Department of Health and Ageing - Medicines Australia

joint monitoring report on

Trends in and drivers of Pharmaceutical Benefits Scheme expenditure

Report for the Access to Medicines Working Group

May 2013

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Executive Summary

- In September 2010, the Australian Government and Medicines Australia signed a Memorandum of Understanding (MoU). The MoU set out a number of ways in which the Government and Medicines Australia could continue to cooperate and collaborate, including a project for joint monitoring of the trends in and drivers of PBS expenditure. This is the second report jointly developed by Department of Health and Ageing and Medicines Australia.
- For the joint monitoring, the Access to Medicines Working Group (AMWG) Sub-group established the Data Working Group (DWG). The DWG is comprised of officials from the Department of Health and Ageing (DoHA), representatives from Medicines Australia (MA) and some of its member companies.
- The DWG is expected to monitor and to report on PBS expenditure trends and growth drivers on a half-yearly basis to the AMWG.
- The primary data source for the joint monitoring project is PBS data processed by the Department of Human Services (DHS – formerly Medicare Australia). Where appropriate, additional data may be sourced from the BEACH survey (compiled by the Australian General Practice Statistics and Classification Centre), PBAC's Drug Utilisation Sub Committee (DUSC), the Department of Families, Housing, Community Services and Indigenous Affairs (FaHCSIA) and the Australian Institute of Health and Welfare (AIHW).
- As part of joint monitoring, the DWG will not forecast or measure future actual expenditure against any forecasts.
- As a starting point in decomposing the PBS expenditure, the Data Working Group (DWG) looked at the two key elements that make up the PBS expenditure - Price and Volume; any factor that impacts (negatively or positively) either price paid by the Government or volume of PBS benefits or both will have a flow on impact on overall PBS expenditure and growth. In addition the DWG also identified a number of subfactors that may also influence price or volume.
- The DWG also identified the various linkages between the key drivers and their subdrivers noting their influence on PBS expenditure growth and their interdependencies.
- This is the second report to the AMWG and extends the analysis contained in the first report tabled in August 2011.

Key Findings

- Overall, Pharmaceutical Benefits expenditure on concessional and general categories (PBS Section 85¹) makes up the vast majority of expenditure in the time period analysed. In terms of growth since 2007-08, the contribution of general and concessional prescriptions to overall growth has fallen whereas the contribution of the Highly Specialised Drugs program had increased.
- The analysis of key drivers shows that in the time period analysed, changes in volume of existing medicines and new listings added to PBS expenditure and growth

¹ PBS Section 85 refers to medicines dispensed under Section 85 of the *National Health Act 1953*. Refer: <u>http://www.comlaw.gov.au/Details/C2012C00607</u>

while changes in prices of existing medicines and delisting of medicines reduced PBS expenditure and growth.

- In terms of burden of disease, cancers, cardiovascular diseases and mental disorders contributed to almost half (48%) of the projected disease burden in 2010. DWG analysis shows that a significant proportion of PBS expenditure continues to be on medicines to treat or manage these diseases (62% in 2010-11). Antineoplastics (used in the treatment of cancer) and immunomodulating agents (agents acting on the immune system), along with drugs that act on nervous system and sensory organs are key contributors to PBS growth (accounting for 80% of growth in 2010-11).
- Trend analysis into Government expenditure on section 85 (S85) drugs by age groups shows that persons aged 65 years and over contributed to over half of all Government expenditure and nearly two-thirds of all the growth in PBS expenditure in the time period analysed (2006-2011).
- Trend analysis into Government expenditure on S85 drugs by general/concessional status shows that the majority of PBS expenditure (78%-80%) in the time period was on concessional patients and concessional patients contributed between two-thirds (66%) to over three-quarters (78%) of all the growth in Government expenditure on S85 drugs in the time period analysed (2006-2011).
- Trend analysis into patient contributions show that the Government contributes to the great majority of expenditure on medicines for concessional patients and up to two-thirds of expenditure for general patients.
- Trend analysis into Government expenditure on S85 drugs by PBS formularies shows that, with variations, over half of all the PBS expenditure in the time period (2007-2011) analysed relates to medicines on the F1 formulary. The remaining expenditure is more likely to be on medicines on the F2 formulary (decreasing from 38% to 33%) rather than combination medicines (9%-10%). However in terms of growth, the contribution of F1 formulary medicines continued to fall and that of medicines of the F2 formulary continued to rise throughout the time period analysed (2006-2011). It is interesting to note the growing contribution of combination items to overall PBS growth in 2010-11.
- Trend analysis into PBS S85 prescriptions reveals the majority of PBS subsidised scripts (six out of every 10 scripts) were dispensed for a medicine in the F2 formulary. Three out of every 10 scripts dispensed on the PBS were written for a medicine in the F1 formulary. This indicates that F2 medicines are being prescribed more frequently in healthcare settings.
- Trend analysis into Government expenditure on S85 drugs for supply chain participants shows that the supply chain expenditure contribution to PBS S85 growth fell from around 40% in 2008-09 to 20% in 2010-11. Supply chain remuneration as a proportion of PBS expenditure rose marginally between 2006 and 2008 (26% to 27%) and has remained relatively steady at around 27% since then.
- Trend analysis into Government expenditure on the Highly Specialised Drugs (HSD) program shows that the majority of expenditure on the HSD program is in public hospitals (73%-78%) and that its contribution to overall growth in HSD program increased throughout the analysis time period (2006-2011). Immunosuppressive Agents, HIV/AIDS Antiretroviral Agents and Pulmonary Arterial Hypertension Agents contributed to over half of all the growth in HSD expenditure in 2009-10.

Background

In September 2010, the Australian Government and Medicines Australia signed a Memorandum of Understanding (MoU) aimed at "ensuring access to quality medicines at a lower cost to the taxpayer, and providing certainty to the pharmaceutical industry in relation to PBS pricing policy."² The MoU set out a number of ways in which the Government and Medicines Australia could continue to cooperate and collaborate, including a project for joint monitoring of the trends in and drivers of PBS expenditure:

Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.

Clause 7, MoU

To progress the joint monitoring project, the Access to Medicines Working Group (AMWG) Sub-group³ established the Data Working Group (DWG). The DWG is comprised of officials from the Department of Health and Ageing (DoHA) and representatives from Medicines Australia (MA) and some of its member companies. Together, they have been tasked with the development and implementation of a joint monitoring framework, joint production of monitoring reports and resolution of operational and policy matters related to the initiative.

All parties have agreed to a set of governance and process principles to guide the project.⁴ Top level governance for the joint monitoring project and for the operation of the DWG is provided by the AMWG, which will give final approval and endorsement of joint monitoring reports. The DWG also seeks advice from and reports to the AMWG Sub-group, which considers higher level policy matters arising under the project and will endorse reports before tabling to the AMWG.

The DWG is expected to monitor and to report on PBS expenditure trends and growth drivers on a half-yearly basis, and this is the second report. It is proposed that wherever possible, and as endorsed by the AMWG and approved by the Minister for Health and Ageing, reports or summaries of reports by the DWG should be made publically available.

At the request of the AMWG, the DWG began the development of the joint monitoring project by identifying a set of high level guiding questions against which Pharmaceutical Benefits Scheme (PBS) expenditure could be analysed. These questions, refined with the feedback and advice of the AMWG Subgroup and the AMWG, include:⁵

- Are there particular groups of patients contributing more than others to PBS growth?
- Are there particular drugs or groups of drugs contributing more than others to PBS growth?
- What is the contribution of newly listed medicines to PBS expenditure growth in comparison to already listed medicines?
- Are generic PBS medicines growing at a faster or slower rate than the general PBS?

² Second Reading, *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, Minister for Health and Ageing the Hon Nicola Roxon, 29 September 2010. Available online at:

http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Title%3Anational%20Title%3Ahealth%20Title%3Aamendment%20Da tabase%3Achamber%20Title%3A%22second%20reading%22%3F%20%20Context_Phrase%3Abill%3F%20Speaker%3A%3F%20Date% 3A01%2F05%2F2010%20%3E%3E%2030%2F11%2F2010%20Speaker_Phrase%3A%22roxon,%20nicola,%20mp%22;rec=1;resCount= Default.

³ The Access to Medicines Working Group (AMWG) was formed by the Department of Health and Ageing and Medicines Australia as part of the 2007 PBS reforms to encourage the Government and the industry to work together and consider access to medicines issues. The AMWG oversees the AMWG Sub-group, which coordinates joint work undertaken by the DoHA and MA.

⁴ See Data Working Group Framework (attachment A).

⁵ See Data Working Group Framework – Attachment A (attachment A).

- To what extent do factors such as changes in pharmacy remuneration impact PBS growth?
- To what extent do changes to PBS pricing policy affect PBS growth?
- Do patient compliance programs have an impact on PBS growth?
- What is the contribution of medicines listed on both S100⁶ and the Highly Specialised Drugs Program⁷ to overall PBS growth?

The AMWG endorsed these guiding questions in December 2010 alongside the overall framework developed by the DWG for the examination of these questions under the joint monitoring project.⁸ The framework outlines the background, scope and monitoring and reporting schedule for the project. Broadly, the framework charts the basic steps for identifying potential drivers, establishing the base line for evaluation, analysing the chosen variables and reporting.⁹

Under the endorsed framework, the DWG is expected to monitor PBS expenditure against a list of key drivers and data sets that are mutually agreed between MA and DoHA. To achieve this, the DWG developed a table of variables, metrics and possible data sources for the first joint monitoring report.¹⁰ The attached table shows, for example, that to examine how drug formulary groups affect the PBS (the variable), the DWG will look to Medicare PBS data and formulary allocation under the PBS (the data sources) to determine the percentage contribution to PBS expenditure growth of each formulary (the metric). The DWG identified guiding metrics and data sources for the following variables:

- New listings on the PBS in the previous 12 months
- New listings on the PBS in the previous 4 years
- Prescriptions volume
- Price of medicines
- Changes in policy
- Drug formulary groups
- Drug ATC2 groups
- Individual drugs
- Age of population
- Concession card holders
- Disease burden
- Patient compliance
- Below co-payment market
- Highly Specialised Drugs program

The DWG is expected to monitor and to report on PBS expenditure trends and growth drivers on a half-yearly basis, and this is the second report. This report is organised based on the first level of analysis which compares PBS expenditure on new medicine listings against the expenditure on existing listings, which is further divided into price factors and volume factors. Additional depth of analysis, to consider the agreed variables such as age of population, disease groups, and general and concessional status of patients, is also provided. It must be noted that while seemingly independent, variables that affect price and volume are interlinked; this presents a methodological challenge which has been extensively considered by the DWG and is discussed throughout the report.

⁶ Medicines supplied under Section 100 of the National Health Act 1953.

⁷ See definition in Appendix A.

⁸ See Data Working Group Framework (attachment A).

⁹ See Data Working Group Framework – Attachment B (attachment A).

¹⁰ See Data Working Group Framework – Attachment C(attachment A).

Project Scope

The DWG framework sets out provisions to control the scope of the project:

- The primary data source for the joint monitoring project is PBS data processed by the Department of Health and Ageing (DHS – formerly Medicare Australia); where appropriate, additional data may be sourced from the Bettering Evaluation And Care in Health (BEACH) survey¹¹, PBAC's Drug Utilisation Sub Committee (DUSC), the Department of Families, Housing, Community Services and Indigenous Affairs (FaHCSIA) and the Australian Institute of Health and Welfare (AIHW).
- There are a number of caveats around the completeness of the PBS expenditure due to data limitations, primarily
 - PBS expenditure on prescriptions not processed through DHS, for example below co-payment prescriptions, is not available
 - S100 expenditure, including expenditure on Highly Specialised Drugs, is available at an aggregate level only
 - Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions are not included in this report.
- The DWG will not forecast or measure future actual expenditure against any forecast.
- Requests for analysis outside of the endorsed framework must be formally approved by the AMWG Sub-group. Requests should outline the reasons for and the benefits of the additional analysis and must give due consideration to the sensitivity of the proposed data sets and the resource burden on the DWG.

Data coverage in this report

Unless otherwise indicated, expenditure and prescriptions are Section 85 (S85) general and concessional government expenditure and prescriptions only, excluding Doctors Bag¹² prescriptions, processed through Medicare Australia.

All data (unless the indicated source is DUSC, BEACH, S100 or other) is date of processing data, i.e. prescriptions and expenditure are reported in the year processed by Medicare Australia and not necessarily the year dispensed.

Together these factors limit the comparability of the expenditure in this report with the PBS expenditure reported in budget papers and DoHA Annual Reports. The published PBS expenditure includes PBS S85 general and concessional expenditure, expenditure on highly specialised drugs, Doctors Bag prescriptions, other S100 expenditure and expenditure for fees paid for the issuing of Safety Net cards.

