act on the reduction day, the difference between 100% and the average of the percentages by which the

approved ex-manufacturer price of any one brand of each of the listed component items have been reduced.

Example 1: if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced, and that brand is reduced by 5% on the reduction day, then the *differential reduction percentage* will be $100\% - 5\% = 95\%$

Example 2: if there are two listed component items and the approved ex-manufacturer price of a brand of one listed component item has been reduced by 5%, and a brand of the other listed component item has been reduced by 26.1% on the reduction day, the average of the percentages by which the approved ex-manufacturer prices were reduced will be $(5\% + 26.1\%) \div 2 = 15.55\%$ and the *differential reduction percentage* will be $100\% - 15.55\% = 86.45\%$.

Subsection (3) would adjust the approved ex-manufacturer price of a brand of a listed component item for the purposes of the definitions of *day before component AEMPs*, *reduction day component AEMPs* and *non-listed component price*. The approved ex-manufacturer price would be adjusted for any difference in quantity or amount or pricing quantity of the listed component drug in the listed component item.

Example 1: if the combination item contains 125mg of Drug A and the listed component item contains 100mg of Drug A, and a brand of the listed component item has an approved ex-manufacturer price of \$100, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug A reflects the difference as follows: $\$100 \times (125/100) = \125 .

Example 2: if the combination item contains 100mg of Drug B and has a pricing quantity of 30 and the listed component item also contains 100 mg of Drug B, and a brand of the listed component item has an approved ex-manufacturer price of \$50 and a pricing quantity of 28, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug B reflects the difference as follows: $\$50 \times (30/28) = \53.57 .

Example 3: if the combination item contains 125mg of Drug C and has a pricing quantity of 30 and the listed component item contains 100 mg of Drug C, and a brand of the listed component item has an approved ex-manufacturer price of \$50 and a pricing quantity of 28, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug C reflects the difference as follows: $\$50 \times (125/100) \times (30/28) = \66.96 .

Subsection (4) would deal with the circumstance where there is more than one pharmaceutical item that has the smallest difference as referred to in the definition of *listed component item*. In these circumstances, the pharmaceutical item, that is not an exempt item, that would result in the smallest reduction to the approved ex-manufacturer price of the brand of the combination item under this section would be taken to be the *listed component item*.

Item [2] new section 85A

Item 2 would insert a new section 85A at the end of the Principal Regulations which would prescribe a formula in subsection 85A(2) for price reductions to brands of combination items for the purposes of section 99ADHB(2) of the Act. From 1 July 2022, section 99ADHB will specify that the price of a brand of combination item that has a drug on F2 is to be reduced in accordance with the formula prescribed in the regulations when a brand of a pharmaceutical item that has a common drug and the same manner of administration becomes subject to a price disclosure reduction under Division 3B.

New section 85A would apply in relation to reduction days occurring on or after 1 July 2022 (see new section 103 of the Principal Regulations, inserted by item 10) and would be made

in anticipation of amendments to the Act by the Enhancing the PBS Amendment Act which commence on 1 July 2022.

The formula for subsection 85A(2) is:

$$\text{reduction day component AEMPs} \times \frac{\text{day before combination item AEMP}}{\text{day before component AEMPs}}$$

The effect of the formula would be that the approved ex-manufacturer price of the brand of combination item that has a drug on F2 would be reduced by an amount that reflects the price reduction to the drug or drugs in the combination item.

For example, for a brand of combination item that has a drug containing Drug A and Drug B with a **day before combination item AEMP** of \$150, and where a brand of the listed component item that has Drug A has been reduced by 10% from an approved ex-manufacturer price of \$100 to \$90 on the reduction day, and the approved ex-manufacturer price of the brand of component item that has Drug B has an approved ex-manufacturer price of \$50 that is not reduced on the reduction day, the reduced approved ex-manufacturer price will be worked out as follows: (**reduction day component AEMPs** \$90 + \$50) x ((**day before combination item AEMP** \$150) / (**day before component AEMPs** \$100 + \$50)) = \$140.

