Australian Government
Department of Health

FACT SHEETS

PBS Access & Sustainability Measures

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Extension of Existing Pharmacy Location Rules

What will the measure do?
From 1 July 2015, the Commonwealth will extend the Pharmacy Location Rules (Location Rules) to 30 June 2020 (a further five years).

The Location Rules are a regulatory tool intended to support the geographical distribution of community pharmacies from which people can access Pharmaceutical Benefits Scheme (PBS) medicines. The Location Rules set out location based criteria that regulate the establishment of new pharmacies and the relocation of existing pharmacies approved to supply Pharmaceutical Benefit Scheme (PBS) medicines under section 90 of the *National Health Act 1953* (the Act).

The Location Rules are made as a Ministerial Determination and their extension is covered by Section 99(Y) of the Act.

While the Location Rules will be retained for the duration of the Sixth Community Pharmacy Agreement (6CPA), it is important to ensure their effectiveness is assessed in how they support access to timely and affordable PBS medicines for all Australians. For this reason, within the first two years of the 6CPA a public review, conducted by an independent reviewer, will be undertaken (refer to the fact sheet *A Comprehensive Review of Pharmacy Remuneration and Regulation*).

What is the impact?
Retention of the Location Rules will continue to ensure all Australians continue to have access to medicines subsidised via the PBS, while the Comprehensive Review is undertaken.

Discounting PBS Patient Co-Payment

What will the measure do?
From 1 January 2016, pharmacists will be given the option to discount the Pharmaceutical Benefits Scheme (PBS) patient co-payment, providing access to cheaper medicines for consumers.

Community pharmacies will be allowed (but not mandated) to discount the co-payment by a maximum of $1.00 (for example, discounting the current maximum concessional co-payment to as low as $5.10 from $6.10, and the maximum general co-payment to $36.70 from $37.70).

This initiative will:

- enable competition between pharmacies and drive value for consumers;
- support increased substitution of generic medicines (which are generally less expensive to consumers);
- reduce an inequity where PBS concessional scripts can be discounted consistently with general scripts; and
- provide immediate benefits to patients through the reduction of out-of-pocket costs.

What is the impact?
This measure will increase competition in the pharmacy sector and provide all Australians the ability to negotiate a reduction to the price of their PBS co-payment.

The existence of a maximum discount level will support a continued price signal for consumers, while offering pharmacies a choice as to what discount they may elect to provide.

Many general patients already benefit from discounting practices in the pharmacy sector, and this measure will enable concessional patients to also benefit from potential discounts. This provides the opportunity for concessional patients to access cheaper medicines, with up to $1 off every script where a pharmacy offers a discount.

The average concession card holder uses 17 scripts per year, and most do not reach their safety net. Therefore, these consumers could save $17 per year.

High volume users will benefit from upfront lower costs, and as safety net arrangements will continue, will still receive medicines for free after reaching the safety net.

General patients who use medicines that cost more than $37.70 will also be eligible for the $1 discount.

Expansion of the Safety Net 20 Day Rule Arrangements

What will the measure do?
This measure extends the Pharmaceutical Benefits Scheme (PBS) early supply provisions, known as the Safety Net 20 Day Rule (SN20DR), to apply to a broader range of PBS listed medicines, as recommended by the Pharmaceutical Benefits Advisory Committee (PBAC).

This change recognises it is important to ensure an appropriate interval is maintained for patients in filling PBS and Repatriation Pharmaceutical Benefits Scheme prescriptions (eg 20 days). While this change does not stop supply within this interval, it means that if resupply is, for example within the 20 days, the patient's usual co-payment will not count towards their safety net threshold.

This change, which extends the original SN20DR policy, reflects the PBAC recommending the default position should be all medicines that are suitable for inclusion in the SN20DR should fall under these arrangements, unless evidence is provided to the contrary. It will therefore improve the consistency of access to consumers – an important principle of the PBS.