In addition, Government published PBS expenditure is reported on an accrual basis, whereas the expenditure analysed in this report is on a cash basis. The detailed breakdowns of PBS S85 expenditure used in this report are not available for accrualised PBS expenditure, or for the other components of PBS expenditure not included in this report.

For a more detailed description of the data items being analysed in this report see Appendix 1 – Background definitional and methodological information.

¹¹ The BEACH survey is compiled by the Australian General Practice Statistics and Classification Centre

¹² Certain pharmaceutical benefits are provided without charge to prescribers who in turn can supply them free to patients for emergency use. These are known as Doctors Bag prescriptions (also known as emergency supply prescriptions).

Breakdown of PBS expenditure

As a starting point in decomposing the PBS expenditure, the DWG looked at the two key elements that make up the PBS expenditure - Price and Volume. It was widely acknowledged within the DWG that any factor that impacts (negatively or positively) either price paid by the Government or volume of PBS subsidised prescriptions or both will have a flow on impact on overall PBS expenditure and growth. A number of sub-factors affect both price paid by the Government for medicines or the volume of PBS prescriptions (see Figure A below).

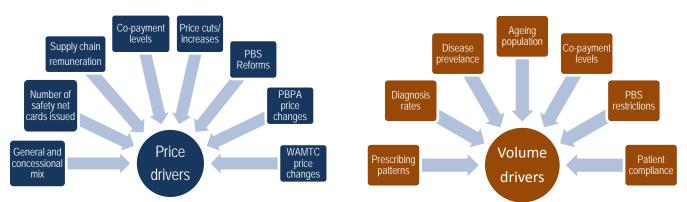


Figure A: Factors affecting the price government pays for PBS prescriptions

It was also agreed at least two additional elements affect both government expenditure and PBS prescription volume directly: 1) the listing of new medicines and 2) the de-listing of older medicines from the PBS.

Linkages between drivers of PBS expenditure

Figure B provides a schematic of the various linkages between the key drivers and their subdrivers and summarises their influence on PBS expenditure. These linkages demonstrate the complexities in examining growth of PBS expenditure in any time period, as there are multiple factors at play. The DWG have attempted to separate the effect of drivers, to the extent possible, in this report to demonstrate their impact. However, a number of drivers cannot be separated from each other due to lack of granularity in datasets. DWG will continue to examine ways to approximate/estimate the impact based on sound assumptions going forward.

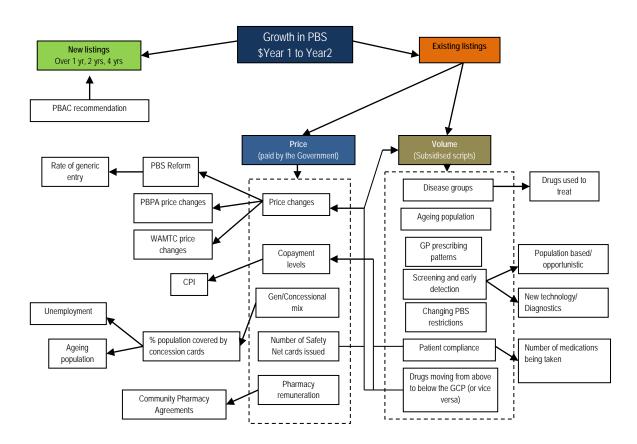


Figure B: Linkages between drivers of PBS expenditure

Price Drivers and their influence

- Prices cuts/increases: Changes to the price paid by the Government for medicines on the PBS has a direct effect on medicines expenditure. A number of pricing policies have been introduced in the time period analysed (2006-2011) and some policies were already in place. Together these policies have generally worked to reduce the average price paid for affected medicines by the Government and patients. However, overall the average price paid per script by Government has continued to increase. Key pricing policies introduced or existing in the time period include:
 - a. 12.5% policy introduced in 2004-05
 - b. PBS reforms introduced in 2007-08
 - c. Further PBS reforms introduced in 2010-11
 - d. Weighted Average Monthly Treatment Cost (WAMTC) (ongoing)
 - e. Reference pricing (ongoing)
 - f. PBPA price revisions (ongoing)

In this report, the DWG looked at the aggregate effect of price changes on overall PBS growth in the time period. A more substantial analysis could be carried out in the next few iterations of the report (subject to AMWG approval) to separate the effect of each policy measure on the prices in any time period.

2. Co-payment/Patient contribution levels: The co-payment is the amount paid by the patients towards the cost of their PBS medicines. From 1 January 2012, general patients pay up to \$35.40 for most PBS medicines or \$5.80 if they have a concession card. The Australian Government pays the remaining cost. The amount of co-payment is adjusted on 1 January each year in line with the Consumer Price Index (CPI). Every year as the co-payment amount is adjusted a number of medicines fall below the general co-payment. This means that the Government expenditure on those medicines for general patients is reduced. However, the Government continues to pay for concessional patients, as the cost paid by the Government for almost all PBS medicines is above the concessional co-payment.

Although not analysed in this report, the Closing the Gap – Subsidising PBS Medicine Co-Payments measure acts to reduce the co-payment paid by eligible patients.

In this report, the DWG looked at the trends in patient contribution at aggregate level and also by concessional status. It is envisaged that in future reports, the DWG will also look at the impact on Government expenditure of medicines moving below the general co-payment. Data on prescriptions priced below the general co-payment will be available after August 2012.

3. **General/Concessional mix:** In any given year, a percentage of patients access medicines on the PBS using their concession cards. In 2012, these patients pay up to \$5.80 per script compared to general patients who pay up to \$35.40 per script. With different co-payments, this mix of general and concessional patients in any given year impacts the Government's expenditure. This mix in turn is influenced by the percentage of the Australian population covered by concession cards. The percentage of population covered by concession cards may be influenced by their age, income and/or their health status.

To be eligible for a concessional benefit on the PBS, patients need to have one of the following concession cards:

- a. Pensioner Concession Card;
- b. Commonwealth Seniors Health Card;
- c. Health Care Card; or
- d. Department of Veteran's Affairs (DVA) White, Gold, or Orange Card.

DHS (incorporating the former Centrelink) is responsible for the issue and administration of the Pensioner Concession Card, the Commonwealth Seniors Health Card and Health Care Cards. DVA are responsible for White, Gold and Orange Cards. There is also a DVA Pension Card which entitles holders to PBS medicines at the concessional rate (but not RPBS medicines). General benefits apply if patients do not have any of the above cards.

For this report, the DWG analysed high level trends in expenditure and prescriptions across general and concessional patients and their contribution to overall PBS growth in time period from 2006-2011. In future reports, trends in expenditure and prescription volume per patient by concessional and general category will be examined in more detail.

4. Supply chain remuneration: The PBS supply chain comprises three principal participants –manufacturers (originators and generics), wholesalers and pharmacists. The Government price is set on the basis of a formula which comprises the agreed exmanufacturer price plus allowance for the supply of PBS medicines over and above that price.

Every five years, a Community Pharmacy Agreement is negotiated and agreed between the Australian Government and the Pharmacy Guild of Australia. The current agreement commenced on 1 July 2010. One of the major elements of this agreement (which impacts the prices paid by the Government) is pharmacy remuneration. This includes the dispensing fee, the pharmacy and wholesale mark-ups, the extemporaneously prepared and dangerous drug fees. The dispensing fee is generally adjusted on 1 July each year in line with the Consumer Price Index (CPI). According to the Fifth Community Pharmacy Agreement, indexation was not applied to the dispensing fee in 2010-11 and 2011-12.

As part of the Fifth Community Pharmacy Agreement, a wholesale mark up of 7.52% is applied on ex-manufacturer price of most medicines. This approximates a 7.0% wholesale margin when taking into account the flat \$69.94 wholesale mark up applied to high cost medicines¹³. In this report, the DWG analysed trends in supply chain remuneration and their overall contribution to growth in PBS expenditure in the time period from 2006-2011. In future reports, the DWG could undertake analysis to separate the impact of pharmacy and supply chain participants when decomposing PBS expenditure by calculating Government expenditure at derived ex-manufacturer prices.

¹³ Note that the remuneration calculations for medicines supplied under the "Efficient Funding of Chemotherapy" measure are different to those applied for most other medicines

Volume Drivers and their influence

5. Disease prevalence: The results of the 2007-08 National Health Survey indicate a high prevalence of chronic diseases among Australians, including cancer (2% of the population), diabetes (4%), asthma (10%), long-term mental or behavioural conditions (11%), arthritis (15%), and conditions of the circulatory system e.g. high blood pressure (16%). The ageing of the Australian population has played a key role in the rise in the prevalence of chronic disease. In the 2007-08 National Health Survey nearly all people aged 65 years and over reported having at least one long-term condition, and more than 80 per cent of people in this age group reported having three or more long-term conditions (co-morbidity)¹⁴.

Disease prevalence has a profound effect on both the type and quantity of medicines consumed by the patients. Depending on the type of illness – chronic or acute, the type and volume of medicines consumed could vary. This variation in turn affects the expenditure on medicines in a particular time period. The DWG looked at the consumption of a subset of medicines that are generally used to treat/control chronic illnesses e.g. cancer and cardiovascular diseases. In this report, the DWG analysed the trends in disease burden and PBS expenditure on medicines to treat key (chronic) disease groups.

6. Ageing population: Most aspects of health status vary with age, with health issues usually increasing over the life stages. According to the most recent National Health Survey, the proportion of people aged 65 and over who rated their health as only 'fair' or 'poor' was 31%. This compares with 7% and 13% for people aged 15 years and over and 15-24 years olds respectively. As the population ages, more people are likely to develop health conditions that require some medication to control and treat them. In this report, the DWG looked at the trends in PBS expenditure by age groups to identify key demographics that contribute most to the PBS expenditure and examined the inter-linkages between the age of PBS patients and their concessional status.

Price & Volume Drivers and their influence

- 7. New Listings and Delisted PBS products: every year a number of new medicines are listed on the PBS. These medicines affect both the average price paid by the Government and the volume of medicines dispensed/consumed impacting overall PBS expenditure. Similarly, a number of PBS medicines which are older and not widely used get delisted from the PBS each year. These delisted medicines also impact the overall PBS expenditure, albeit negatively. For this report, the DWG examined the contribution of new listings (in their first year of listing) and delisted medicines (in their last year of listing) at an aggregate level to overall PBS growth in the time period.
- 8. **Concessional cardholders:** The number of concessional cardholders can impact both the price paid by the Government and the volume of PBS subsidised medicines dispensed in a time period. This is the case when a formerly non-concessional patient

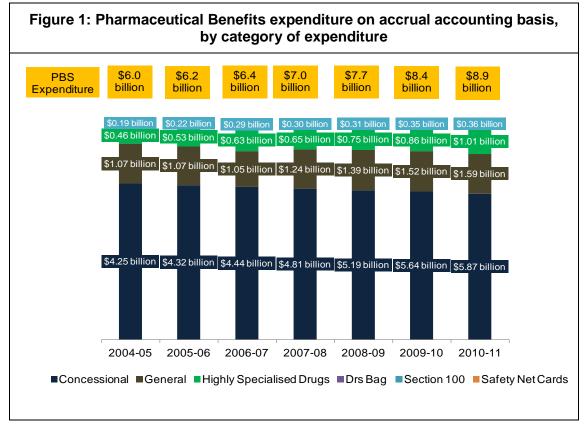
¹⁴ Australian Bureau of Statistics. National Health Survey: summary of results, 2007-08, from Australian Bureau of Statistics website: www.abs.gov.au.

becomes eligible for extra subsidy upon gaining a concession card and when a formerly concessional patient loses eligibility and becomes a general patient. In the former case, the difference in the general co-payment (currently \$35.40) and concessional co-payment (currently \$5.80) is paid by the Government, driving up the Government expenditure on PBS. In the latter case, the difference between the general and concessional co-payments is paid by the patient, reducing Government expenditure on the PBS. Similarly, additional volume and therefore expenditure relating to those medicines that are below the general co-payment threshold gets added to the Government expenditure when a former non-concessional patient uses a concession card. In this report, the DWG examined the trends in concession cards issued in the time period.

PBS expenditure – an overview (2004-2011)

(reference Appendix 2:Table 5 and Table 6)

Since 2004-05, Government expenditure on PBS benefits paid pharmaceuticals¹⁵ has risen by \$2.9 billion dollars to \$8.9 billion in 2010-11. This equates to a compound annual growth rate (CAGR) of around seven percent (6.7%). Throughout the time period (2004-05 to 2010-2011), expenditure on the concessional and general categories made up the vast majority of expenditure (84%-89%). Also, during this time period, the Highly Specialised Drugs¹⁶ (HSD) Program continued to rise as a percentage of total Government expenditure on the PBS, from around 8% to 11% (see Figure 1).



