**EXPLANATORY STATEMENT**

**Select Legislative Instrument No. 163, 2015**

*National Health Act 1953*

*National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015*

By authority of the Minister for Health

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 *National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015* (the Regulation) amends Part 5 (Prescriptions and supply), Part 6A Division 2 (Price disclosure), Part 7 (Arrangements of the Pharmaceutical Benefits Advisory Committee) and Part 8 (Transitional provisions) of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations).

The amendments made by the Regulation are necessary to implement measures contained in the Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package announced by the Australian Government in May 2015 and to align with amendments to the Act made by the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (the Amending Act) for that purpose.

The measures requiring amendments to the Principal Regulations are the expansion of early supply provisions for PBS prescriptions, removal of the originator brand from price disclosure calculations, and changes to Pharmaceutical Benefits Advisory Committee (PBAC) membership arrangements.

The PBS operates under Part VII of the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. Part VII of the Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

The PBS Access and Sustainability Package establishes pharmacy funding, medicines pricing arrangements and a range of sector improvements to ensure ongoing access to innovative medicines through a sustainable PBS. It contains measures negotiated following consultations with a wide range of stakeholders from pharmacy, pharmaceutical industry and consumer groups, including measures relating to the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia and the Strategic Agreement with the Generic Medicines Industry Association (now known as the Generic and Biosimilar Medicines Association).

PBS price disclosure arrangements require pharmaceutical companies to disclose specified information about sales of brands of medicines containing a drug on the F2 formulary. A weighted average price is calculated for a medicine every six months using sales data for the previous period and is used to apply reductions in the PBS listed price. Changes made by the Amending Act provide for a brand of a pharmaceutical item with a drug on the F2 formulary to be determined as an originator brand. Those changes also provide for the regulations to prescribe information, which may include information relating to originator brands, that the method or formula for determining the weighted average disclosed price must not take into account.

The Regulation prescribes when and how disclosed data regarding an originator brand are to be removed from the calculation of the weighted average disclosed price. This would affect the weighted average price and potentially increase price reductions as originator brands tend to maintain higher prices than other brands. Adjusting a PBS price to the weighted average with an originator brand removed means that the Government price would reflect the prices at which generic brands of the medicine are being sold in the market, not the prices of all brands. The amendments include safeguards to ensure that the originator brand is included in the calculation if there were no other listed brand of a pharmaceutical item, and that price reductions do not apply in certain circumstances when there is little discounting and low sales volumes for brands of a pharmaceutical item.

The changes for the PBAC recognise the significant increase in the number and complexity of submissions to list medicines on the PBS. The Amending Act increased the maximum number of members of the PBAC by three, established a new Deputy Chairperson role, and provided the option for an industry representative to be nominated and appointed as a member. The amendments support implementation of those changes and the operation of the PBAC under the new membership arrangements.

Safety net early supply provisions were amended by the Amending Act to remove reference to 20 days as the period for an early supply and to provide for the supply interval for a medicine to be specified in a legislative instrument. This will allow the use of a medicine, the listed quantity and the period for an early supply to be better aligned. The Regulation supports implementation of those changes by providing that the supply interval specified in a legislative instrument made under subsection 84AAA(2) of the Act for the purposes of early supply of a specified pharmaceutical benefit applies also as the interval for repeated supply of a pharmaceutical benefit.

The Regulation amends the Principal Regulations by:

* providing the circumstances in and the method by which an originator brand’s disclosed data is to be removed from price disclosure calculations. These include that the originator brand cannot be removed unless:
	+ the drug in the originator brand has been on the F2 formulary for at least 30 months (worked out from the beginning of the data collection period);
	+ within the drug and manner of administration group used for price disclosure, at least 30 months ago there were at least two brands of the same pharmaceutical item, or, at least two brands of different pharmaceutical items that are bioequivalent or biosimilar to each other (again, worked out from the beginning of the data collection period); and
	+ there are at least two brands of the same pharmaceutical item (which applies on an ongoing basis).
* establishing a mechanism to exclude low discount/low sales pharmaceutical items from price disclosure price reductions in some circumstances;
* recognising the new position of Deputy Chairperson for the PBAC;
* identifying the bodies which may nominate PBAC members representing industry ;
* making technical changes so that procedural committee processes which are dealt with in the *Acts Interpretation Act 1901* are not duplicated;
* aligning the interval periods for when repeated supplies of pharmaceutical benefits may be supplied with the new provisions relating to early supply of specified pharmaceutical benefits; and
* simplifying drafting, including removing spent provisions, and providing for transition to the changed price disclosure arrangements.