Medicines specifically excluded from this rule include treatments for cancer, palliative care and individual treatments with high dosage variability. Further, the policy does not affect the operation of special provisions which allow a prescriber to direct that all repeats of a PBS prescription be supplied at the one dispensing, should there be a need, clinical or otherwise, to do so.

What is the impact?
Under this measure, the financial incentive for patients to obtain excess supplies in advance of treatment is removed. This measure supports the quality use of PBS medicines by discouraging access in advance, or in excess, of therapeutic need, reducing quantities of unused medicines in the community, and reducing waste.

The implementation date of 1 January 2016 is in line with the PBS safety net which operates by calendar year. Changes to pharmacy software and the Department of Human Services claims systems will be required.

F1 Medicines Pricing Arrangements

What will the measure do?
The measure will apply a one-off statutory price reduction of five per cent to all brands of pharmaceutical items on the Pharmaceutical Benefits Scheme (PBS) formulary 1 (F1) after they have been listed for at least five years.

The one-off reductions will commence 1 April 2016 and will be applied each April until 1 April 2020 as different medicines on the F1 formulary reach their five year anniversary on the PBS.

This measure is part of a balanced package of pricing reforms being applied across the PBS and impacting drugs on both the F1 and F2 formularies. This measure will help to create the capacity needed to continue to list new and innovative medicines on the PBS as quickly as possible. It will also increase consumer access to affordable PBS medicines, and contribute to the sustainability of the PBS.

What is the impact?
This measure will result in patients and the Government paying less for some PBS medicines.

While this measure will impact on revenue generated by pharmaceutical companies in the innovator sector, it will also build capacity for new investment in medicines which benefit all Australians and deliver a sustainable and affordable PBS.

This measure is part of a balanced approach to ensuring companies in this sector share a part of the burden of PBS savings and contribute to the ongoing cost of new PBS listings without materially threatening their viability. These companies are the ones that most benefit from new listings, so it is reasonable that they contribute directly from the F1 price reductions to maintain the sustainability of the PBS.

It has been estimated that it takes five years for pharmaceutical companies to recoup the research and development costs associated with bringing a new medicine to market. This measure has taken this into account so the reductions apply to only pharmaceutical items on F1 that have been listed for at least five years.

Improvements to Price Disclosure – Remove Originator

What will the measure do?
The measure will deliver improved value for the taxpayer from price disclosure arrangements, particularly for those medicines which have been listed under the Pharmaceutical Benefits Scheme (PBS) formulary 2 (F2) for three years or more. It will remove the originator brand as part of the calculation of the weighted average disclosed price for medicines.

As originator brands can continue to occupy a large market share and usually do not discount (or discount modestly), excluding their data will allow the PBS prices of medicines to drop more quickly than is currently the case. The originator brand will remain available on the PBS but will only be subsidised up to the level of the Generic Weighted Average Disclosed Price.

This change will commence on 1 October 2015 with the first price disclosure reduction under the new policy able to occur from 1 October 2016.

The implementation of this change includes safeguards to enable policy to be applied in such a way as to maintain the sustainability of the PBS without compromising patient access to certain low-volume medicines.

What is the impact?
This measure will result in patients and the Government paying less for some PBS medicines.

The limitation of this measure to medicines which have been in F2 for three years or more ensures that new generic medicines have an opportunity to build their market share and not be dissuaded from entering the market during that period. Evidence shows generics achieve 50 per cent market penetration by year three.

Removing the originator brand from the price disclosure calculation directly supports the intention of the policy, being to ensure a fair price is paid by the Commonwealth for all PBS medicines. This measure therefore builds on current price disclosure policy and will not increase red tape for industry.

Improvements to Price Disclosure – Combination Items

What will the measure do?
The measure will ensure that price disclosure reductions from discounts on component ingredient drugs are applied consistently to the price of combination items containing those component drugs.

The measure will amend the current pricing policy for multi-ingredient and multi-component medicines ('combination items') listed as formulary 2 (F2) medicines on the Pharmaceutical Benefits Scheme (PBS).