Source: DoHA Expenditure and Prescriptions reports between June 2005 and June 2011, Table 1(a)

In terms of contribution to overall growth in PBS expenditure, the contribution by each category varies across the time period (see Figure 2). Before 2007-08, the majority of growth in pharmaceutical benefits expenditure was contributed by concessional (around 45%) or HSDs (around 40%). Section 100 drugs also contributed up to 25% to the growth over the same time period. The high relative contribution of HSDs and S100 expenditure to overall growth over this period may be explained by the co-pay increase above inflation in January 2005. These co-pay increases had a negative effect on government expenditure on medicines in the general and concessional categories while HSDs and S100 drugs were largely unaffected.

The HSD and S100 categories also consist of innovative medicines which are used to treat serious and complex specialist clinical conditions; conditions which are generally unresponsive to older medicines. It is envisaged that the increasing contribution of HSD and

¹⁵ PBS benefits paid pharmaceuticals are those PBS listed medicines where a benefit is paid by the Government when they are dispensed. This excludes RPBS only listed medicines, but does include medicines that are listed under both the PBS and RPBS where they are dispensed to PBS patients.

¹⁶ See definition in Appendix 1.

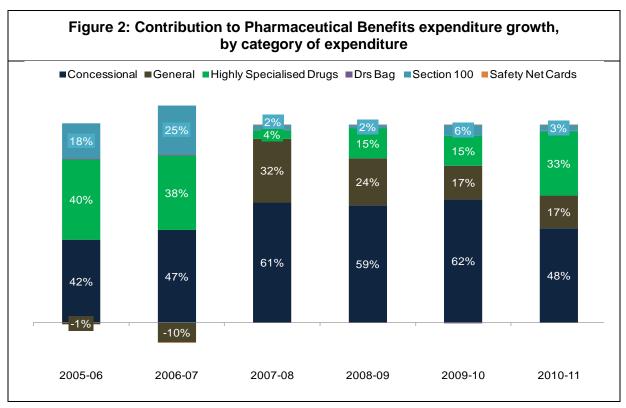
other S100 medicines to PBS growth in recent years will be investigated further by DWG in subsequent reports.

As shown in Table 1, PBS growth in the analysis period has been varied – from 2.7% in 2005-06 to 9.4% in 2007-08 before falling to 5.7% in 2010-11.

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
PBS expenditure (growth, %)	2.7%	4.3%	9.4%	9.2%	9.3%	5.7%

Source: Based on data from DoHA Expenditure and Prescriptions reports between June 2005 and June 2011, Table 1(a)

In terms of contribution to overall growth in the time period analysed (2004-2011), the DWG found variations across the time period. For instance, in 2007-08, concessional patients contributed over three-fifths of all the growth (61%) in PBS expenditure while general patients contributed nearly one third of all the growth (32%). Between 2007-08 and 2009-10, the contribution of concessional remained fairly stable (around 60%), while the contribution of general almost halved to 17%. The contribution of the HSD program in this time period increased significantly to 15% (up from 4% in 2007-08). In 2010-11 the contribution of general patients to PBS growth remained unchanged at 17%, while the contribution of HSDs increased sharply from 15% to 33%.



Source: Based on data from DoHA Expenditure and Prescriptions reports between June 2005 and June 2011, Table 1(a)

The HSD program's contribution to overall growth in Government expenditure on the PBS has continued to grow over the period (2007-2011). In 2010-11, the HSD program cost the Australian Government upwards of \$1 billion. In view of its growing contribution to PBS expenditure and growth, the DWG have examined trends in HSD expenditure in this report.

Key drivers of growth and their influence on PBS expenditure

(Reference Appendix 2: Table 7 and Table 8)

The following section looks at the decomposition of PBS expenditure by key drivers such as net new listings¹⁷ (both in their first year of listing and over four years), the change in prices of existing or already listed medicines and the change in the volume of existing medicines.

The general methodology used here is based on the methodology used by Sweeny (2002)¹⁸ to decompose PBS expenditure growth in the effects of net new drugs (first year of listing), demand and prices.

For each PBS item listed in each year, scripts and expenditure were extracted. Net new listings were calculated as expenditure due to PBS items that were listed in the current year, but not listed in the previous year, minus expenditure on PBS items that were listed in the previous year, but not in the current year.

For all PBS items that were listed in both years (continuing items), expenditure in the current year is calculated using constant average cost to Government (those costs that applied in the previous year; in this analysis constant average price to Government is used as a proxy for constant prices). The difference between the current year's expenditure in constant prices and the previous year's expenditure is considered the effect of changes in volume (or demand). The effect due to changes in price is calculated as the difference between the total change in expenditure minus the effect due to volume.

There are a number of caveats with the methodology, such as how trends to use more or less expensive drugs to treat the same condition are handled and whether chain linked indexes would be a better way of examining this decomposition.

¹⁷ Net new listings = New listings *less* delisted medicines.

¹⁸ Sweeney, K, "Trends in the Use and Cost of Pharmaceuticals under the Pharmaceutical Benefits Scheme", Centre for Strategic Economic Studies, 2002.

As shown in Figure 3, at a high level, the impact of change in volume of existing medicines is the key contributor to overall increase in PBS expenditure. The analysis also shows that changes in the price paid for existing medicines on the PBS in the time period have actually worked to offset additional expenditure due to net new listings when considering the effect of new listings at least in their first year on the PBS.

The high negative contribution of average price change in 2005-06 and 2006-07 is closely related to the PBS co-pay and Safety Net threshold increases from 1 January 2005, the introduction of 12.5% price reduction policy from 1 August 2005 and the introduction of the Safety Net 20 Day Rule from 1 January 2006 (see below for a detailed description of each of these measures). The combination of these measures would have the effect of reducing the average price paid by the Government for existing PBS medicines, magnifying the negative effect of price change, and the positive effect of volume change over a three year time period between 2004-05 and 2006-07.

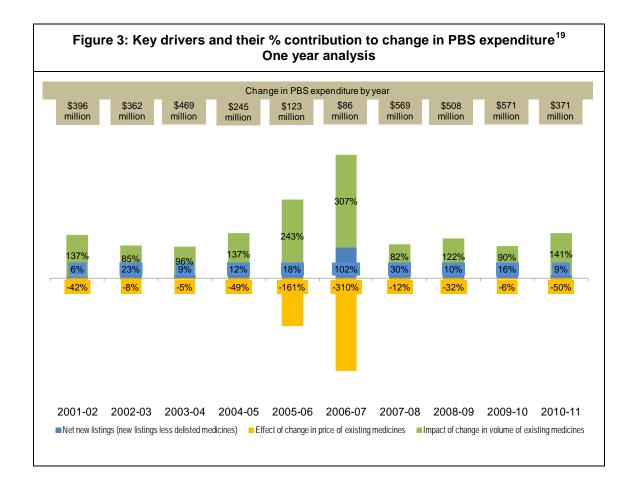
In the four years to 2003-04, PBS growth averaged around 13% per annum. From 1 January 2005, the PBS co-payment for concessional patients rose from \$3.80 to \$4.60, an increase of \$0.80 or 21%. For general patients the co-payment rose from \$23.70 to \$28.60, an increase of \$4.90 or 21%. Before this time (and after) patient co-payments were indexed each year by CPI, then rounded to the nearest 10 cents. This was a substantial saving measure for government and resulted in a significant reduction in the average cost to government per prescription for PBS medicines.

Also from 1 January 2005, the PBS Safety Net thresholds increased (for concessional patients it increased by \$41.60 or 21% and for general patient it increased by \$148.10 or 20%). In addition to this, each year from 2006 to 2009, the PBS Safety Net thresholds increased by an amount equal to two patient contributions, in addition to the usual annual Consumer Price Index (CPI) adjustment. The effect of these measures would have been to increase the amount of time it would take patients their respective Safety Nets, thereby reducing the average cost to government for PBS prescriptions over the course of a year.

In addition, from 1 August 2005 it became mandatory that when the first new brand of a PBS medicine was included on the PBS, a price reduction of at least 12.5% had to be offered. This again would have had the effect of reducing the average price paid by government for PBS listed medicines.

Finally, from 1 January 2006, the Safety Net 20 Rule was introduced. This rule meant that for certain PBS medicines a repeat supply of the same medicine within 20 days falls outside the safety net. This meant that (1) the cost of the supply would not count towards a person's Safety Net threshold; and (2) if the Safety Net threshold had been reached, the charge would be a patients usual PBS contribution – not the reduced Safety Net amount. This had the effect of reducing general and concessional safety net expenditure in 2005-06 and particularly in 2006-07, again reducing the average price paid by government for PBS listed medicines.

The large change in PBS growth between 2006-07 (\$86 million) and 2007-08 (\$569 million) was largely demand driven. In 2006-07 PBS prescriptions increased by only 0.1%, whereas in 2007-08 prescriptions increased by 1.6%.



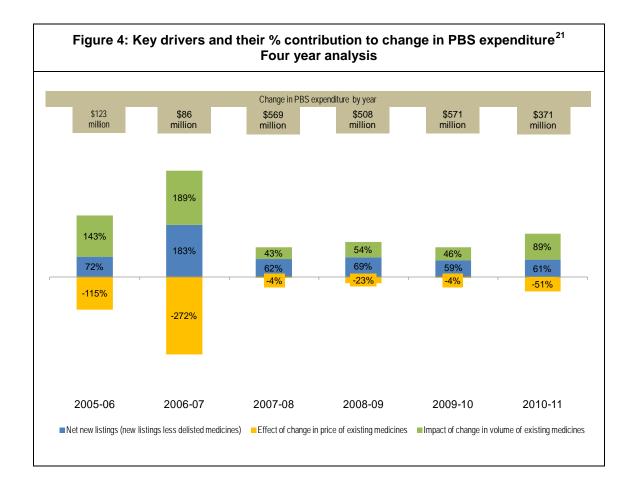
New listings account for, on average, around 10% of PBS expenditure growth in their first year of listing. With exceptions, on average it takes a number of years for a medicine to reach its typical annual PBS cost²⁰. Also, new listings usually displace or replace expenditure on some existing medicines. To gauge the impact of new listings over time and its corresponding impact on the PBS, DWG extended the one year analysis to four years.

To achieve this DWG identified the new (first time) listings in the time period 2001-2011 and separated their expenditure from the existing medicines and added it to the expenditure attributable to new listings in each year.

The impact of change in volume of existing medicines from the one year analysis (Figure 3) can be seen to be accounted for, to an extent, by new medicines listed in the last four years. Over the long term, the change in volume of existing medicines, combined with the effect of medicines listed over the last four years are the significant drivers of growth. The analysis also confirms that even after including the impact of net new listings, the impact of change in prices (as approximated by changes in the average cost to Government) of existing medicines continues to have a significant dampening effect on PBS expenditure growth.

¹⁹ This analysis is based on Drug Utilisation estimates as provided by the Drug Utilisation Sub-Committee for all years except 2009-10 and 2010-11. Data used in this analysis for 2009-10 and 2010-11 is 'date of supply' data from Medicare Australia.

²⁰ Sweeny K, Trends and Outcomes in the Australian Pharmaceutical Benefits Scheme, Working Paper No. 36, Centre for Strategic Economic Studies, December 2007 accessed on 15 August 2011. Available at http://www.cfses.com/documents/pharma/36-trends_Outcomes_PBS_Sweeny.pdf



The effect of Expanded and Accelerated Price Disclosure (EAPD) is not evident in the above analysis as the first main round price reductions occurred on 1 April 2012. However the price effect of associated measures 2% F2A and 5% F2T price reductions from 1 February 2011 is evident in 2010-11. It is anticipated that the impact of EAPD will be seen when this analysis is extended to include data from 2011-12 and 2012-13.

Additionally, as noted earlier within the caveats, the current analysis does not include the impact of price changes of existing medicines on PBS expenditure in the subsequent years. It is acknowledged that further analysis needs to be undertaken to address this issue. This ex-post quantification of price revisions poses methodological challenges and sensitivities. Work will continue towards developing an agreed methodology to examine reasonable ways of integrating this into the current analysis.

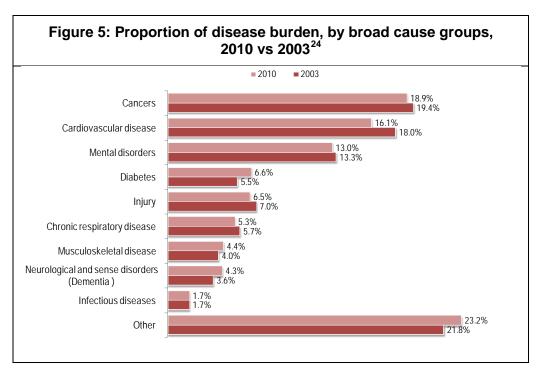
²¹ This analysis is based on Drug Utilisation estimates as provided by the Drug Utilisation Sub-Committee for all years except 2009-10 and 2010-11. Data used in this analysis for 2009-10 and 2010-11 is 'date of supply' data from Medicare Australia.