The **component drug**, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug. This definition is the same as the definition of ‘component drug’ for section 65A, which is defined by subsection 99ACA(1) for the purposes of Division 3A of Part VII of the Act.

The **day before combination item AEMP** is the approved ex manufacturer price of the brand of the combination item on the day before the reduction day.

The **day before component AEMPs** are the sum of:

- (a) the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item; and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price.

For example, if the combination item contains Drug A and Drug B and a brand of the listed component item that has Drug A has an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$100, and a brand of the listed combination item that has Drug B has an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$50, then the **day before component AEMPs** will be \$100 + \$50 = \$150.

The **listed component drug** is a component drug in relation to which a declaration under subsection 85(2) is in force. This definition is the same as the definition of ‘component drug’ for section 65A, which is defined by subsection 99ACA(1) for the purposes of Division 3A of Part VII of the Act.

The **listed component item**, for each listed component drug contained in the combination item, and in the non-combination item mentioned in paragraph 99ADHB(1)(d), is the pharmaceutical item that has:

- (a) the same listed component drug as the non-combination item; and

- (b) the same manner of administration as the combination item as referred to in subsection 99ADHB(7) of the Act; and
- (c) subject to subsection 85A(4), the smallest difference in the total quantity or amount of the listed component drug contained in the quantity or number of units in the pricing quantity of any one brand of the pharmaceutical item compared to the total quantity or amount of the listed component drug in the pricing quantity of the brand of the combination item.

For example, if the combination item contains 125mg of Drug C and has a pricing quantity of 5 tablets and there are three pharmaceutical items that have 50mg, 100mg, and 200mg of Drug C respectively all with a pricing quantity of 5 tablets, the **listed component item** will be the pharmaceutical item that has 100mg of Drug C x pricing quantity of 5 = 500mg, as this is the closest quantity of Drug C to the amount of Drug C in the combination item (125 mg x pricing quantity of 5 = 600mg).

The **non-listed component price** is the day before combination item AEMP reduced (but not below zero) by the sum of the approved ex-manufacturer prices, on the day before the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item.

For example, if a brand of combination item that has an approved ex-manufacturer price of \$200 on the day before the reduction day has a drug that contains Drug A, Drug B and Drug N, and Drug N is not a listed drug, and the sum of the approved ex-manufacturer prices (adjusted in accordance with subsection 85A(3)) for any one brand of the listed component item for Drug A and any one brand of the listed component item for Drug B are \$100 + \$50 = \$150. The non-listed component price for Drug N will be \$200 - \$150 = \$50.

The **reduction day component AEMPs** means the sum of:

- (a) the approved ex-manufacturer prices, on the reduction day, of any one brand of each of the listed component items, adjusted in accordance with subsection (3) to reflect any difference in quantity or amount or difference in pricing quantity of the listed component drug in the listed component item; and
- (b) if the combination item includes one or more component drugs that are not listed component drugs—the non-listed component price multiplied by the differential reduction percentage.

Example 1: if the combination item contains Drug A and Drug B and the brand of the listed component item that has Drug A has been reduced by 10% from an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$100 to \$90 on the reduction day, and the brand of listed component item that has Drug B has an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$50 on the reduction day then the **reduction day component AEMPs** will be \$90 + \$50 = \$140.

Example 2: if the drug in the combination item contains Drug A, Drug B, and Drug N, and Drug N is not a listed drug, and the brand of the listed component item that has Drug A has been reduced by 10% from an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$100 to \$90 on the reduction day, and the brand of the listed component item that has Drug B has an approved ex-manufacturer price (adjusted in accordance with subsection 85A(3)) of \$50 on the reduction day, and the non-listed component price of Drug N, after being multiplied by the differential reduction percentage of 90%, is \$45, then the **reduction day component AEMPs** will be \$95 + \$50 + \$45 = \$190.

The **differential reduction percentage** is to be determined as follows:

- (a) if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision in Division 3B of Part VII of the Act on the reduction day, the difference between 100% and the percentage by which the approved ex-manufacturer price has been reduced; or
- (b) if there are two or more listed component items for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced under a provision in Division 3B of Part VII of the Act on the reduction day, the difference between 100% and the average of the percentages by which the approved ex-manufacturer price of any one brand of each of the listed component items have been reduced.