The process of flowing on F2 component medicine price reductions to F2 combination items will commence on 1 April 2016.

There can be significant price differences between component medicines and combination items containing the component medicines, in some cases more than 80% different. This is due to an existing 'loophole' in the price disclosure framework. Accordingly, this change will address the loophole by ensuring appropriate price reductions are applied to combination items on the PBS.

There are 34 combination items out of 95 that are listed on the PBS that have significant price differentials between the component medicines and combination items containing the component medicines. This means that currently the Government and consumers are paying more than the sum of the individual ingredients for combination items. It is estimated government has paid over $200 million more through this loophole.

What is the impact?
This measure will result in savings for both the Government and consumers through reduction in prices paid for PBS-listed medicines, with over $600 million being saved over five years.

There will be some savings to patients.

While there are some individual pharmaceutical companies that will be impacted by this measure, it is supported by all stakeholders including the Pharmacy Guild, Medicines Australia, the Generic Medicines Industry Association, and consumers.

Improved Market Access for Generic Medicines

What will the measure do?
The measure will support the ongoing sustainability of the Pharmaceutical Benefits Scheme (PBS) by increasing the number of dates on which the price of a PBS medicine can change from the current three dates per year, to six per year.

The listing of the first generic brand of a medicine triggers a statutory price reduction of 16 per cent. Under previous arrangements, only three price changes per year would occur. Under new arrangements, this measure will expand the number of times a new generic brand can be listed per year.

This will allow some, first to market, generic brands of medicines to list and trigger statutory price reductions earlier than currently possible, resulting in reduced prices for medicines flowing to both the consumer and the Government earlier and more frequently.

This change is part of a balanced package of reforms being applied across the PBS and will enable price changes to occur on 1 February, 1 April, 1 June, 1 August, 1 October and 1 December each year.

What is the impact?
Consumers will directly benefit through the ability to access generic medicines sooner. These medicines will deliver the same health benefits, but be at a lower cost. The changes will be implemented administratively through the Department of Human Services payment systems.

Streamlining of Pharmaceutical Benefits Advisory Committee Processes

What will the measure do?
From 1 July 2015 the measure will seek to streamline the operations of the Pharmaceutical Benefits Advisory Committee (PBAC) and the process for listing medicines on the Pharmaceutical Benefits Scheme (PBS).

This measure is designed to improve the operations of the PBAC. It will streamline and strengthen the PBAC's capacity to consider the increasing number and complexity of submissions and make recommendations for listings in the most effective and efficient way. These enhancements follow feedback from various stakeholder groups on ways the operation of the PBAC could be improved. It also follows a Senate Inquiry in early 2015, and reflects discussions with many groups during the negotiation of the PBS Access and Sustainability package.

This measure will expand the PBAC membership from 18 to 21 members, including a new Deputy Chair, and provide the opportunity for members to be nominated and appointed from industry. It will also create a PBAC Executive for triaging and considering certain applications.

The changes will allow for an improved level of engagement with key stakeholders such as consumers and clinicians to inform the PBAC's decision-making process. The improved transparency of the process and outcomes will generate more informed public debate about the true benefits of a medicine, and allow patients and prescribers to make informed decisions.

The changes will facilitate data collection and research for PBS drugs to track real-life benefits and side effects to ensure the listing of medicines on the PBS is properly targeted. This is particularly the case where a medicine addresses an area of high clinical need, but where the extent of additional clinical benefit is unclear.

As a package, the changes will improve the capacity, flexibility, efficiency and transparency of PBAC processes and improve PBS listing timeframes.

What is the impact?
Stakeholder groups support changes that will streamline and strengthen the PBAC's capacity and capability to consider and recommend the listing of clinically and cost-effective medicines in the shortest possible timeframe and at the lowest cost and regulatory burden to industry.

Maintain and Refocus Fees for the Efficient Funding of Chemotherapy Medicines

What will this measure do?