Trends in disease prevalence and PBS expenditure

(reference Appendix 2: Table 9)

According to the Australian Institute of Health and Welfare (AIHW), "chronic diseases are a leading cause of death and disability in Australia. Chronic diseases are also associated with high use of health care services, contributing to major funding pressures in Australian health care that are expected to rise over coming decades as prevalence increases. The increased prevalence of chronic disease has been attributed to a range of causes including the ageing of our population and lifestyle factors such as smoking, physical inactivity and excess alcohol intake".

The DWG looked at the disease burden²² by broad cause groups as reported by the AIHW. As shown in Figure 5, cancers, cardiovascular diseases and mental disorders contributed to almost half (48%) of the projected disease burden in 2010²³. Although as a proportion of all diseases the contribution of these diseases is projected to fall, for now they continue to be major causes of death and disability in Australia. It is no surprise that a significant proportion of PBS expenditure continues to be on medicines to treat or manage these diseases.

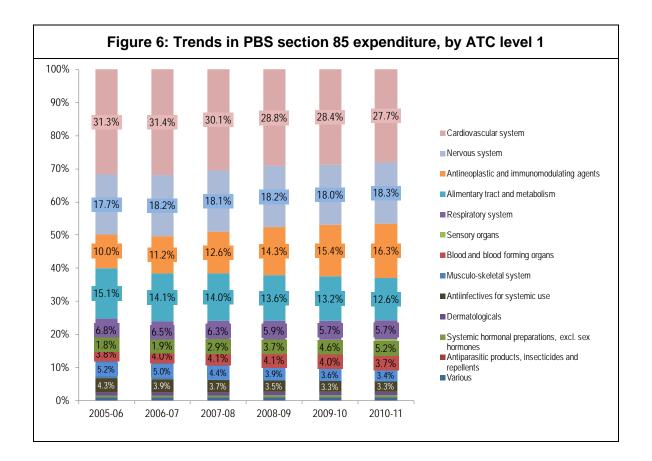


As shown in Figure 6, a significant proportion of all PBS S85 Government expenditure is on medicines used to treat either cardiovascular diseases (31% in 2005-06 reducing to 28% in 2010-11) or Nervous system conditions (18%). Around one quarter of the expenditure was either on anti-cancer medications (10% in 2005-06 increasing to 15% in 2010-11) or drugs used to treat condition of the alimentary tract and metabolism (15% in 2005-06 reducing to 13% in 2010-11) such as diabetes.

²² Disease burden is defined as a measure of the number of years of 'healthy life' lost due to disease or injury.

²³ AIHW, 2010, Australia's Health 2010, Chapter 4, Diseases and Injury, Box 4.1, pg 133.

²⁴ AIHW,2008, Australia's Health 2008, Chapter 5, Diseases and Injury, Box 5.1, pg 175.



In terms of contribution to PBS growth, there were variations across the time period analysed. However, medicines to treat cancers, cardiovascular diseases, illnesses of sensory organs (including ophthalmologic conditions) and nervous system drugs contributed most to the growth in the time period (see Table 2).

Of particular note is the impact of Antineoplastic and immunomodulating agents on PBS growth in 2006-07. This was due to a combination of low overall growth in the year (\$82 million across all of PBS S85, due in large part to savings measures implemented in 2005 and 2006 – see previous section) and strong growth in a number of high cost cancer related medicines: etanercept (\$19.4 million), adalimumab (\$12.5 million), anatrazole (\$7.9 million) and rituximab (\$7.8 million).

Table 2: Contribution to total growth in Government expenditure on S85 drugs,by ATC level

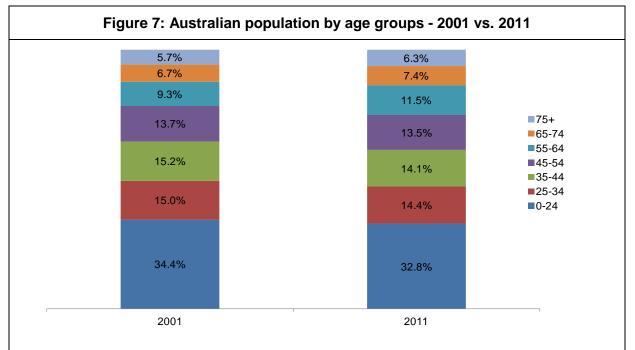
	2006-07	2007-08	2008-09	2009-10	2010-11
Antineoplastic and immunomodulating agents	86.4%	29.8%	30.3%	30.4%	35.8%
Nervous system	49.8%	17.1%	18.8%	14.7%	24.8%
Sensory organs	6.6%	15.4%	11.1%	16.7%	19.7%
Cardiovascular system	36.9%	14.4%	17.1%	22.9%	12.8%
Respiratory system	-14.5%	3.7%	2.8%	2.2%	5.8%
Antiinfectives for systemic use	-23.8%	1.7%	1.3%	1.0%	3.8%
Systemic hormonal preparations, excl. sex hormones	3.7%	0.4%	1.1%	1.1%	1.5%
Genito urinary system and sex hormones	-2.7%	0.5%	0.8%	-0.7%	0.9%
Dermatologicals	-1.4%	1.1%	1.3%	0.8%	0.6%
Antiparasitic products, insecticides and repellents	-1.0%	0.0%	0.0%	0.0%	0.0%
Alimentary tract and metabolism	-48.1%	12.5%	9.7%	7.9%	-0.9%
Blood and blood forming organs	16.7%	5.4%	4.7%	2.6%	-2.8%
Musculo-skeletal system	-8.5%	-2.9%	-0.2%	-0.3%	-2.9%
Various	-0.1%	0.9%	1.2%	0.7%	0.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

PBS and the Australian population

(reference Appendix 2: Table 10, Table 11 and Table 12)

Trends in population by age

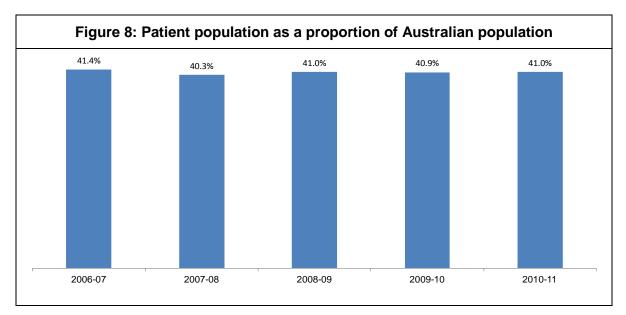
To contextualise some of the findings contained in this report, the DWG analysed trends in the Australian population as a whole and the patient population within it. Figure 7 shows the variation in population composition by age groups in the decade to 2011. The analysis shows the trends in ageing; the proportion of the Australian population aged 55 years and over is steadily rising. This is consistent with the demographic changes in other similar OECD countries. It is noteworthy that since 2001, the estimated Australian resident population has grown by an average 2% per annum or 3.2 million persons. In subsequent reports, the DWG will continue to analyse the trends in estimated Australian resident population to discern changes in the composition of Australian population over time.



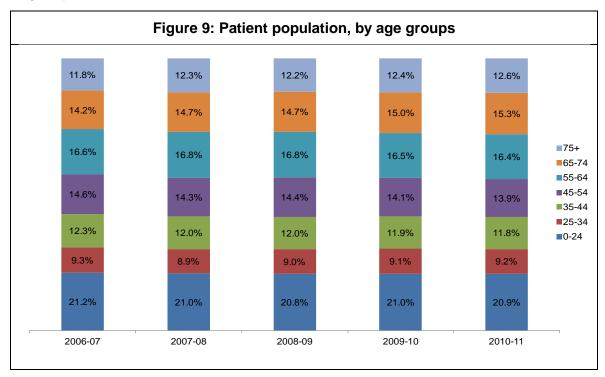
Source: ABS, Catalogue number 3101 corresponding years

Patient population

In the year to June 2011, there were 9.27 million patients²⁵ in Australia. This is just over two-fifth (41%) of the estimated resident population of Australia in 2010-11. As shown in Figure 8, since 2006, the patient population as proportion of the overall population has remained relatively unchanged. This suggests that the increase in patient population has kept pace with the increase in population.



In line with the changes in the demography of the Australian population in general there are subtle changes in the composition of the Australian PBS patient population. As shown in Figure 9, since 2006, the proportion of patients aged 65 and over has increased while that of patients in younger age groups (below 65 years) has remained steady or has declined marginally.

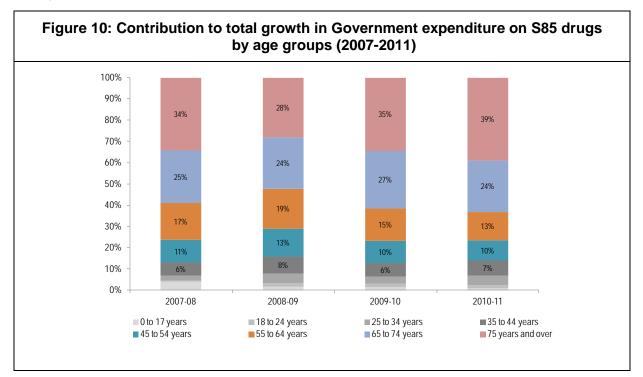


²⁵ A patients in this context is defined as an individual who has claimed at least one benefits paid S85 PBS script in the year. It does not include patients who used one or more HSD medicines, but no S85 medicine.

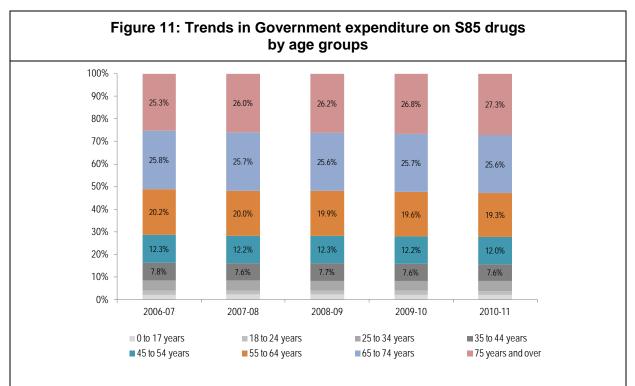
Trends in PBS expenditure by age group (2006-2011)

(reference Appendix 2: Table 13 and Table 14)

As shown in Figure 10, in terms of their contribution to overall PBS growth, the 65 and over age group contributed to nearly two-thirds of all growth in PBS expenditure in the time period analysed (2007-2011).



As shown in Figure 11, in the time period analysed (2006-2011), persons aged 65 years and over contributed to over half of all PBS expenditure (51%-53%) with approximately half of that expenditure contributed by over 75 year and over age group (25%-27%). In 2010-11 patients aged 25 - 54 years contributed to a quarter of the total expenditure (24%).



PBS expenditure by General/Concessional mix (2006-2011)

(reference Appendix 2: Table 15 and Table 16)

As shown in Figure 12, in terms of their contribution to overall growth, concessional patients contributed between two-thirds (66%) to over three-quarters (78%) of all S85 PBS expenditure growth in the time period analysed. The remaining growth was contributed by general patients.

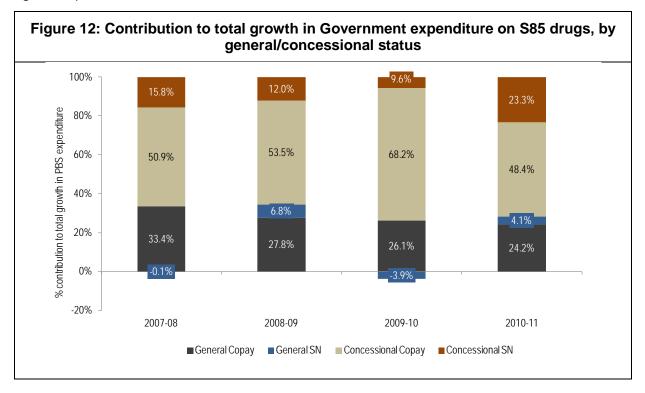
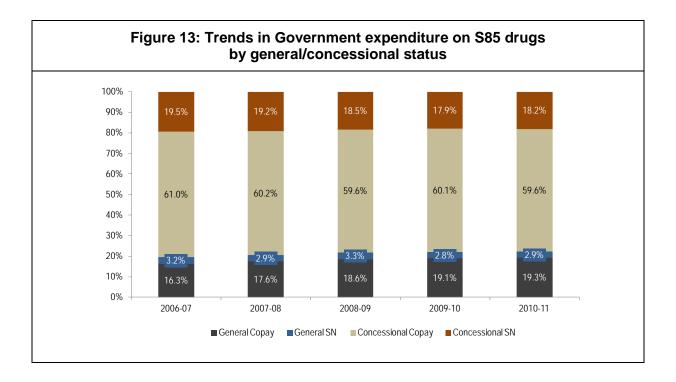


Figure 11 also shows that the contribution of concessional co-pay patients dropped between 2009-10 and 2010-11 from 68.2% to 48.2% while the contribution of concessional safety net patients rose sharply from 9.6% to 23.3%. This is not fully explained by the modest 2.9% increase in the number of concessional patients reaching the safety net in 2010-11 compared to 2009-10. However, the DWG could undertake further work to examine whether patients reached the safety net faster in 20010-11 compared to 2009-10.