Details of the Regulation are set out in the Attachment.

The PBS Access and Sustainability Package includes measures relating to the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia and the Strategic Agreement with the Generic Medicines Industry Association (now known as the Generic and Biosimilar Medicines Association). The measures were negotiated following consultations during the first half of 2015 by the Minister for Health and the Department of Health with stakeholders from the pharmaceutical sector including industry, consumer, medical, pharmacist and wholesaler groups. Organisations represented included Medicines Australia, the Generic Medicines Industry Association, the Consumers Health Forum, NPS MedicineWise, the Australian Medical Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, and the National Pharmaceutical Services Association.

The Regulation was drafted taking into consideration the discussions with stakeholders. In mid‑July 2015, a confidential draft was provided to nominated representatives of five key stakeholder groups who had participated in the consultations earlier in the year. Two stakeholder organisations, Medicines Australia and the Generic Medicines Industry Association, accepted invitations to meet with the Department regarding the draft provisions. Comments were received at the meetings and in writing over the ten-day consultation period.

Several changes to the draft Regulation were made as a result of the consultation, including changes to the calculation method for identifying low volume products when a price disclosure price reduction should not apply. The changes resolved the issues raised where that was consistent with maintaining the policy intent.

Communication with industry, pharmacy and other stakeholders will continue as part of the implementation. This will include updates to fact sheets and guidelines for PBS price disclosure.

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 it is registered.

 Authority: Section 140 of the

*National Health Act 1953*

**ATTACHMENT**

**Details of the National Health (Pharmaceutical Benefits) Amendment (2015 Measures No 1) Regulation 2015**

1 - Name of regulation

This section provides that the title of the regulation is the *National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015.*

2 - Commencement

This section provides that sections 1 to 4, Schedule 1 items 5, 6 and 8 to 16, and anything in the instrument not elsewhere covered by the table, commence on the day after it is registered; Schedule 1 items 1 and 2 commence on 1 January 2016; and Schedule 1 items 3, 4 and 7 commence on 1 May 2016.

3 - Authority

This section provides that the regulation is made under the *National Health Act 1953* (the Act).

4 - Schedules

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

**Schedule 1 - Amendments**

*National Health (Pharmaceutical Benefits) Regulations 1960*

Items 1 and 2 – Paragraph 25(3)(a) and Paragraph 25(4)(a)

Items 1 and 2 align the interval periods for when a repeated supply of a pharmaceutical benefit may be supplied with the provisions relating to early supply made by the Amending Act. The period for repeated supplies changes from being a fixed 20 day or 4 day period based on the number of repeats that may be prescribed to being the same period as specified for the pharmaceutical benefit as an early supply under subsection 84AAA(2).

Subregulation 25(2) of the Principal Regulations provides that subregulation 25(3) applies for pharmaceutical benefits which the Minister has determined under paragraph 85A(2)(b) of the Act may be prescribed with more than four repeats, and under paragraph 85A(2)(c) have a manner of administration which is not application to the eye.

Subregulation 25(3) of the Principal Regulations provides that a repeated supply of the benefit may be made to a person only if the supplier reasonably believes that the person has not received a supply of that, or another brand of the benefit, in the period of 20 days immediately preceding the day on which it is to be supplied, or that the previous supply has been destroyed, lost or stolen, or that the repeated supply is necessary, without delay, for the treatment of the person.

Subregulation 25(4) of the Principal Regulations provides that for pharmaceutical benefits other than those to which subregulation 25(3) applies, a repeated supply of the benefit may be made to a person only if the supplier reasonably believes that the person has not received a supply of that, or another brand of, the benefit in the period of four days immediately preceding the day on which it is to be supplied, or that the previous supply has been destroyed, lost or stolen, or that the repeated supply is necessary, without delay, for the treatment of the person.

Item 1 changes the repeat supply period in paragraph 25(3)(a) for a pharmaceutical benefit with more than four repeats to refer to the period specified in a legislative instrument made under subsection 84AAA(2) of the Act for the purposes of early supply of specified pharmaceutical benefits. If no period is specified for the pharmaceutical benefit in the instrument, the period will remain 20 days.