From 1 July 2015, this measure will continue to provide additional remuneration for chemotherapy compounders to ensure continued access to chemotherapy medicines for Australians.

This measure will also revise the payment structure within the funding envelope to implement a two-tiered fee structure to recognise Therapeutic Goods Administration (TGA)-licensed compounders, and alter the current payment arrangements to directly reimburse chemotherapy compounders.

Community pharmacies and private hospitals will continue to receive the existing fee of $80.26 for each chemotherapy infusion and public hospitals, participating in the Pharmaceutical Reforms, will receive $42.67.

In addition to the above, a new, two-tiered fee structure will be implemented:

- a $60 per infusion fee for compounders that meet TGA-licensing requirements; and
- a lower fee of $40 for other compounders, including pharmacies and hospitals which compound in-house.

To support all compounders, and ensure the most efficient payment model, compounders will be directly remunerated this additional fee, with the amount payable dependent on whether they are TGA licensed. This approach addresses concerns raised by the findings of the 2013 Review of Funding Arrangements for Chemotherapy Services and the ANAO review of the Fifth Community Pharmacy Agreement, and provides greater visibility of compounder costs and payment arrangements.

This measure will further recognise that the viability of chemotherapy medicines must be secured, to ensure people continue to receive high-quality and appropriate medicine according to their needs. It will further ensure that chemotherapy access will not be reduced and costs will not be increased for patients.

To ensure sufficient time to transition to these new arrangements, pharmacies will be able to continue to claim a $40 fee through the usual PBS online process up to 31 August 2015. During this time the Department will consult with the full range of stakeholders to ensure effective implementation of the new arrangements from 1 September 2015. From that point forward the intention is that the full $40/$60 fees as applicable would be paid directly to compounders, and TGA-licensed compounders will be paid an additional $20 for any compounds prepared during the transitional period.

What is the impact?

All Australians who require access to chemotherapy medicines will continue to have access to these medicines.

Chemotherapy providers must make a substantial financial investment to meet the technical requirements associated with preparation of chemotherapy. As a result, there are only a small number of providers, with 80 per cent of all chemotherapy services delivered through one per cent of all pharmacies.

A Comprehensive Review of Pharmacy Remuneration and Regulation

What will the measure do?
The measure will deliver a comprehensive review and public evaluation of pharmacy remuneration and regulation within the first two years of the Sixth Community Pharmacy Agreement (6CPA). It will support a transparent and public assessment of the cost-effectiveness of all parts of remuneration (both to pharmacy and wholesalers), as well as the appropriateness of regulations such as Pharmacy Location Rules. This will help inform arrangements for pharmacy, including dispensing and wholesaling arrangements, into the future.

Many recent reports, including the 2014 National Commission of Audit, the Productivity Commission's Competition Policy Review, the Australian National Audit Office (ANAO) report into the *Administration of the Fifth Community Pharmacy Agreement*, and the Productivity Commission paper titled *Efficiency in Health*, have highlighted the need to look more closely at pharmacy remuneration and regulation. This includes the application of Pharmacy Location Rules, which determine where pharmacies are located and approved to provide Pharmaceutical Benefits Scheme (PBS) medicines to consumers.

The review also specifically addresses findings from the ANAO report on the Fifth Community Pharmacy Agreement, which highlighted pharmacy remuneration has not been fully reviewed since 1989.

The review is expected to commence on 1 September 2015, and be completed by 1 March 2017.

The review will be conducted by a panel of three eminent reviewers, in order to provide a diversity of views and to show the significant public interest. The review will cover:

- Pharmacy Location Rules, and their role in supporting access to PBS medicines;
- remuneration through pharmacy, both in terms of the level of funding and how this is provided to pharmacy for dispensing PBS medicines; and
- PBS supply chain arrangements, including logistics and distribution of medicines across Australia, including regulatory requirements and cost to the community and Government.