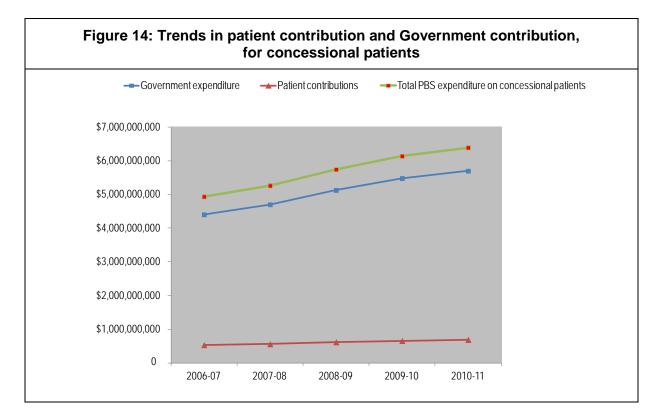
As shown in Figure 13, the consistent contributor to the majority of PBS expenditure in the time period was concessional patients (80% decreasing to 78%). Less than a quarter of all expenditure in the time period was on general patients (20% increasing to 22%). This trend is consistent across the time period analysed (2006-2011).



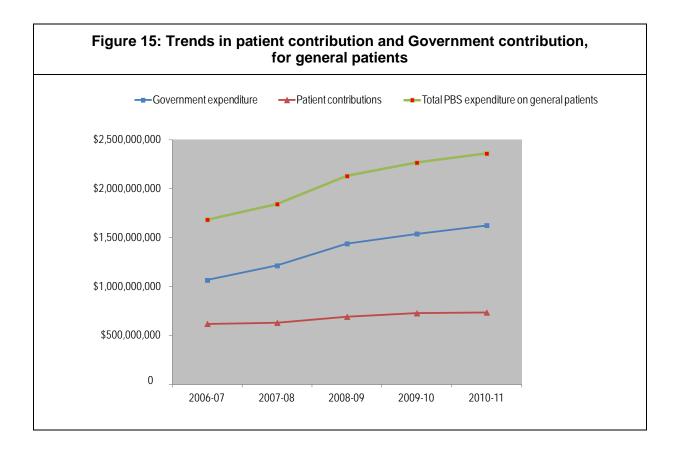
Trends in patient contribution (2006-2011)

(reference Appendix 2: Table 17)

The DWG analysed the trends in patient contribution in the time period between 2006 and 2011. It is important to note here that the following analysis looks at overall expenditure on S85 PBS subsidised medicines which comprises both Government expenditure and patient contribution. The following analysis does not include patient contributions towards medicines that are below the general co-payment as this data is not available. Overall, the Government contributes to the great majority of expenditure on PBS subsidised medicines for concessional patients (see Figure 14) and up to two-third of such expenditure on medicines for general patients (see Figure 15).



Between 2006-07 and 2010-11 the level of patient contribution has remained relatively flat, increasing marginally, while at the same time the level of government contribution has increased sharply both for concessional and general patients.



The flattening of patient contribution from 2009-10 onwards could be related to the cessation of the annual safety net threshold increase, and the increase in number of prescriptions required to hit the safety net, introduced as part of the National Health Amendment (Budget Measures—Pharmaceutical Benefits Safety Net Bill 2005²⁶). Since 2009, no new policies have been introduced that would impact the proportion that patient contributions contribute to overall PBS expenditure. Currently, general and concessional co-payments are indexed to CPI and change every year on 1 January.

In future reports, this information will be examined in conjunction with script and expenditure per patient data by concessional category to examine whether increases in Government expenditure are due to increases in the number of patients and/or increased volume per patient and/or changes in the average PBS benefit per patient.

²⁶ Under the 2005-06 Budget measure: *Pharmaceutical Benefits Scheme — increase concessional and general safety net thresholds*, for concessional patients, the safety net threshold increased from 1 January 2006 from 52 prescriptions to 54 prescriptions, with further increases of two prescriptions occurring each year up to and including 1 January 2009. For general patients, the safety net threshold increased from the current level of \$874.90 by the dollar equivalent of two co-payments each year from 1 January 2006 until 1 January 2009. These increases were on top of the existing annual indexation of the safety net thresholds by the Consumer Price Index.

Trends in PBS expenditure by formularies (2007-2011)

(reference Appendix 2: Table 18 and Table 19)

The following section analyses PBS section 85 General and Concessional expenditure and scripts across the F1 and F2 formularies. The analysis includes expenditure on Doctor's Bag medicines but excludes expenditure on extemporaneously prepared items²⁷.

Since 1 August 2007, drugs on the PBS, except those in single brand combination items²⁸, have been included in separate formularies:

- a) Formulary 1 (F1) which comprises drugs with only a single brand;
- b) Formulary 2 (F2) comprising drugs with multiple brands and single brand drugs that are in a Therapeutic Group with a drug that has multiple brands.

Different pricing mechanisms are applicable to each formulary. While value based pricing²⁹ is used for setting prices for medicines in the F1 formulary, the prices for most medicines in the F2 formulary are based on market competition between multiple suppliers. The separation of drugs into F1 and F2 formularies allows the Australian Government to pay competitive prices for multiple brand drugs without affecting the viability of single-brand drugs that do not operate in a competitive market.

Under the 2007 PBS reforms, this was achieved through de-linking the prices of drugs in F1 from the prices of drugs in F2 and then applying statutory price reductions of 12.5% (increased to 16% under the 2010 *further PBS reforms*) to drugs transitioning to the F2 formulary followed possibly by ongoing price adjustments, via price disclosure, to reflect prices they are being sold at in the marketplace.

It is important to note this distinction between pricing mechanism for medicines in the F1 and F2 formulary when comparing the trends in and contribution to PBS growth or expenditure by formularies in the following section.

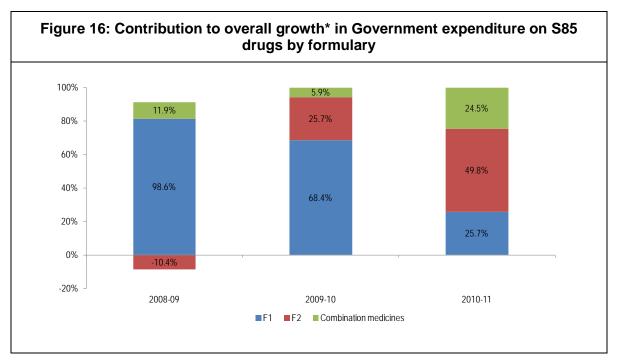
As shown in Figure 16, the contribution of F1 medicines to overall PBS growth declined whereas the contribution of F2 medicines increased in the time period analysed (2008-2011). The contribution of F1 fell from 98.6% in 2008-09 to 25.7% in 2010-11. The contribution of the F2 formulary in the same time period increased from -10.4% to half of all the expenditure growth in 2010-11 (49.8%). It is interesting to note the growing contribution of combination items to overall PBS growth in 2010-11. If the trend continues, the DWG may investigate the rising contribution of combination medicines in future reports.

²⁷ An extemporaneously prepared formula is a PBS medicine compounded by a pharmacist from basic ingredients.

²⁸ Since 1 August 2007, drugs on the PBS, except those in single brand combination items, are included in separate formularies

⁽Formulary 1 (F1) and Formulary 2 (F2)). Single brand combination items are referred to as combination items.

²⁹ Pricing based on the clinical benefit and cost-effectiveness compared with other treatments or products for the same condition or use.

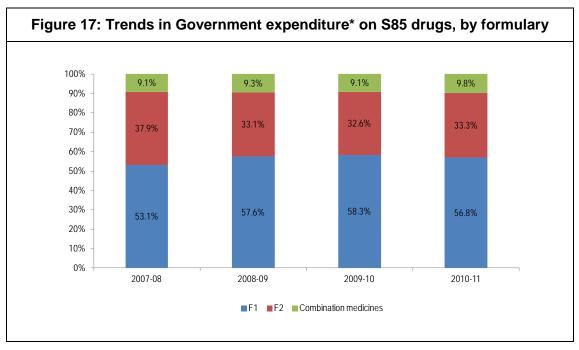


^{*} Percentages may not add to 100 as analysis does not include extemporaneously prepared items

As shown in Figure 17, over half of all the PBS expenditure in the time period analysed relates to medicines on the F1 Formulary (53%-58%). The remaining expenditure is more likely to be on medicines on the F2 formulary (33%-38%) rather than combination medicines (9%). As a trend, in the four years analysed starting 2007-08, the expenditure on F1 medicines as a proportion of overall expenditure rises from 53% in 2007-08 to 57% in 2010-11 whereas F2 medicines, as a proportion, drops to 33% in the same time period. This fall in expenditure on F2 medicines can be partially attributed to statutory price reductions and ongoing price disclosure fuelled by competition within the F2 market. It can also, in part, be attributed to the ongoing listing of new medicines, which move directly into the F1 Formulary.

It should be noted that the analyses conducted in this report do not take into consideration any special pricing arrangements³⁰ on PBS items. There are a number (more than 73 medicines in 2009) of special pricing arrangements in place mostly for F1 products and some F2 products. Some of these arrangements may have an impact on overall government expenditure for these medicines. In 2009-10 the cost reduction to Government was in the order of \$50 million (around 0.5% of the total cost of the PBS) and in 2010-11 was \$98 million (around 1.1% of the total cost of the PBS).

³⁰ Special pricing arrangements are commercial-in-confidence arrangements between the Commonwealth and pharmaceutical companies that affect the actual price paid by the Commonwealth for supplied medicines.



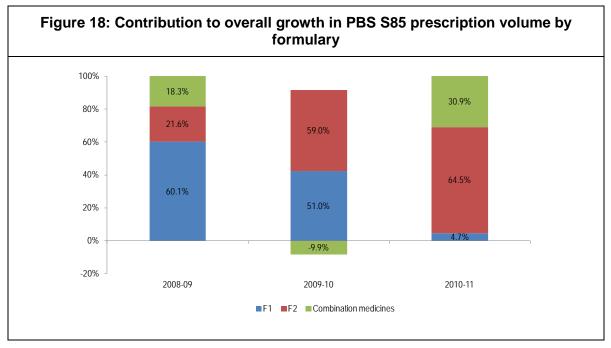
* Percentages may not add to 100 as analysis does not include extemporaneously prepared items

Under the current reforms, as proportion of overall expenditure, the expenditure on F2 medicines may be expected to continue to fall over time as the Government prices start to reflect actual market prices more closely. This will be taken into account by the DWG when examining the relative contributions to PBS expenditure and growth of the F1 and F2 formularies going forward.

Also, these data do not reflect the price reductions on 1 April 2012 from the Expanded and Accelerated Price Disclosure (EAPD) guarantee round. It would be useful to compare the volumes post 1 April 2012 price reductions when comparing the contribution of each formulary to PBS expenditure in the next report which will allow a more complete understanding of the dynamics of PBS growth in each formulary.

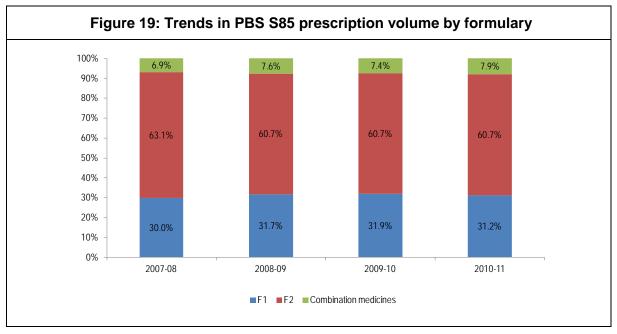
Trends in PBS script volume by formularies (2007-2011)

As shown in Figure 18, the contribution of F2 scripts to PBS prescription volume growth continued to increase across the time period analysed whereas the contribution of F1 scripts fell throughout the time analysed (2007-2011). This is consistent with the expenditure trends in the previous section.



* Percentages may not add to 100 as analysis does not include extemporaneously prepared items

As shown in Figure 19, in volume terms, the majority of PBS subsidised scripts (six out of every 10 scripts) were dispensed for a medicine in the F2 formulary. Three out of every 10 scripts dispensed on the PBS were written for a medicine in the F1 formulary. This trend is consistent across the time period analysed. F2 formulary's growing contribution to the growth in the PBS may reflect the increased volume of F2 medicines being prescribed, due to the increased number of medicines moving into the F2 formulary as patents expire and greater consumer confidence following a number of generic awareness campaigns. In the subsequent reports, the DWG may be able to see the relationship between change in prices (as a result of patent expiries and generic competition) and the shift in volume on overall PBS expenditure growth.