Item 2 makes changes to paragraph 25(4)(a) similar to the changes Item 1 makes to paragraph 25(3)(a), but in relation to the repeat supply period for pharmaceutical benefits which can be prescribed with four or less repeats or have a manner of administration which is application to the eye. The repeat supply period in paragraph 25(4)(a) refers to the period specified for the pharmaceutical benefit in the legislative instrument made under subsection 84AAA(2) of the Act, or if no period is specified, the period will remain four days.

Items 1 and 2 also change paragraphs 25(3)(a) and 25(4)(a), respectively, to include that the relevant period during which a person has not received a supply of the pharmaceutical benefit may also be calculated from the date another benefit with the same pharmaceutical item (i.e. another brand), or benefit that is Schedule equivalent to the benefit is supplied.

Item 3 – Subregulation 37F(3) (note)

Item 3 replaces “Note” as the label of the existing note for regulation 37F with the label “Note 1”. This allows the additional note added under item 4 to be numbered sequentially as “Note 2”.

Item 4 - At the end of subregulation 37F(3)

Item 4 adds as an additional note for regulation 37F, and labelled as “Note 2”, that Subdivision 2A prescribes information that must not be taken into account in determining a weighted average disclosed price. Subdivision 2A is inserted by item 7.

Item 5 - At the end of regulation 37S

Regulation 37S of the Principal Regulations is Step 11, the final step, of the method prescribed in Regulations 37G to 37S for determining the weighted average disclosed price of a listed brand of a pharmaceutical item for a data collection period. Step 11 works out the weighted average disclosed price for the listed brand by reducing the average approved ex‑manufacturer price for the brand over the data collection period by the weighted average percentage difference for all related brands (i.e. brands of pharmaceutical items with the same drug and with the same manner of administration) worked out under Step 10.

Item 5 adds subregulation 37S(4) to provide that Regulation 37S has effect subject to new regulation 37SA, which is added under item 6.

The effect of adding subregulation 37S(4) is that notwithstanding the weighted average disclosed price of a listed brand worked out under regulation 37S (in Step 11), that would otherwise become the approved ex‑manufacturer price of the brand, if the circumstances set out in new regulation 37SA are met, the weighted average disclosed price for the brand is taken to be the applicable approved ex‑manufacturer price. That is, the price of the brand is not reduced by the weighted average percentage difference calculated in Step 10 for the data collection period and a price disclosure price reduction does not occur for that or any brand of the pharmaceutical item. The applicable approved ex‑manufacturer price is defined under section 99ADB of the Act to be the approved ex‑manufacturer price of the brand on the day after the end of the period for which the weighted average price of the brand is determined. The applicable approved ex‑manufacturer price is used in paragraph 99ADH(1)(c) of the Act (the ‘10% test’). Since the 10 per cent test is failed, a price disclosure reduction does not occur.

Item 6 - At the end of Subdivision 2 of Division 2 of Part 6A

37SA When weighted average disclosed price is the same as the applicable approved ex-manufacturer price

Item 6 adds regulation 37SA to set out when the weighted average disclosed price of a listed brand of a pharmaceutical item calculated under regulation 37S for the data collection period is taken to be the amount of the applicable approved ex‑manufacturer price of the brand. Under new subregulation 37S(4), added under item 5, application of the weighted average disclosed price of a listed brand would be subject to new regulation 37SA.

The effect of new regulation 37SA is that price disclosure reductions do not apply in certain circumstances when there is little discounting and low sales volumes for brands of a pharmaceutical item.

New regulation 37SA provides that application of the weighted average disclosed price calculated in regulation 37S would be subject to whether:

* the total adjusted volume for brands of the pharmaceutical item worked out under regulation 37N (Step 7) is more than zero and no more than ten per cent of the sum of the total adjusted volumes for the brands of each pharmaceutical item sharing the same drug and manner of administration, also worked out under regulation 37N (Step 7), and including the total adjusted volume of the pharmaceutical item of the listed brand;
* the weighted average percentage difference worked out for brands of the pharmaceutical item under regulation 37P (Step 8) is not more than three per cent;
* there is not a brand of a pharmaceutical item with the same drug and manner of administration as the listed brand that is bioequivalent or biosimilar to the listed brand of the pharmaceutical item and to which paragraph 37SA(a) (a total adjusted volume of no more than ten per cent of summed total adjusted volumes) and paragraph 37SA(b) (a weighted average percentage difference of no more than three per cent) do not apply;
* the Pharmaceutical Benefits Advisory Committee has not advised the Minister that the pharmaceutical item does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies.