What is the impact?
This comprehensive review will assist with future remuneration and regulation of community pharmacy (and wholesalers) arrangements.

Pharmacy Remuneration

What will the measure do?

The measure changes how pharmacies are remunerated through the Sixth Community Pharmacy Agreement (6CPA), to support access to, and quality use of, Pharmaceutical Benefit Scheme (PBS) medicines in Australia.

The changes, which follow comprehensive consultation and discussion with a range of pharmacy stakeholders, as well as industry and consumers, will:

- continue to provide pharmacy dispensing fees and dangerous drug fees. Other existing fees (eg, container fees) will also continue;
- delink pharmacy remuneration from the price of PBS subsidised medicines through the introduction of a predominantly fixed, Administration, Handling and Infrastructure (AHI) fee, to replace the current six tier retail mark-up. This recognises that the impact of PBS pricing policy, such as price disclosure, had previously impacted the remuneration provided to pharmacy for handling and dispensing PBS medicine. While for some medicines the AHI fee paid by the Commonwealth will be higher than the previous pharmacy mark-up, for other medicines it will be lower. The new three tier AHI does not replace the four tier mark-up applied to certain s100 medicine dispensing situations (eg, s100 Highly Specialised Drugs Private Hospital and Community Pharmacy);
- continue, but better target, the Premium Free Dispensing Incentive (PFDI) to further support uptake of generic medicines and drive value for the consumer. For more information about the PFDI, please see the PFDI Fact Sheet; and
- apply the Consumer Price Index rather than the Wage Cost Index 9 (WCI9) for annual indexation of specified fees, namely PFDI fee, dangerous drug fee, dispensing fee and AHI fee. All other indexation will use WCI9.

What is the impact?

This measure will ensure that consumers can continue to access their medicines through over 5,400 pharmacies across Australia. It ensures pharmacies are remunerated fairly for providing medicines to consumers, and delivers surety while a full review of pharmacy remuneration and regulation is undertaken in the first two years of the 6CPA.

The delinking of remuneration from the price of a medicine will allow changes to pricing policy, while not having significant impact on pharmacy remuneration.

Continuation of Pharmacy Programmes and Services

What will the measure do?
Previous Community Pharmacy Agreements have recognised a range of professional programmes and services that can be delivered by community pharmacy and pharmacists to support consumers. Under the Sixth Community Pharmacy Agreement (6CPA), the measure will support this continued investment through providing up to $613 million to:

- deliver services which support medication management and adherence, such as Home Medicines Reviews and Dose Administration Aids;
- support programmes which improve health outcomes for Aboriginal and Torres Strait Islander peoples, and people in rural and remote Australia;
- continue to support an accessible and robust rural pharmacy workforce; and
- support initiatives which drive the use of electronic health, and through this enable medication information to be included as part of personally-controlled electronic health records.

In addition, the 6CPA will require that all continuing programmes be evaluated for clinical and cost-effectiveness, to ensure they are based on sound clinical evidence and offer the most cost-effective interventions for consumers. This will ensure all programmes which are delivered through pharmacy and by pharmacists are assessed to the same level of evidence and standards as for all other professions.

These assessments will be undertaken by an independent health technology assessment committee, such as the Medical Services Advisory Committee (MSAC), to be determined by the Minister, and will inform how to best target investment in evidence-based services delivered by pharmacy and pharmacists in the future (refer to the fact sheet *Cost-Effectiveness Assessment of Pharmacy Programmes and Services*).

As part of this investment in programmes and services, the Government and the Guild have jointly agreed to look at ways of improving access to pharmacy services for all Australians (such as through increasing opening hours and the reach of services where appropriate).

What is the impact?
This measure ensures that patients can receive services through pharmacy and by pharmacists which improve their health outcomes and offer value to the Australian community. During the first year of the 6CPA, a number of programmes will continue at current funding levels while these assessments are undertaken. Any changes to programme arrangements will be informed by recommendations made by independent assessment groups, and will inform ongoing levels of investment in the future.