Example 1: if there is only one listed component item for which the approved ex-manufacturer price of any one brand of the listed component item has been reduced and that brand is reduced by 10% on the reduction day then the *differential reduction percentage* will be $100\% - 10\% = 90\%$

Example 2: if there are two listed component items and the approved ex-manufacturer price of a brand of one listed component item has been reduced by 10% and a brand of the other listed component item has been reduced by 20% on the reduction day, the average of the percentages by which the approved ex-manufacturer prices were reduced will be $(10\% + 20\%) \div 2 = 15\%$ and the *differential reduction percentage* will be $100\% - 15\% = 85\%$.

Subsection (3) would adjust the approved ex-manufacturer price of a brand of a listed component item for the purposes of the definitions of *day before component AEMPs*, *reduction day component AEMPs*, and *non-listed component price*. The approved ex-manufacturer price would be adjusted for any difference in quantity or amount or pricing quantity of the listed component drug in the listed component item.

Example 1: if the combination item contains 125mg of Drug A and the listed component item contains 100mg of Drug A, and a brand of the listed component item has an approved ex-manufacturer price of \$100, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug A reflects the difference as follows: $\$100 \times (125/100) = \125 .

Example 2: if the combination item contains 100mg of Drug B and has a pricing quantity of 30 and the listed component item also contains 100 mg of Drug B, and a brand of the listed component item has an approved ex-manufacturer price of \$50 and a pricing quantity of 28, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug B reflects the difference as follows: $\$50 \times (30/28) = \53.57 .

Example 3: if the combination item contains 125mg of Drug C and has a pricing quantity of 30 and the listed component item contains 100 mg of Drug C, and a brand of the listed component item has an approved ex-manufacturer price of \$50 and a pricing quantity of 28, the approved ex-manufacturer price of the listed component item will be adjusted so that the value attributed to Drug C reflects the difference as follows: $\$50 \times (125/100) \times (30/28) = \66.96 .

Subsection (4) would deal with the circumstance where there is more than one pharmaceutical item that has the smallest difference as referred to in the definition of *listed component item*. In these circumstances, the pharmaceutical item, that is not an exempt item, that would result in the smallest reduction to the approved ex-manufacturer price of the brand of the combination item under this section would be taken to be the listed component item.

Item [3] new section 103

Item 3 would insert a new section 103 that specifies that new sections 65A and 85A would apply in relation to reduction days occurring on or after 1 July 2022. From this date

onwards, flow-on price reductions to combination items under the Act will occur automatically without need for the Minister and responsible person to enter into a new price agreement.

Part 2 – Amendments commencing on 1 October 2022

This Part amends the circumstances for when originator brands are not taken into account in the calculation of the weighted average disclosed price so that where a drug in the brand of a pharmaceutical item has been listed on F2 for at least 18 months, and there has been no price disclosure reduction to any brands of that pharmaceutical item, the originator brand will not be taken into account.

Items [4] and [5] paragraph 84(1)(b) and paragraph 84(1)(c)

Section 84 specifies the circumstances in which information about an originator brand must not be taken into account when working out the weighted average disclosed price for a brand of pharmaceutical item.

Item 4 would repeal paragraph 84(1)(b) of the Principal Regulations and replace it with a new paragraph that provides additional circumstances for when originator brand information must not be taken into account. New subparagraph 84(1)(b)(i) would provide that information about an originator brand must not be taken into account in calculating the weighted average disclosed price if the drug in brand had been on F2 for at least 18 months and during that period there had been no price disclosure reduction under Division 3B of Part VII of the Act to any brand of pharmaceutical item that has the same drug and manner of administration as the brand.

If subparagraph 84(1)(b)(i) were to not apply, new subparagraph 84(1)(b)(ii) would provide that originator brand information must not be taken into account if at the end of the previous data collection period the drug in the brand had been on F2 for at least 30 months.