If all of the above apply, the weighted average disclosed price of the brand is taken to be the amount of the applicable approved ex‑manufacturer price of the listed brand of the pharmaceutical item.

Disclosed originator brand data is not excluded when determining whether the conditions in new regulation 37SA all apply due to item 7 and new subregulation 37SB(3).

Item 7 - After Subdivision 2 of Division 2 of Part 6A

Item 7 adds after Subdivision 2 of Division 2 of Part 6A, new Subdivision 2A which is made for subsection 99ADB(6A) of the Act. Subsection 99ADB(6A) is a new subsection added by the Amending Act. Subdivision 2A includes a new heading, ‘Information that must not be taken into account’ and new regulations 37SB and 37SC.

Subsection 99ADB(6A) of the Act provides that the regulations may prescribe information that the method used to determine the weighted average disclosed price for a brand must not take into account (including information that has been provided in compliance with the price disclosure requirements). The information not to be taken into account may include information relating to originator brands.

37SB Information that must not be taken into account

New regulation 37SB contains provisions regarding the purpose and scope of Subdivision 2A, including reference to subsection 99ADB(6A) of the Act.

It includes as new subregulation 37SB(2) that new regulation 37SC (originator brands) prescribes information that must not be taken into account in determining the weighted average disclosed price of a listed brand of a pharmaceutical item (the *WADP brand*) in respect of a data collection period. The term ‘WADP brand’ is introduced for use in new regulation 37SC.

New subregulation 37SB(3) ensures that new regulation 37SA does use originator brand data that would otherwise be excluded.

New subregulation 37SB(4) clarifies that provisions in new Subdivision 2A for excluding information about originator brands are to apply despite the method for determining the weighted average disclosed price for a brand in Subdivision 2, and even if the data to be excluded relates to the brand for which the weighted average disclosed price is being determined.

37SC Originator brands

New regulation 37SC sets out the circumstances where disclosed data for an originator brand would be excluded when determining the weighted average disclosed price of a brand, and the timing for when this would first occur.

Data is disclosed by the responsible person for a brand in accordance with subsection 99ADC(1) of the Act and regulation 37T of the Principal Regulations. The disclosed data essentially relates to sales (revenue, incentives, volume of sales). It is only disclosed data that is excluded. Originator brands continue to contribute otherwise to the method, for example, when using PBS pricing and PBS ‘pricing quantity’ in the method.

New regulation 37SC provides that disclosed data about an originator brand must not be taken into account if three requirements are met. Firstly, that on the first day of each calendar month on which the originator brand is a listed brand in the data collection period, there is another listed brand of the same pharmaceutical item that is not another originator brand. Secondly, that by the end of the previous data collection period, the drug in the WADP brand must have been on F2 for at least 30 months. Thirdly, that on a day at least 30 months before the end of the previous data collection period, there must have been a related brand of the WADP brand that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the WADP brand, or there must have been two or more related brands of the WADP brand that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.

A ‘related brand’ has the same drug and manner of administration: subregulation 5(1) of the Principal Regulations. By assessing whether at least 30 months has run at ‘the end of the previous data collection period’, the 30 months is always applied at the beginning of 1 April or 1 October of the data collection period for which the weighted average disclosed price is being determined.

The two 30 month tests mean that once a drug and manner of administration has a ‘match’ (either two brands of the same pharmaceutical item, or different pharmaceutical items that are bioequivalent or biosimilar to each other) a minimum of three years pass before the weighted average disclosed price is determined without the originator brand data, and a minimum of three and a half years pass before an affected reduction can occur.

The Act considers competition to have entered the PBS market for a drug when at drug level there is a bioequivalent or biosimilar match (or across different drugs if the drugs are in a therapeutic group): section 85AB of the Act. Once this occurs, the drug moves to F2 and price disclosure starts. Situations can arise where there is no bioequivalent or biosimilar match at the level of a particular drug or manner of administration – in these cases the 30 months does not start until there is a match within the same drug and manner of administration. This allows further delay, for example, in situations where a drug has moved to F2 because it is in a therapeutic group, or a particular manner of administration does not have a ‘match’.