Cost-Effectiveness Assessment of Pharmacy Programmes and Services

What will the measure do?
This measure will ensure all programmes and services delivered through community pharmacy and by pharmacists deliver maximum benefits for the Australian consumer, and represent cost-effective services that improve patient health. It will achieve this by ensuring all programmes and services are reviewed for clinical and cost-effectiveness and the health benefits they offer to the community by an independent health technology assessment body, such as the Medical Services Advisory Committee (MSAC), to be determined by the Minister.

This process will ensure pharmacy programmes and services are assessed against the same standards of evidence as for other health professions. It supports a consistent approach to informing investment that delivers the greatest benefit to consumers, and will include existing programmes and services, as well as investment in a range of new programmes and services delivered through community pharmacy.

This measure directly addresses feedback from many groups through consultations on the development of the Sixth Community Pharmacy Agreement (6CPA), particularly around differential standards by which Government makes decisions to invest in healthcare related services. It also ensures objective assessment by an independent assessment body.

It is expected that the way programmes and services are assessed will differ, based on levels of existing evidence. Many services have a greater evidence base as they are well established, and some services are more recent. In addition, assessments will look prospectively at what information may be needed to inform recommendations, particularly for trial programmes which will be implemented under the 6CPA.

What is the impact?
For the first year of the 6CPA, programmes and services which are continuing from the Fifth Community Pharmacy Agreement will continue to be supported, while a clinical and cost-effectiveness assessment is undertaken. Outcomes from these assessments will inform future funding priorities, and ensure funding is invested in programmes and services that are clinical and cost-effective, and deliver the best benefit and value to consumers.

This measure represents a broad shift towards outcome-based funding of services to deliver demonstrable and measureable benefits to the consumer, such as improved medication adherence and compliance.

Promoting Innovative Pharmacy through Trialling New Pharmacy Programmes and Services

What will the measure do?
The measure will support investment of up to $50 million for a Pharmacy Trial Programme (PTP), which will explore services and programmes which seek to expand the role of pharmacists as part of the primary healthcare team in the delivery of a range of services that improve outcomes for consumers. This may include services that support screening and early intervention, improved medication adherence and compliance, as well as a range of services that support health checks and minor ailments management through pharmacy.

In determining priorities for the PTP and the trials to be undertaken, there will be extensive consultation with the Pharmacy Guild and a range of stakeholders and bodies as required.

A particular focus of the PTP will be on programmes and services that support consumers in rural and remote areas of Australia, as well as particular population groups such as Aboriginal and Torres Strait Islander peoples. It is expected that trials will seek to integrate (not duplicate) other areas of investment in the health sector, including eHealth and Primary Healthcare Networks.

Trials will be determined following wide consultation with stakeholders across pharmacy, consumers and other health professional groups, and will be assessed by an independent health technology group, such as the Medical Services Advisory Committee (MSAC), to be determined by the Minister to inform decisions around future investment (refer to the fact sheet *Cost-Effectiveness Assessment of Pharmacy Programmes and Services*). As part of the Sixth Community Pharmacy Agreement (6CPA), funding of up to $600 million has been set aside to invest in new programmes or services which are recommended following this assessment, and deliver clinical and cost-effective outcomes to the community.

What is the impact?
This measure will fund a number of trials that seek to expand programmes and services delivered by pharmacy, as an accessible healthcare point. This will include a range of programmes which support quality use of medicines for all consumers, as well as services which seek to integrate pharmacy as part of the primary healthcare team.

In supporting any future investment, the measure will also ensure all programmes and services going forward are clinically and cost effective to the benefit of patients. Specifically the proposal creates a mechanism for the trial of new programmes and services, which will be tested and evaluated for cost-effectiveness in the first two to three years of the 6CPA.