* Percentages may not add to 100 as analysis does not include extemporaneously prepared items

In addition to analysing the trends and contribution to overall growth by formulary, the DWG examined the average cost per PBS subsidised script under each formulary in each year since 2007. As shown in Table 3, the average cost per PBS subsidised script is increasing in both the F1 and F2 formularies. In 2010-11 the average cost per script in the F2 formulary increased at a faster rate than the F1 formulary for the first time.

	F1	% change	F2	% change	Combir	nation items	% change
2007-08	\$ 61.40		\$ 20.79		\$	45.23	
2008-09	\$ 65.82	7%	\$ 19.79	-5%	\$	44.51	-2%
2009-10	\$ 69.91	6%	\$ 20.57	4%	\$	47.15	6%
2010-11	\$ 71.01	2%	\$ 21.41	4%	\$	48.03	2%

Table 3 : Average cost per PBS subsidised S85 script, by formulary
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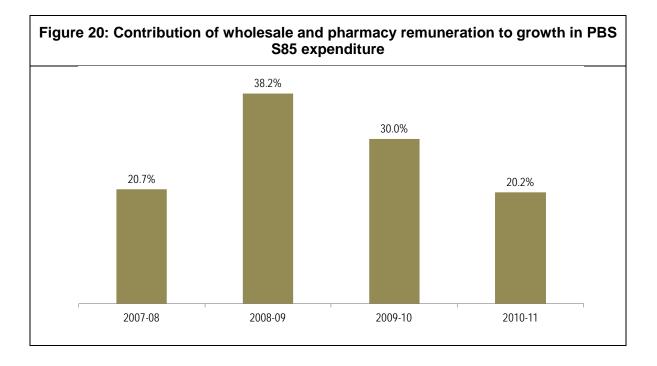
The impact of the 1 August 2008 F2A and F2T price reductions can be clearly be seen in Table 3 while the impact of the 2007 PBS Reform price disclosure measure is not as obvious. This may be due to the fact that medicines are impacted by price disclosure gradually (only a few medicines at a time, every couple of months) as opposed to the 1 August 2008 changes which affected all F2 medicines at the same time. Also, there is a 'lag' in price disclosure price adjustments. Under the 2007 PBS reforms price disclosure arrangements, it could take nearly 24 months for the price of a medicine in the F2A formulary to adjust to reflect the weighted average market price.

It will be interesting to see the impact of expanded and accelerated price disclosure (EAPD) on the growth in average cost of per PBS subsidised S85 scripts in the F2 formulary going forward.

Trends in PBS Section 85 expenditure by supply chain participants (2006-2011)

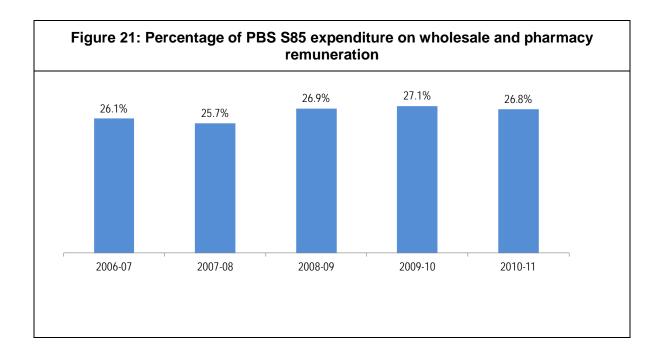
(reference Appendix 2: Table 20 and Table 21)

The following section examines the trends in Government expenditure on PBS by supply chain participants – the wholesalers and the pharmacist. As shown in Figure 20, after peaking in 2008-09, as result of changes in the dispensing fee and pharmacy wholesale mark-ups under the Fourth Community Pharmacy Agreement, the overall contribution of the supply chain participants to PBS expenditure growth returned to 20% in 2010-11. This drop may be attributed to the freezing of dispensing fee for the first two years under the Fifth Community Pharmacy Agreement.



The DWG will continue to monitor the impact of the indexed dispensing fee (ready prepared) and the wholesale and pharmacy retail mark ups on overall PBS expenditure and growth in the future.

As a proportion of overall government expenditure on the PBS, the share of supply chain participants (wholesalers and pharmacy) increased in 2008-09 but has stayed stable since (see Figure 21).

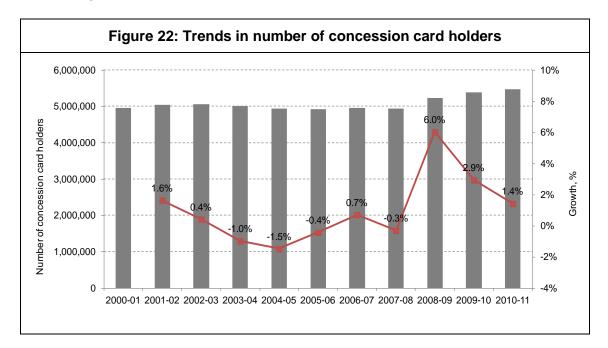


It is important to note that due to commercial arrangements that may exist between pharmacies, wholesalers and manufacturers, the actual proportion of government expenditure going to each participant in the supply chain is unknown.

Trends in concession card holders

(reference Appendix 2: Table 22 and Table 23)

The DWG looked at the trends in the number of concession cards holders by financial year using data available from the Department of Families, Housing, Community Services and Indigenous Affairs (FaHCSIA) annual reports and calculated the growth (year on year) in the time period from 2001 to 2011. As shown in Figure 22, the number of concession card holders remained fairly stable between 2000-01 and 2007-08. However, the number rose by six percent in 2008-09. The growth in concessional card holders has moderated since but continues to grow.



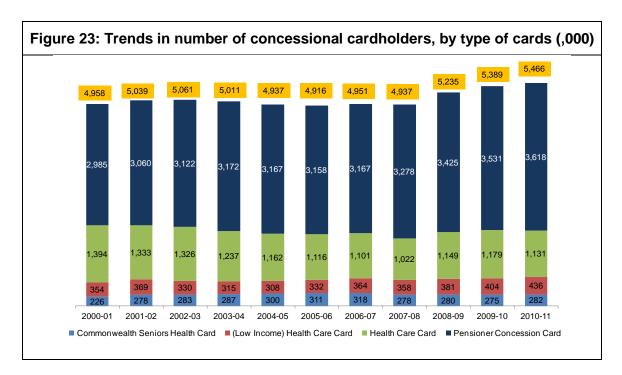
The strong growth seen in 2008-09 was mainly driven by increases in the number of Health Care Cards and Pensioner Concession Cards (see Figure 23).

In the 2006-07 Federal Budget there was a measure that extended Health Care Card eligibility for some students aged 16-25 years, from 1 July 2008.

Also, on the 20 September 2007 the social security pension assets test taper was halved. This change meant that thousands of seniors who were previously unable to get a pension because of their assets' worth became entitled to a part pension. All of these additional Part Aged Pension recipients became eligible for and automatically received a Pensioner Concession Card.

In addition to these factors, unemployment grew strongly over 2008-09 and the stockmarket fell heavily, most likely as a result of the global financial downturn. The stockmarket fall would have seen the value of many older Australians assets reduce markedly. This would have further impacted on the number of people becoming eligible for the Pensioner Concession Card.

Figure 23 shows trends in number of concessional cardholders by type of concession cards in the time period from 2000 to 2011. Overall there has been a steady increase in number of Pensioner Concession Card holders and (low income) Health Care Card since 2007-08. However, there has been a decline in number of Health Care Card holders in 2010-11 after consecutive increases in the previous two years.



Commonwealth Seniors Health Card - The Commonwealth Seniors Health Card is available to older Australians who are of age pension age, satisfy residence and some other requirements and are not receiving an income support payment from the Department of Human Services or from the Department of Veterans' Affairs.

(Low Income) Health Care Card - A Low Income Health Care Card is available to people with incomes below set levels. An income test applies to average gross income for the eight weeks immediately before an application for a new or renewed card. The card is not subject to an assets test.

Health Care Card - A Health Care Card is available to people residing in Australia and receiving any of these payments: Newstart Allowance, Sickness Allowance, Youth Allowance (job seekers only), Partner Allowance, Parenting Payment (partnered), Widow Allowance, Special Benefit, Carer Payment for short-term or episodic care under six months, Exceptional Circumstances Relief Payment for farmers, Family Tax Benefit Part A, (maximum rate only), Mobility Allowance (for persons not receiving Disability Support Pension), Carer Allowance (caring for a child under 16 years)

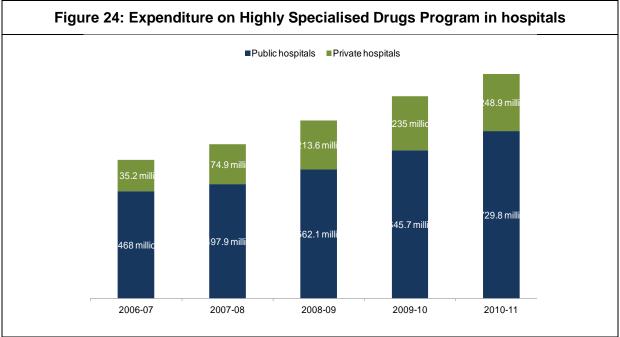
Pensioner Concession Card - A Pensioner Concession Card is available to people in receipt of any of the following income-support payments: Age Pension, Bereavement Allowance, Carer Payment, Disability Support Pension, Newstart Allowance or Youth Allowance (job seeker), Parenting Payment (single). A Pensioner Concession Card is also available to people who are aged over 60 and have been receiving other certain income-support payments for nine months or more. A Pensioner Concession Card may also be

available for people who are receiving other income support payments and have a partial capacity to work because of a medical condition.

Highly Specialised Drugs³¹ (HSD) Program - General Trends (2006-2011)

(reference Appendix : Table 24, Table 25 and Table 26)

The HSD program has grown from expenditure of just over \$600 million dollars in 2006-07 to over a billion dollars in 2010-11³². As shown in Figure 24, the majority of the expenditure on the HSD program is through public hospitals (73%-78%). This trend is consistent across the time period analysed (2006-2011).



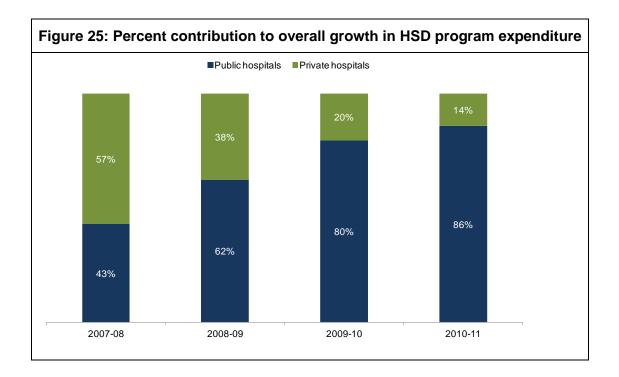
Source: PBPA annual reports, various years (2006-07 to 2009-10), DoHA unpublished (2010-11)

However, in terms of the contribution to growth, in the time periods analysed (2006-2011), the contribution to growth from public hospitals rose from 43% in 2007-08 to 86% in 2010-11 whereas contribution to growth from private hospitals fell from 57% in 2007-08 down to 14% in 2010-11 (see Figure 25). This is a large increase and to some extent is accounted for by the fact that three quarters (75%) of all HSD expenditure is in public hospitals.

Due to some tightening of the counting rules applied to the allocation of HSD expenditure to public vs private hospitals, 2009-10 and 2010-11 may not be directly comparable.

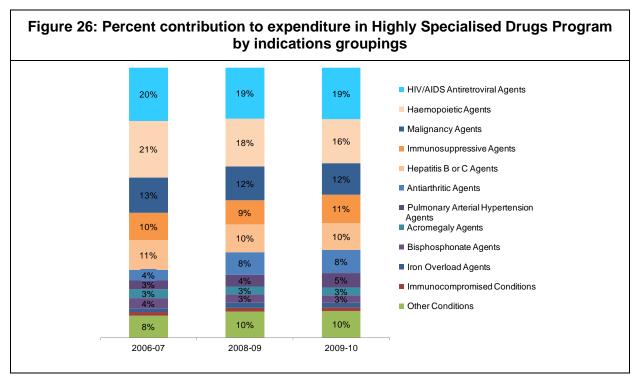
³¹ See definition in Appendix A.

³² According to DoHA publication (Expenditure and prescription twelve months to 30 June 2011), expenditure on HSD for year ending June 2011 was \$1014.8 million.



Indication groupings

All the medicines listed on the HSD program are classified into 12 indication groupings. Between 2006 and 2010, 17 new medicines were added to the HSD program across the 12 indications groupings. The top 5 indications groups by value include HIV/AIDS antiretrovirals, Haemopoietic, malignancy, immunosuppressive and Hepatitis B or C agents. Together these categories contributed the vast majority of the expenditure on the HSD program (68%-75%) in the time period analysed (2006-2010).