On an ongoing basis, even when the 30 month test is met, new paragraph 37SC(1)(a) does not require the removal of an originator brand for a particular pharmaceutical item within a manner of administration unless there is a non-originator brand match. Otherwise, due to removal of the originator brand data, the price disclosure calculations would not have data at the pharmaceutical item level, either because the pharmaceutical item only has an originator brand, or, all brands of the pharmaceutical item are originator brands.

New subregulation 37SC(2) ensures that new paragraph 37SC(1)(a) still works, provided there is a match, if the particular originator or non-originator listed brand is not constant.

New subregulation 37SC(3) provides that the requirement to exclude originator brand data does not apply if taking the originator brand data into account would result in a higher weighted average percentage difference calculated under regulation 37R for the WADP brand and related brands. The method is applied twice, with originator brands excluded, and with them included, and the result that is more likely to achieve a reduction is chosen.

Item 8 - Regulation 38 (definition of *Chairperson*)

This item amends regulation 38 which contains definitions for ‘Part 7 – Arrangements of the Pharmaceutical Benefits Advisory Committee’. The definition of ‘Chairperson’ no longer refers to ‘appointed under regulation 39’ and refers instead to Chairperson of the Pharmaceutical Benefits Advisory Committee (PBAC).

Due to the Amending Act, the Minister must appoint a member of the PBAC under subsection 100B(1C) of the Act, shifting this requirement from the Principal Regulations to the Act. The reference to regulation 39 is no longer required. Item 13 removes regulation 39 from the Principal Regulations.

Appointments made under old regulation 39 are unaffected as the requirement to appoint under subsection 100B(1C) only applies to appointments made after Schedule 1 of the Amending Act commenced: item 40, Schedule 1, Amending Act.

Item 9 - Regulation 38

This item inserts as a new definition in regulation 38 that ***Deputy Chairperson*** means the Deputy Chairperson of the Pharmaceutical Benefits Advisory Committee. Due to the Amending Act, subsection 100B(1D) of the Act provides that the Minister may appoint a PBAC member (other than the Chairperson) as the Deputy Chairperson of the PBAC.

Item 10 - Subregulation 38A(1)

Regulation 38A specifies nominating bodies for PBAC membership. Regulation 38A now also specifies, in subregulation 38A(1), nominating bodies for paragraph 100B(1AA)(a) (industry organisations for PBAC industry member).

The Amending Act inserted new paragraph 100A(3)(aa) referring to ‘industry’ as one of the member groups from which members of the PBAC may be nominated and selected. Appointment of an industry member is not mandatory as it is not one of the groups of interests or professions from which at least one member must be selected. The reference to an ‘industry’ member in the Act is intended to provide for the appointment of a member with expertise in a pharmaceutical or health-related industry relevant to the work of the PBAC.

New subsection 100B(1AA) of the Act provides for an industry member to be appointed from nominations made by industry organisations specified by the regulations, and by industry organisations invited by the Minister to make nominations for an industry member.

New subsection 100B(1AB) of the Act continues to provide for a consumer member to be appointed by the Minister from nominations made by consumer organisations specified in regulations (as previously provided in paragraph 100B(1A)(a) of the Act), and now also provides for individuals and consumer organisations to be invited by the Minister to make nominations for a consumer member.

Item 10 provides that for paragraph 100B(1AA)(a) of the Act, the industry organisations prescribed as bodies which can nominate persons for appointment of an industry member to the Committee are: Medicines Australia Limited, the Generic Medicines Industry Association Pty Ltd trading as the Generic and Biosimilar Medicines Association, and Ausbiotech Ltd.

This item also provides that for paragraph 100B(1AB)(a) of the Act, the consumer organisations prescribed as bodies which can nominate persons for appointment of a consumer member to the Committee are: the Consumers Health Forum of Australia Ltd, the Australian Federation of AIDS Organisations Incorporated, and the Australian Consumers’ Association. The consumer bodies have not changed – they have been relocated from subregulation 38A(1) of the Principal Regulations.

Item 11 - Paragraph 38A(4)(c)

Subregulation 38A(4) prescribes the professional associations of medical practitioners, for paragraph 100B(1A)(d) of the Act, which can make nominations for the appointment of general practitioners as members of the Committee.