Removal of PBS Subsidy for certain Low-Cost, Over-The-Counter Medicines

From 1 January 2016, some medicines that are also available over-the-counter will be delisted from the Pharmaceutical Benefits Scheme (PBS). Over-the-counter medicines can be sold directly to a consumer without a prescription from a healthcare professional. Some relieve aches, pains and itches. Others treat conditions such as athlete's foot.

In general, over-the-counter medicines are inexpensive but after applying the pharmacy remuneration charges for dispensing, the cost of these products to the Government when accessed via the PBS is disproportionally inflated. For example:

- Paracetamol 500mg tablets can be purchased over-the-counter for less than two dollars ($2) for a pack of 100 tablets. However, the price to the PBS is $5.97.

This measure is based on the April 2015 recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC), which considered the effect of removing a PBS subsidy for certain medicines costing less than $6.10.

PBS subsidies will continue for: emergency drugs; nicotine replacement therapy; palliative care listings; nutritional products; intravenous drugs; listings relevant for Aboriginal and Torres Strait Islander peoples and Paraquad programme; enzyme replacements; and vitamin supplements.

The availability of over-the-counter medicines will not change, and consumers can continue to buy them from pharmacies or other retailers.

While it is recognised some consumers will not be able to access some of these over-the-counter medicines for free, once they reach their safety net, there are a range of other measures that will make medicines more affordable. These include the discounting of the PBS co-payment and price changes that encourage greater access to lower cost generics.

This is one part of a balanced package of measures and will help to ensure medicines, which carry a high cost to consumers and would otherwise be unaffordable, can continue to be listed on the PBS as quickly as possible. For example, savings on subsidised paracetamol alone would fund the drug ipilimumab for late stage melanoma.

The proposed final list was considered by the PBAC in July 2015 and the final list of products to be delisted was published in November 2015.

Efficient National Diabetes Services Scheme Supply and Delivery Arrangements

What will the measure do?
From 1 July 2016, the Commonwealth will create efficiencies in the delivery of products under the National Diabetes Services Scheme (NDSS) by directing product supply and delivery through the established Community Services Obligation (CSO) distribution network to community pharmacy.

The CSO Funding Pool already supports supply of the full range of Pharmaceutical Benefits Scheme (PBS) medicines to community pharmacies across Australia within 24 hours, regardless of location. In addition, community pharmacy comprises over 96% of NDSS access points in Australia.

While this change will mean NDSS products will generally only be available through pharmacy in the future, this is consistent with how people access their medicines and in some cases will increase access for consumers. An example includes insulin pump consumables, which are currently only available by mail order or through State and Territory Diabetes Associations.

This measure does not impact the range of products available to eligible registrants under the NDSS, which remains based on clinical evidence. It only impacts on supply and delivery arrangements of these products to Australians.

The Department will work through the implementation of these new arrangements with Diabetes Australia and other affected stakeholders to ensure that people with diabetes continue to be able to readily access the products they need to manage their diabetes, no matter their location.

What is the impact?
All Australians who need access to subsidised diabetes products will still have access to these products through community pharmacy. Around 94% of patients already access these products through community pharmacy.

The benefits of this measure include cost efficiencies through consolidated deliveries of PBS medicines and NDSS products, improved timely access through the provision of products within a set time period nation-wide, and improved customer access by enabling pharmacies to directly order and supply insulin pump consumables to registrants.

It is expected that the efficiencies from new supply arrangements will enable a proportion of the savings from this measure to be reinvested in registrant services and activities which help people more effectively self-manage their diabetes, such as through improved education and support services.

Efficient PBS Wholesaler Arrangements

What will the measure do?
From 1 July 2015 the measure will continue to support the Pharmaceutical Benefits Scheme (PBS) supply chain, ensuring people can continue to receive needed PBS medicines in a timely and efficient manner.