Note: HSD Expenditure data by indication groupings is currently not available for 2010-11.

In terms of contribution to year on year growth, there were variations across the time period. In terms of trends, Immunosuppressive agents, HIV/AIDS anti-retrovirals continued to contribute to overall growth throughout the time period, whereas the contribution of Antiarthritic agents and Haemopoetic agents to HSD growth fell throughout in the same time period.

by mateau	ons grouping	3	
	2007-08	2008-09	2009-10
Immunosuppressive Agents	3.8%	5.5%	22.2%
HIV/AIDS Antiretroviral Agents	11.0%	19.6%	20.8%
Pulmonary Arterial Hypertension Agents	10.2%	6.6%	13.2%
Antiarthritic Agents	19.5%	27.6%	8.9%
Hepatitis B or C Agents	12.4%	4.0%	8.4%
Haemopoietic Agents	1.7%	9.7%	5.7%
Malignancy Agents	19.7%	3.7%	5.0%
Acromegaly Agents	2.7%	1.8%	2.9%
Immunocompromised Conditions	2.7%	0.6%	1.0%
Bisphosphonate Agents	-1.7%	0.6%	0.2%
Iron Overload Agents	10.0%	0.9%	0.0%
Other Conditions	8.0%	19.2%	11.7%

 Table 4: Contribution to total growth in Highly Specialised Drugs Program by indications groupings

Note: HSD Expenditure data by indication groupings is currently not available for 2010-11.

Conclusions

Based on the analysis in this report, the DWG conclude that the ageing profile of the Australian population has a significant impact on PBS expenditure and growth. This is demonstrated by the proportion of PBS expenditure and growth accounted for by patients aged 55 years and over and the increasing proportion of the population aged 55 years and over. Linked to the ageing of the patient population, most older patients are concessional (90% of patients aged 65 years and over were concessional in 2010-11³³) and the Government pays a higher proportion of the total cost of medicines for concessional patients (89% for concessional patients as opposed to 69% for general patients in 2010-11).

The DWG notes the significant impact of the change in volume of existing medicines and new medicines in the four years after they were listed on changes in PBS expenditure. The high prevalence of chronic diseases among Australians together with the ageing of the population is likely to continue to increase the demand for prescription medicines in Australia. Currently, antineoplastics and immunomodulating agents, along with medicines that act on nervous system and sensory organs are the key contributors to PBS growth.

The combined impact of high disease prevalence and ageing of the population is further magnified by concessional entitlements. The majority of Australian patients accessing government subsidised medicines have concessional entitlements which allows them access to pharmaceuticals at highly subsidised rates (\$5.80 in 2012). As a result, the Government continues to pay a large share of expenditure for PBS subsidised medicines in Australia (84% for general and concessional patients in 2010-11).

As noted above, listings of new medicines along with increased usage of existing medicines are contributing to the increases in PBS growth and expenditure. This is balanced to some extent by changes in the average cost to Government, which may reflect price changes instituted by Government policies such as the 2007 PBS reforms and the 2010 further PBS reforms. Further analysis of the relative impact of new listings and existing listings across a longer time period confirms this finding.

There are a number of welfare policies that have an impact on the eligibility and entitlements of individuals to subsidised PBS medicines; the DWG has made cursory attempts to examine some of these policies but the complexity of relationships and lack of data remains a challenge.

DWG further notes that the F2 formulary is currently driving growth in PBS expenditure and that the split in government expenditure of F1 and F2 are constant over time. The F1 formulary's contribution to growth should be seen in the context of the rebated prices for some medicines as a result of the special pricing arrangements in place. Although the special pricing arrangements do not impact the administered PBS cost directly, they do impact, to a small degree, overall Government expenditure on the PBS indirectly.

Based on DWG analysis, medicines on the F2 formulary contributed to nearly half of all the change in PBS expenditure and two-thirds of the change in the volume of PBS medicines in 2010-11. Further analysis suggests that the 2007 PBS reforms had a negative impact on costs per script in the F2 formulary in 2008-09 (falling by 5%). However, since then the average growth in Government cost per script for medicines in the F2 formulary has remained fairly stable.

³³ DoHA unpublished

The DWG also noted that the average Government cost per F1 script remains higher than F2 scripts (\$71 compared to \$21 in 2010-11 - this is not unexpected given F1 and F2 medicines exist in different markets with separate pricing mechanisms³⁴).

Although falling, F1 medicines continue to contribute a significant minority of PBS expenditure growth (26% in 2010-11, down from 68% in 2009-10) while F1 scripts contributed to 5% of total PBS script growth in 2010-11 (down from 51% in 2009-10).

DWG also notes that wholesale and pharmacy remuneration has the potential to contribute to PBS S85 expenditure. For instance, in 2008-09, supply chain remuneration accounted for nearly two-fifths (39%) of all the growth in PBS expenditure.

The DWG will continue to monitor the impact of indexed dispensing fee (ready prepared), the wholesale and pharmacy retail markups on overall PBS expenditure and growth over time.

Overall, the DWG concludes that following key drivers of PBS expenditure should be analysed and reported with policy context on a regular basis to the AMWG:

- 1. ageing of the Australian population and in particular the PBS medicines usage in older Australians;
- price changes both policy related or otherwise (including the impact of successive Price Disclosure rounds);
- 3. the overall disease burden, in particular of chronic diseases and age related diseases such as neurological and sense disorders;
- 4. usage of existing and new medicines; and
- 5. Highly Specialised Drugs (HSD) program.

It is envisaged that the DWG will continue to monitor the remaining drivers on a regular basis. In an event of a significant shift in contribution to growth from other drivers, the DWG will bring the analysis to AMWG sub-group's attention in the first instance and based on their advice escalate the analysis further to the AMWG at the next available opportunity.

³⁴ Value based pricing is used for setting prices for medicines in the F1 formulary whereas the prices for medicines in the F2 formulary are based on market competition between multiple suppliers.

Appendix 1: Background definitional and methodological information

S85 expenditure and prescriptions

Unless otherwise indicated throughout the analysis, expenditure and prescriptions are Section 85 general and concessional government expenditure and prescriptions, excluding Doctors Bag prescriptions, processed through Medicare Australia.

All data (unless the indicated source is DUSC, BEACH or S100) is date of processing data. This means that the scripts and expenditure reported in a particular year relate to the scripts processed by Medicare Australia in that year, and not scripts dispensed by pharmacies in that year.

Analysis by patient age

In counting patients by age in a year (Table 12 and Table 13), the patients latest age in the year is used so as to avoid double counting patients as they age throughout the year.

Supply chain

The supply chain expenditure includes an estimate of the amount the government pays for the supply chain remuneration components:

dispensing fee, pharmacy retail markup, container fee, dangerous drug fee, wastage fee and wholesaler markup.

It does not include Community Service Obligation, Premium Free Dispensing Incentive or PBS Online Incentive expenditure as this expenditure is not included in the PBS expenditure normally reported in the Annual Report or Budget papers.

Analysis by Formulary

The formulary data is provided on a slightly different basis to the data used in other tables. The data in Tables 3, 17 and 18 is PBS S85 general and concessional INCLUDING Doctors Bag, but excluding extemporaneously prepared items. All other PBS expenditure includes extemporaneously prepared items.

Highly Specialised Drugs

Highly Specialised Drugs (HSD) are subsidised through the PBS. These medicines are for the treatment of chronic conditions that, because of their clinical use or other special features, are restricted to supply through public and private hospitals that have appropriate specialist facilities.

Figures for the public and private hospital disaggregation of Highly Specialised Drugs (HSDs) were produced on a slightly different basis in 2010-11 to previous years so figures are not directly comparable. The revised methodology tightens up counting rules around what is public and what is private expenditure, however the difference is not large and total HSD expenditure remains consistent and comparable across all time periods.

Appendix 2: Supporting tables

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Concessional	4,252,756,142	4,320,976,347	4,445,205,256	4,814,338,331	5,198,031,063	5,642,410,001	5,872,450,153
General	1,075,476,316	1,074,263,041	1,048,209,419	1,243,133,352	1,395,610,392	1,516,879,746	1,596,541,406
Highly Specialised Drugs	462,244,297	527,631,676	627,881,969	653,078,415	750,749,744	858,451,556	1,014,835,508
Drs Bag	9,462,425	10,382,160	12,145,525	14,807,842	15,950,231	14,987,649	15,617,141
Section 100	193,262,310	221,993,462	286,975,503	300,455,526	310,585,936	350,462,616	364,327,645
Safety Net Cards	7,981,556	7,882,853	7,880,972	8,002,110	8,345,075	8,486,678	8,895,477
Total	6,001,183,045	6,163,129,539	6,428,298,644	7,033,815,575	7,679,272,440	8,391,678,245	8,872,667,330

Table 5 : Pharmaceutical Benefits expenditure on accrual accounting basis, by category of expenditure

Source: DoHA Expenditure and Prescriptions reports between June 2005 and June 2011, Table 1(a)

Table 6: Contribution to Pharmaceutical Benefits expenditure growth, by category of expenditure

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Concessional	42%	47%	61%	59%	62%	48%
General	-1%	-10%	32%	24%	17%	17%
Highly Specialised Drugs	40%	38%	4%	15%	15%	33%
Drs Bag	0.6%	0.7%	0.4%	0.2%	-0.1%	0%
Section 100	18%	25%	2%	2%	6%	3%
Safety Net Cards	-0.1%	0.0%	0.0%	0.1%	0.02%	0.1%
Total	100%	100%	100%	100%	100%	100%

Source: Based on data from DoHA Expenditure and Prescriptions reports between June 2005 and June 2011, Table 1(a)

Table 7: Key Drivers and their contribution to PBS growth (\$m) – 1 year analysis

	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Net new listings (new listings less delisted medicines)	\$ 22.32	\$ 82.63	\$ 42.48	\$ 29.37	\$ 22.07	\$ 88.26	\$ 170.55	\$ 50.06	\$ 92.21	\$ 34.43
Effect of change in price of existing medicines	-\$ 168.02	-\$ 27.83	-\$ 24.02	-\$ 119.18	-\$ 198.36	-\$ 267.15	-\$ 67.76	-\$ 162.25	-\$ 34.86	-\$ 184.97
Impact of change in volume of existing medicines	\$ 542.01	\$ 306.72	\$ 450.23	\$ 335.03	\$ 299.57	\$ 265.19	\$ 466.39	\$ 619.77	\$ 513.99	\$ 521.22
Total change	\$ 396.32	\$ 361.52	\$ 468.68	\$ 245.21	\$ 123.28	\$ 86.30	\$ 569.17	\$ 507.58	\$ 571.34	\$ 370.68

This analysis is based on Drug Utilisation estimates as provided by the Drug Utilisation Sub-Committee in various years.

Table 8: Key Drivers and their contribution to PBS growth (\$m) - 4 year analysis

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Net new listings (new listings less delisted medicines)	\$ 88.32	\$ 158.29	\$ 351.01	\$ 350.92	\$ 334.71	\$ 227.23
Effect of change in price of existing medicines	-\$ 141.31	-\$ 234.97	-\$ 24.35	-\$ 117.09	-\$ 25.67	-\$ 188.18
Impact of change in volume of existing medicines	\$ 176.27	\$ 162.98	\$ 242.51	\$ 273.75	\$ 262.29	\$ 331.63
Total change	\$ 123.28	\$ 86.30	\$ 569.17	\$ 507.58	\$ 571.34	\$ 370.68

Table 9: Trends in PBS section 85 expenditure, by ATC level 1.