This item removes paragraph 38(4)(c), which refers to ‘the Australian Divisions of General Practice Limited’, from the list of professional associations of medical practitioners as the organisation is no longer in existence.

Item 12 - Regulation 38B

Regulation 38B is made for subsection 100B(1B) of the Act and relates to nominations, in particular, the number of nominations. Regulation 38B continues to provide that the Minister must ask nominating bodies specified in the regulations to nominate at least three persons for selection for appointment. The amendment inserts reference to new subsections 100B(1AA) (industry member) and (1AB) (consumer member) of the Act.

This regulation does not apply to nominations that the Minister may choose to invite from bodies not specified in the regulations, from industry organisations for an industry member, or individuals or consumer organisations for a consumer member.

Item 13 - Regulations 39 to 41

Item 13 removes regulation 39 (Minister to appoint a PBAC member as Chairperson) as this requirement is now located in subsection 100B(1C) of the Act.

Regulation 40 continues to provide for resignation by providing that a PBAC member (including the Chairperson and any Deputy Chairperson), may resign by notice in writing given to the Minister.

Regulation 41 continues to provide for the Chairperson to be the presiding member if the Chairperson is present at a meeting. To reflect the new Deputy Chairperson role, the Deputy Chairperson presides at a meeting if the Chairperson is absent. If neither is present, reflecting the procedure under regulation 41 now, the members attending the meeting elect a member to preside at the meeting.

Regulation 40 is also simplified by relying on section 33B of the *Acts Interpretation Act 1901* (Participating in meetings by telephone, etc) which indicates that a body established by an Act (such as the PBAC) may permit its members to participate in a meeting by telephone, closed-circuit television, or any other means of communication. The member (or all members, as the case may be) are taken to be present and to form part of the quorum for the meeting.

Item 14 - Subregulations 42(1) to (3)

Regulation 42 deals with meetings of the Committee. The amendment simplifies regulation 42 by providing that the Chairperson may, from time to time, by notice in writing to all members, convene a meeting of the Committee. Other detail provided for in regulation 42 is removed, in order to simply rely on section 33B of the *Acts Interpretation Act 1901* (Participation in meetings by telephone, etcetera).

Item 15 - Regulations 44 and 45

Regulations 44 and 45 refer to voting and disclosure of pecuniary interests by the Chairperson and members of the PBAC. This item replaces subregulations 44 and 45, which continue to have the same effect, but now also reflect the new role of Deputy Chairperson. The amendments make use of ‘member’ to include all PBAC members, including the Chairperson and Deputy Chairperson, whenever possible, to keep the wording simple and avoid repetition.

44 Voting

Subregulation 44(1) provides that at a meeting of the Committee, the Chairperson and other members present each have a deliberative vote. This item amends the provision to read that at a meeting of the Committee, the members present each have a deliberative vote. The reference to members includes the Chairperson and the Deputy Chairperson.

Subregulation 44(2) provides that a decision at a meeting must be determined by a majority of the votes of the Chairperson and other members present and voting. The provision is revised to refer more simply to a majority of the votes of the members present and voting.

Subregulation 44(3) relates to the situation where an equal number of votes is cast for and against a matter at a meeting and provides that the Chairperson, or the member elected to preside at the meeting, may exercise a casting vote, or that if they decline to do so, the matter is resolved in the negative.

Subregulation 44(3) is amended in a similar fashion to subregulations 44(1) and (2) to change references to the Chairperson, or member appointed to preside to refer more generally to the member presiding at the meeting. This more general reference would also accommodate a Deputy Chairperson presiding in the Chairperson’s absence.

Subregulation 44(4) provides that decisions of the Committee must be recorded in the minutes of the Committee. This is the same as current subregulation 44(4) of the Principal Regulations.

45 Disclosure of pecuniary interests by members

Regulation 45 relates to disclosure of pecuniary interests by PBAC members. The heading to regulation 45 is simplified by removing reference to ‘Chairperson’ and simply referring to ‘members’ (which includes the Chairperson).

Although the obligations remain the same, the simplified drafting allows the role of Deputy Chairperson to be incorporated, and reduces the length of the regulation.