Item 5 would make a consequential amendment to Paragraph 84(1)(c) of the Principal Regulations to reflect that, in the circumstances where section 84(1)(b)(i) applies, the originator brands must not be taken into account only where on a date at least 18 months before the end of the previous data collection period there were two or more related brands that shared the same drug and manner of administration as the brand and had the same pharmaceutical item or where bioequivalent or biosimilar to each other.

The amendments that would be made by item 5 and item 6 would apply to data collection periods beginning on or after 1 October 2022 (see new section 103 of the Principal Regulations, inserted by item 10).

Items [6] and [7] new subsection 103(2)

Items 6 and 7 would insert a new subsection 103(2) that specifies that the amendments to section 84 by items 4 and 5 would apply to data collection periods beginning on or after 1 April 2022.

Part 3 – Amendments commencing on 1 April 2023

This Part introduces a the concept of **adjusted net revenue** to be used in the method for determining a weighted average disclosed price in sections 71 to 81 of the Principal Regulations, that will apportion the value of any discounts offered for brands of a

responsible person that have an approved ex-manufacturer price that is less than \$4 to brands of the same responsible person that have an approved ex-manufacturer price that is more than \$4. This Part also removes the requirement that responsible persons exclude information about supplies to public hospitals in the information to be provided under the price disclosure requirements once a drug has been listed on F2 for at least 42 months.

Item [8] new section 73A

Item 8 would insert a new section 73A after section 73 of the Principal Regulations which would introduce a new step in the weighted average disclosed price calculation in sections 71 to 81. The new section would introduce a new concept of *adjusted net revenue* which would be used in place of the existing concept of net revenue in the weighted average disclosed price calculation.

The intention of this amendment is that discounting of a responsible persons brands of pharmaceutical items that have approved ex-manufacturer prices of \$4 or less would be reflected in the net revenue of the responsible person's brands that have approved ex-manufacturer prices that are more than \$4. Brands of pharmaceutical items that have an approved ex-manufacturer price of \$4 or less will not be subject to price disclosure reductions under new floor price provisions (new Division 3BA of the Act) to be inserted by the Enhancing the PBS Amendment Act commencing 1 July 2022. New section 73A would apply to data collection periods beginning on or after 1 October 2022 (see new section 103 of the Principal Regulations, inserted by item 10).

Subsection (1) would specify which method applies for working out the *adjusted net revenue* for a brand of pharmaceutical item. If the approved ex-manufacturer price for the brand of pharmaceutical item were \$4 or less, the *adjusted net revenue* would be worked out using the method in subsection (2). If the approved ex-manufacturer price of the brand of pharmaceutical item were more than \$4, the *adjusted net revenue* would be worked out using the method in subsection (3).

Subsection (2) would prescribe the method for working out *adjusted net revenue* for a brand of pharmaceutical item that has an approved ex-manufacturer price that is \$4 or less. *Adjusted net revenue* would be worked out by multiplying the adjusted volume of the listed brand of the pharmaceutical item sold for the data collection period (worked out under section 72) by the average approved ex-manufacturer price (worked out under section 73) of the listed brand of the pharmaceutical item for the data collection period.

Subsection (3) would prescribe the method for working out *adjusted net revenue* for a brand of pharmaceutical item that has an approved ex-manufacturer price that is more than \$4. This method would apportion the value of any discounts offered by a responsible person for their brands that have an approved ex-manufacturer price that is \$4 or less to the net revenue of that responsible person's brands that have an approved ex-manufacturer price that is more than \$4. This would be done by:

- (a) working out the net revenue for all brands of the responsible person that have an approved ex-manufacturer price that is \$4 or less.
- (b) working out what the net revenue would have been had those brands been sold at the approved ex-manufacturer price.

- (c) obtaining the total value of discounts and incentives that were offered for brands that were \$4 or less by subtracting the amount worked out under (a) from the amount worked out under (b).
- (d) working out the *net revenue adjustment percentage* by dividing the total value of discounts and incentives offered for brands of the responsible person that had an approved ex-manufacturer price that was \$4 or less under (c) by the total net revenue for all brands of the responsible person that had an approved ex-manufacturer price of more than \$4.
- (e) reducing the net revenue for the brand of pharmaceutical item by the percentage worked out under (d).