This measure seeks to:

- continue the Community Service Obligation (CSO) Funding Pool, which provides funding to wholesalers for the timely distribution of medicines across over 5,400 community pharmacies in Australia; and
- freeze the indexation for the CSO, but couple this with improvements to the administration of the CSO through the simplification of reporting, regulation and compliance processes, such as:
    - relaxing the reporting requirements for breakages and other specific items; and
    - recognising that high-volume PBS items, which are more regularly ordered, can be ordered less often and more efficiently with the timing of deliveries reflecting a 72 hour commitment for supply to pharmacies.

Arrangements for the CSO, as well as wholesaler remuneration, will be reviewed as part of a comprehensive review of pharmacy remuneration and regulation (refer to the fact sheet *A Comprehensive Review of Pharmacy Remuneration and Regulation*). Regulatory compliance will be reduced by more appropriately targeting key quality and service delivery arrangements.

What is the impact?
This measure will not impact on Australians being able to have continued timely access to essential medicines, regardless of their location.

Community pharmacies will continue to receive products through the CSO in a timely manner, and given high-volume PBS products are the subject of more regular and known ordering patterns by pharmacy it is not expected there would be any impact from relaxing supply chain arrangements for high-volume PBS products.

Pharmaceutical Services Federal Committee of Inquiry – Operations

What will the measure do?
The Government will establish the Pharmaceutical Services Federal Committee of Inquiry (the Committee) under the *National Health Act 1953 (*the Act).

The role of the Committee is to inquire into, and report on, matters relating to the services or conduct of approved pharmacists' supply of pharmaceutical benefits. This includes inquiries into alleged instances of misconduct of approved pharmacists, including cases where approved pharmacists may be claiming supplies made from non-approved pharmacy premises.

The Act allows for the Committee to investigate suspected misconduct by pharmacists approved under Section 90 of the Act. Following an investigation, the Committee is required to provide a report to either the Minister or the Secretary on its findings. The Government is allocating the necessary resources to support the administration and operation of the Committee, given Pharmacy Location Rules will be continuing as part of the Sixth Community Pharmacy Agreement (6CPA).

What is the impact?
After considering a report from this Committee, the Minister may impose a number of compliance measures which can include reprimanding the approved pharmacist, or suspending or revoking their approval. This is in addition to any recovery of monies by the Department of Human Services of inappropriately claimed benefits.

Premium Free Dispensing Incentive (PFDI)

What will the measure do?
As of 1 July 2015, changes to the Premium Free Dispensing Incentive (PFDI) will be implemented as one of the components of the Sixth Community Pharmacy Agreement between the Government and the Pharmacy Guild of Australia.

The PFDI is a separate fee paid to pharmacists when they dispense a brand of medicine that does not have a price premium associated with its brand (thereby encouraging the dispensing of cheaper brands to consumers).

How will PFDI be paid from 1 July 2015?
From 1 July 2015, PFDI will be paid to an approved supplier where the Commonwealth is satisfied that such approved suppliers have dispensed a listed brand in all of the following circumstances:

- the price of the dispensed quantity is above the patient co-payment;
- the brand with the patient contribution is substitutable with one or more brands that do not have a patient contribution; and
- the brand that is dispensed does not have a patient contribution.

What does not attract PFDI?
Items in the following programmes do not attract PFDI:

- Department of Veterans' Affairs Repatriation Pharmaceutical Benefits Scheme (R1);
- Public Hospital Highly Specialised Drugs (HB);
- Public Hospital non-infusible Chemotherapy related medicines (CT);
- Para-Quad medicines (PQ); and
- Prescriber Bag (Emergency Drug Supply) (DB).

Any product listing that has any patient contribution (Brand Premium, Special Patient Contribution or Therapeutic Group Premium) does not attract the PFDI.
Those product listings where the Commonwealth pays the patient contribution are excluded.

The substitutable product listing must not be the same Trade Product Pack.

The substitutable product listing must be in the same programme.

PFDI is not applicable to supplies and claims made from public hospitals participating in the Pharmaceutical Reform arrangements.

What is the impact?
The PFDI will be better targeted to meet the policy intent of increasing the use of generic medicines. The PFDI will now be applied only when brand substitution is available.