Item 16 - At the end of Part 8

**Division 5 – Provisions for the National Health (Pharmaceutical Benefits) Amendment (2015 Measures No.1) Regulation 2015**

**62 Application**

This item is an application provision and provides that the amendments made by items 5 and 6 of this regulation in relation to new regulation 37SA do not apply to a data collection period that ends before 30 September 2015. This has the effect that the provisions made by item 5, that the application of the weighted average disclosed price for a brand is subject to new regulation 37SA, and by item 6, that sets out in new regulation 37SA when the weighted average disclosed price of a listed brand of a pharmaceutical item calculated under regulation 37S is taken to be the amount of the applicable approved ex‑manufacturer price of the brand, do not apply until the data collection period ending 30 September 2015.

**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 (2015 Measures No. 1) Regulation 2015**

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 *National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015* (the Regulation) amends the *National Health* *(Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to support amendments to the *National Health Act 1953* (the Act) made by the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (the Amending Act).

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the Act which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

The amendments made by the Amending Act and the Regulation are necessary to implement measures contained in the PBS Access and Sustainability Package announced by the Australian Government in May 2015. The measures establish community pharmacy funding through the Sixth Community Pharmacy Agreement, change pricing arrangements for PBS medicines, and facilitate improvements to the pharmaceutical sector.

The amendments in the Regulation relate to supply intervals for repeat supplies of PBS medicines, removal of the originator brand from price disclosure weighted average price calculations, and changes to Pharmaceutical Benefits Advisory Committee (PBAC) membership arrangements.

**Human rights implications**

This legislative instrument is compatible with Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights 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 assists with advancement of this human right by providing subsidised access to medicines for Australians.

The measures in the PBS Access and Sustainability Package are designed to build and maintain capacity to provide consumer access to new, and increasingly expensive, medicines as quickly as possible.

The Regulation changes the method for assigning intervals for repeated supplies of prescriptions. The period that applies for ‘immediate supply’ of a medicine under the circumstances prescribed in the Principal Regulations will now be the period specified in a legislative instrument made for the early supply provisions under the Act. The changes made by the Amending Act provide for different intervals to be specified for different medicines. This allows the period to be better aligned to the use of a medicine and the listed quantity. The Regulation supports implementation of those changes and provides greater clarity for consumers and pharmacists by using the same period as the supply interval for both purposes.

The Regulation prescribes when and how disclosed data regarding an originator brand are to be removed from the calculation of the weighted average disclosed price. This would affect the weighted average price and potentially increase price reductions as originator brands tend to maintain higher prices than other brands. Adjusting a PBS price to the weighted average with an originator brand removed means that the Government price would reflect the prices at which generic brands of the medicine are being sold in the market, not the prices of all brands. The amendments include safeguards to ensure that the originator brand is included in the calculation if there were no other listed brand of a pharmaceutical item, and that price reductions do not apply in certain circumstances when there is little discounting and low sales volumes for brands of a pharmaceutical item.

The price disclosure changes will improve the operation of the PBS by delivering better value for money for PBS medicines through price reductions and by protecting some products from price reductions. This will assist consumers by reducing out-of- pocket costs for some PBS medicines and helping to maintain the availability of low usage items.

The changes for the PBAC recognise the significant increase in the number and complexity of submissions to list medicines on the PBS. The Amending Act increased the maximum number of members of the PBAC by three, established a new Deputy Chairperson role, and provided the option for an industry representative to be nominated and appointed as a member. The Regulation supports implementation of those changes and the operation of the PBAC under the new membership arrangements. Changes to PBAC membership arrangements will improve the capacity, flexibility, efficiency and transparency of PBAC processes and reduce the time to list medicines for certain types of submissions. This will benefit consumers through faster access to new medicines.

The PBS Access and Sustainability Package is the result of extensive consultation with stakeholders across the PBS supply chain. The Government worked with more than 20 stakeholder groups to develop a package of measures that will ensure ongoing access to innovative medicines through a sustainable PBS. Inputs and ideas were canvassed and received from all sectors and detailed negotiations were held with the pharmacy, pharmaceutical industry, and consumer organisations.

Together, the measures provide a fair and balanced approach. PBS benefits and savings are shared across Government, suppliers and consumers. Patients benefit from the changes as they support sustainable mechanisms for supply, subsidy and ongoing affordable access to medicines.

**Conclusion**

This Legislative Instrument is compatible with human rights as it advances the protection of human rights.

**The Hon. Sussan Ley MP, Minister for Health**