Item [9] subparagraph 74(2)(b)(i)

Item 4 would amend subparagraph 74(2)(b)(i) of the Principal Regulations to use the adjusted net revenue worked out under the new section 73A instead of net revenue when calculating the disclosed price for a brand of pharmaceutical item under section 74. This is the next step in the calculation of the weighted average disclosed price. The weighted average disclosed price would therefore be worked out using adjusted net revenue instead of net revenue.

Items [10] and [11] subsection 85(2) and new subsection 85(2A)

Section 85(2) specifies the information that responsible persons must provide to comply with the price disclosure requirements under section 99ADC of the Act. Item 7 would amend section 85(2) of the Principal Regulations to remove the general exception that information about supplies to public hospitals is not required to comply with price disclosure requirements. New section 85(2A) would provide a more limited exception for information about supplies to public hospitals. New section 85(2A) would specify that subsection (2) would not apply to supply of a brand of a pharmaceutical item to a public hospital if the drug in the pharmaceutical item has not been on F2 for at least 42 months at the end of the previous data collection period for the brand.

The amendments that would be made by item 7 and item 8 would apply to data collection periods beginning on or after 1 October 2022 (see new section 103 of the Principal Regulations, inserted by item 10).

Item [12] new subsections 103(3) and 103(4)

Items 12 would insert new subsections 103(3) and 103(4) which would specify that new section 73A and amended section 74 would apply to data collection periods beginning on or after 1 April 2022. Item 12 would also insert new subsection 103(5) which would specify that the amendments to section 85 by items 10 and 11 would apply to information in relation to supplies of brands of pharmaceutical items occurring on or after 1 October 2022.

Part 4 – Amendments commencing on 1 July 2023

This Part introduces a method for ascertaining the usual demand for a brand of a pharmaceutical item for the purposes of determining the required amount of stock of the brand of the pharmaceutical item that must be kept by the responsible person to comply with new stockholding requirements under new Division 3CAA of the Act which commences on 1 July 2023. This Part also introduces stockholding disclosure requirements for responsible

persons to provide information in relation to the quantity of brands of pharmaceutical items kept in Australia that will be subject to the new stockholding requirements.

Item [13] Part 7 (heading)

Item 13 would repeal the heading of Part 7 of the Principal Regulations and substitute it with ‘Price reduction, price disclosure and stockholding’ to reflect the new stockholding requirements that are to be inserted into this part by the Regulations.

Item [14] new Division 3 sections 85B and 85C

Item 14 would also insert a new Division 3 – Stockholding requirements and new sections 85B and 85C after new section 85A.

New section 85B would specify the method for determining *usual demand* for a brand of a pharmaceutical item for the purposes of subsection 99AEKC(5) of the Act. The usual demand for a brand of a pharmaceutical item would be relevant to determining the minimum quantity of the brand that a responsible person must keep in stock in Australia where the brand is subject to a minimum stockholding requirement under the new Division 3CAA of the Act that will commence on 1 July 2023.

Subsection 85B(1) specifies that the *usual demand* for a brand of pharmaceutical item for a month in a data collection period would be the number of packs of the brand supplied during the data collection period before previous data collection period (the corresponding data collection period in the previous year) for the brand divided by the number of months in that period. Subsection 85B(2) would specify that the number of packs of a brand supplied during a data collection period would be taken to be the number provided in accordance with the price disclosure requirement under paragraph 85(2)(h) adjusted as if the size of the pack equals the pricing quantity of the brand. Subsection 85B(3) clarifies that if a brand of pharmaceutical item is not listed in the period that usual demand would be based on, then usual demand for that brand would be taken to be zero.

New section 85C would specify the information that must be provided by a responsible person for the purposes of the stockholding disclosure requirements under subsection 99AEKF(1) of the Act.

Subsection 85C(2) would specify that the following information must be provided in relation to the quantity of a brand of pharmaceutical item kept in Australia:

- (a) the start and end dates of the period to which the information relates;
- (b) the name of the brand;
- (c) the name of the responsible person;
- (d) the name of the drug in the pharmaceutical item;
- (e) the form of the drug, including its strength;
- (f) the manner of administration of the form of the drug;
- (g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
- (h) the number of packs held in stock at the end of each month in the period.

Subsection 85C(3) would specify that the responsible person must provide the information to the same person to whom the responsible person must give information under the price disclosure requirements under subsection 85(6). Subsection 85(6) requires the responsible person to provide the information to Australia Healthcare Associates Pty Ltd, or to the

Secretary if the responsible person received written notice for the Department to provide the information to the Secretary.

Subsections 85C(4)-(7) would specify the manner and form that the stockholding information must be provided in and prescribe times for that information to be provided.

New sections 85B and 85C would apply to periods beginning on or after 1 October 2023 (see new section 103 of the Principal Regulations, inserted by item 10) and this amendment would be made in anticipation of amendments to the Act by the Enhancing the PBS Amendment Act which commence on 1 July 2023.

Item [15] new subsection 103(6)

Item 15 would insert new subsection 103(6) specifying that the new sections 85B and 85C would apply to information in relation to supplies of brands of pharmaceutical items occurring on or after 1 July 2023.

Statement of Compatibility with Human Rights

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

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) (2021 MEASURES NO. 1) AMENDMENT REGULATIONS 2021

This Disallowable 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 Disallowable Legislative Instrument

This legislative instrument amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (Principal Regulations) to implement measures negotiated in new Strategic Agreements with Medicines Australia and the Generic and Biosimilar Medicines Association acting on behalf of the medicines industry in Australia. These amendments to the Principal Regulations support amendments to the *National Health Act 1953* (the Act) introduced by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021*.

Amendments to the Act and the Principal Regulations relate to the supply of medicines listed on the Pharmaceutical Benefits Scheme (PBS) and arrangements for statutory price reductions to the PBS price (the approved ex-manufacturer price) of PBS listed brands. The measures are intended to:

- a. generate savings to be reinvested in the PBS to support the subsidisation of the continuously growing treatment options for patients; and
- b. mitigate the impact of global medicines shortages on the ability for patients to access PBS listed medicines in Australia.

The measures do this by improving statutory price reductions for PBS medicines and, at the same time, supporting provisions in the act to prevent the prices of PBS medicines from being reduced below what is needed to support reliable supply, and introducing a requirement that pharmaceutical companies that supply older and low-cost medicines that are more susceptible to global supply disruptions hold greater stocks of those medicines in Australia.

This legislative instrument amends the Principal Regulations to specify the detail for the calculation of price reductions and define the ‘usual demand’ for a brand of a pharmaceutical item for the purposes of stockholding requirements. The amendments also specify the information that responsible persons for brands of pharmaceutical items must provide in relation to price disclosure and the quantity of the brand kept in Australia.

Human rights implications

This legislative instrument engages the following rights:

- the right to social security under Article 9 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)
- the right to the enjoyment of the highest attainable standard of physical and mental health under Article 12 of the ICESCR.

Article 9 of the ICESCR recognises the right to social security. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. The PBS is a social security measure that provides subsidised access to medicines for Australians. These amendments to the Principal Regulations assist with the advancement of the right to social security by generating savings that can be reinvested in the PBS to support the subsidisation of medicines.

Article 12(1) of the ICESCR recognises the right of all individuals to enjoy the highest attainable standard of physical and mental health. These amendments to the Principal Regulations support reforms to statutory price reductions of PBS medicines and the implementation of stockholding requirements for the supply of certain older and low-cost medicines. The reforms promote the progressive realisation of the right of everyone to essential healthcare and the enjoyment of the highest attainable standard of physical and mental health by:

- providing savings that can be reinvested into the PBS. This will help to ensure continued subsidised access to the best available treatments as new treatments are discovered and brought to market by the pharmaceutical industry.
- improving the reliability of supply for a large number of medicines that have become increasingly susceptible to global medicines shortages. This will help to ensure the continuity of access to subsidised medicines necessary for the proper treatment and management of common medical conditions.

Conclusion

This legislative instrument is compatible with human rights because it promotes the progressive realisation of the rights to health and social security.