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Alimentary tract and metabolism	\$ 810,942,845	\$ 771,683,522	\$ 827,530,870	\$ 890,847,263	\$ 926,699,120	\$ 923,799,439
Blood and blood forming organs	\$ 202,273,505	\$ 215,943,807	\$ 239,879,460	\$ 270,168,496	\$ 281,844,190	\$ 272,833,540
Cardiovascular system	\$ 1,682,559,715	\$ 1,712,647,730	\$ 1,776,782,680	\$ 1,888,147,756	\$ 1,992,102,108	\$ 2,033,188,679
Dermatologicals	\$ 56,209,465	\$ 55,063,836	\$ 59,997,886	\$ 68,444,605	\$ 72,282,298	\$ 74,064,623
Genito urinary system and sex hormones	\$ 85,351,856	\$ 83,125,428	\$ 85,393,440	\$ 90,449,888	\$ 87,343,723	\$ 90,374,996
Systemic hormonal preparations, excl. sex hormones	\$ 28,390,815	\$ 31,425,135	\$ 33,360,719	\$ 40,441,756	\$ 45,629,958	\$ 50,366,163
Antiinfectives for systemic use	\$ 231,520,481	\$ 212,097,020	\$ 219,536,515	\$ 227,729,048	\$ 232,170,089	\$ 244,419,139
Antineoplastic and immunomodulating agents	\$ 539,426,177	\$ 609,924,113	\$ 743,198,405	\$ 940,337,930	\$ 1,078,638,710	\$ 1,193,303,228
Musculo-skeletal system	\$ 278,024,622	\$ 271,112,984	\$ 258,332,651	\$ 257,241,203	\$ 255,780,910	\$ 246,393,974
Nervous system	\$ 953,859,572	\$ 994,521,388	\$ 1,070,812,805	\$ 1,193,415,674	\$ 1,260,397,485	\$ 1,339,658,439
Antiparasitic products, insecticides and repellents	\$ 1,348,679	\$ 546,303	\$ 608,891	\$ 735,934	\$ 929,134	\$ 1,077,571
Respiratory system	\$ 364,813,421	\$ 352,993,685	\$ 369,361,313	\$ 387,481,628	\$ 397,300,921	\$ 415,867,759
Sensory organs	\$ 98,624,379	\$ 103,990,868	\$ 172,949,367	\$ 245,064,929	\$ 321,195,495	\$ 384,176,609
Various	\$ 47,386,611	\$ 47,286,604	\$ 51,202,938	\$ 59,192,540	\$ 62,153,685	\$ 64,844,193
Total	\$ 5,380,732,143	\$ 5,462,362,424	\$ 5,908,947,938	\$ 6,559,698,651	\$ 7,014,467,825	\$ 7,334,368,352

Table 10: Trends in population by age

	June 2001	June 2011
0-24	6,667,732	7,411,478
25-34	2,914,638	3,258,843
35-44	2,952,307	3,184,551
45-54	2,647,195	3,064,788
55-64	1,802,679	2,597,365
65-74	1,301,481	1,683,829
75+	1,100,631	1,419,700

Source: AUSTRALIAN DEMOGRAPHIC STATISTICS, catalogue number 3101, June qtr, 2001 and 2011

Table 11: Trends in patient population as a proportion of total Australian population

	2006-07	2007-08	2008-09	2009-10	2010-11
Patient population	8,731,595	8,672,080	8,994,930	9,128,585	9,265,507
Australian population	21,072,452	21,498,540	21,951,736	22,328,847	22,620,554
Patients as a proportion of Australian population	41.4%	40.3%	41.0%	40.9%	41.0%

Note: Only includes patients accessing prescriptions subsidised by the Australian Government.

Age Group	2006-07	2007-08	2008-09	2009-10	2010-11
0-24	21.2%	21.0%	20.8%	21.0%	20.9%
25-34	9.3%	8.9%	9.0%	9.1%	9.2%
35-44	12.3%	12.0%	12.0%	11.9%	11.8%
45-54	14.6%	14.3%	14.4%	14.1%	13.9%
55-64	16.6%	16.8%	16.8%	16.5%	16.4%
65-74	14.2%	14.7%	14.7%	15.0%	15.3%
75+	11.8%	12.3%	12.2%	12.4%	12.6%

 Table 12: Trends in patient population as a proportion of total patient population, by age

								Financi	al Years								
				2006	b-07				2007-08								
Age group		Cor	ncessional				General			Cor	ncessional				General		
	Scrip	ts	Expenditu	re	Scrij	ots	Expenditur	re	Scrip	lts	Expenditu	re	Scrij	ots	Expenditu	re	
	Numbers	%	\$	%	Numbers	%	\$	%	Numbers	%	\$	%	Numbers	%	\$	%	
0 to 17 years	4,535,528	3.16%	\$87,094,841.52	1.98%	572,272	2.33%	\$29,066,712.36	2.73%	4,586,978	3.12%	\$98,360,675.48	2.09%	673,344	2.79%	\$37,032,456.19	3.05%	
18 to 24 years	2,213,604	1.54%	\$69,367,246.61	1.58%	587,812	2.39%	\$33,625,433.17	3.16%	2,020,089	1.38%	\$66,069,920.28	1.41%	598,438	2.48%	\$39,338,628.74	3.24%	
25 to 34 years	4,220,004	2.94%	\$156,296,974.74	3.55%	1,535,234	6.25%	\$88,186,119.94	8.29%	3,992,620	2.72%	\$154,766,909.31	3.2 <mark>9</mark> %	1,498,109	6.20%	\$100,900,493.84	8.32%	
35 to 44 years	7,349,709	5.12%	\$262,291,698.55	5.96%	3,062,421	12.46%	\$158,554,675.65	14.90%	7,143,029	4.87%	\$267,992,626.60	5.70%	2,953,451	12.22%	\$180,925,307.24	14.92%	
45 to 54 years	11,166,146	7.78%	\$383,024,225.94	8.70%	6,701,369	27.26%	\$284,098,083.53	26.69%	11,078,235	7.55%	\$399,672,579.24	8.51%	6,327,961	26.19%	\$317,486,988.43	26.17%	
55 to 64 years	23,174,165	16.14%	\$750,490,465.53	17.05%	8,939,593	36.37%	\$343,723,722.08	32.29%	23,455,494	15.98%	\$789,745,487.69	16.81%	8,757,505	36.25%	\$385,727,111.18	31.80%	
65 to 74 years	42,307,131	29.46%	\$1,320,312,629.20	30.00%	1,829,838	7.44%	\$75,819,498.82	7.12%	43,964,133	29.95%	\$1,423,125,322.40	30.28%	1,938,016	8.02%	\$89,013,688.76	7.34%	
75 years and over	47,076,030	32.78%	\$1,327,357,045.10	30.16%	1,092,659	4.44%	\$40,069,543.43	3.76%	49,693,592	33.85%	\$1,474,336,416.00	31.37%	1,242,506	5.14%	\$54,390,986.03	4.48%	
Age unknown	1,550,749	1.08%	\$45,118,895.67	1.03%	260,893	1.06%	\$11,259,518.00	1.06%	864,877	0.59%	\$25,149,738.80	0.54%	171,464	0.71%	\$8,135,638.31	0.67%	
Total	143,593,066	100.00%	\$4,401,354,022.90	100.00%	24,582,091	100.00%	\$1,064,403,307.00	100.00%	146,799,047	100.00%	\$4,699,219,675.80	100.00%	24,160,794	100.00%	\$1,212,951,298.70	100.00%	

Table 13: Trends in Government scripts and expenditure for S85 drugs by age groups

								Financi	al Years							
				2008	3-09				2009-10							
Age group		Cor	ncessional				General Concessional General					General				
	Scrip	ts	Expenditu	re	Scrip	ots	Expenditu	re	Scrip	ots	Expenditu	e	Scrip	ots	Expenditur	e
	Numbers	%	\$	%	Numbers	%	\$	%	Numbers	%	\$	%	Numbers	%	\$	%
0 to 17 years	4,766,875	3.07%	\$106,069,462.54	2.07%	738,738	2.81%	\$40,731,406.44	2.83%	4,702,994	2.98%	\$111,146,636.07	2.03%	750,527	2.89%	\$42,347,151.92	2.75%
18 to 24 years	2,093,965	1.35%	\$69,811,688.96	1.36%	641,633	2.44%	\$45,867,276.85	3.19%	2,211,312	1.40%	\$75,834,191.58	1.38%	635,829	2.45%	\$46,909,674.18	3.05%
25 to 34 years	4,150,939	2.68%	\$165,426,273.77	3.23%	1,588,963	6.04%	\$119,528,982.24	8.31%	4,273,441	2.71%	\$173,655,294.48	3.17%	1,605,395	6.18%	\$126,622,976.53	8.23%
35 to 44 years	7,379,441	4.76%	\$287,185,952.36	5.60%	3,117,995	11.84%	\$214,083,598.80	14.89%	7,493,552	4.76%	\$304,045,879.98	5.55%	3,085,947	11.87%	\$226,417,215.98	14.71%
45 to 54 years	11,393,460	7.34%	\$427,715,027.50	8.34%	6,745,993	25.62%	\$374,214,696.26	26.03%	11,528,413	7.32%	\$453,934,723.93	8.28%	6,542,548	25.17%	\$395,326,594.63	25.69%
55 to 64 years	23,996,472	15.47%	\$836,889,949.47	16.33%	9,671,111	36.73%	\$460,169,450.51	32.01%	23,662,901	15.02%	\$873,944,991.01	15.95%	9,468,785	36.43%	\$492,499,276.09	32.01%
65 to 74 years	46,912,382	30.24%	\$1,562,455,515.30	30.48%	2,214,827	8.41%	\$107,199,093.42	7.46%	47,760,596	30.31%	\$1,671,549,850.60	30.50%	2,261,567	8.70%	\$121,176,824.82	7.87%
75 years and over	53,603,528	34.55%	\$1,644,901,766.90	32.09%	1,406,679	5.34%	\$66,219,482.38	4.61%	55,122,347	34.98%	\$1,790,171,277.10	32.67%	1,452,881	5.59%	\$78,085,118.67	5.07%
Age unknown	843,656	0.54%	\$25,178,613.87	0.49%	201,474	0.77%	\$9,753,302.65	0.68%	833,452	0.53%	\$25,828,097.65	0.47%	186,706	0.72%	\$9,396,379.50	0.61%
Total	155,140,718	100.00%	\$5,125,634,250.60	100.00%	26,327,413	100.00%	\$1,437,767,289.50	100.00%	157,589,008	100.00%	\$5,480,110,942.40	100.00%	25,990,185	100.00%	\$1,538,781,212.30	100.00%

				Financia	I Years						
				2010)-11						
Age group		Cond	essional		General						
	Scrip	ts	Expenditu	ire	Scrij	ots	Expenditu	re			
	Numbers	%	\$	%	Numbers	%	\$	%			
0 to 17 years	4,804,767	2.97%	\$ 113,853,863	2.00%	773,992	2.98%	\$ 42,214,441	2.60%			
18 to 24 years	2,301,737	1.42%	\$ 78,820,729	1.38%	639,941	2.46%	\$ 48,678,733	3.00%			
25 to 34 years	4,382,287	2.71%	\$ 178,179,271	3.13%	1,610,067	6.20%	\$ 135,788,981	8.36%			
35 to 44 years	7,618,613	4.71%	\$ 313,212,387	5.50%	3,036,645	11.69%	\$ 238,962,241	14.71%			
45 to 54 years	11,735,050	7.25%	\$ 466,764,620	8.19%	6,339,636	24.41%	\$ 411,718,641	25.34%			
55 to 64 years	23,708,756	14.65%	\$ 886,918,040	15.56%	9,515,303	36.63%	\$ 520,460,581	32.03%			
65 to 74 years	48,971,124	30.26%	\$ 1,731,505,015	30.39%	2,441,895	9.40%	\$ 135,712,100	8.35%			
75 years and over	57,533,298	35.55%	\$ 1,905,173,320	33.43%	1,449,667	5.58%	\$ 82,583,246	5.08%			
Age unknown	773,277	0.48%	\$ 23,995,289	0.42%	168,485	0.65%	\$ 8,607,306	0.53%			
Total	161,828,909	100.00%	\$ 5,698,422,533	100.00%	25,975,631	100.00%	\$ 1,624,726,270	100.00%			

Table 14: Contribution to total growth in Government expenditure on S85 drugs by age groups

Age group		2006-07 to	2007-08			2007-08 te	o 2008-09			2008-0	9 to 2009-10			2009-10	to 2010-11	
Age group	\$ growth	% contrib	Script growth	% contrib	\$ growth	% contrib	Script growth	% contrib	\$ growth	% contrib	Script growth	% contrib	\$ growth	% contrib	Script growth	% contrib
0 to 17 years	\$ 19,231,578	4.31%	152,522	5.48%	\$ 11,407,737	1.75%	245,291	2.33%	\$ 6,692,919	1.47%	- 52,092	-2.47%	\$ 2,574,516	0.85%	125,238	2.96%
18 to 24 years	\$ 2,415,869	0.54%	- 182,889	-6.57%	\$ 10,270,417	1.58%	117,071	1.11%	\$ 7,064,900	1.55%	111,543	5.28%	\$ 4,755,597	1.56%	94,537	2.24%
25 to 34 years	\$ 11,184,308	2.51%	- 264,509	-9.50%	\$ 29,287,853	4.50%	249,173	2.37%	\$ 15,323,015	3.36%	138,934	6.58%	\$ 13,689,980	4.50%	113,518	2.69%
35 to 44 years	\$ 28,071,560	6.29%	- 315,650	-11.34%	\$ 52,351,617	8.04%	400,956	3.82%	\$ 29,193,545	6.41%	82,063	3.89%	\$ 21,711,531	7.14%	75,759	1.79%
45 to 54 years	\$ 50,037,258	11.21%	- 461,319	-16.57%	\$ 84,770,156	13.02%	733,257	6.98%	\$ 47,331,595	10.39%	- 68,492	-3.24%	\$ 29,221,943	9.60%	3,725	0.09%
55 to 64 years	\$ 81,258,411	18.20%	99,241	3.56%	\$121,586,801	18.67%	1,454,584	13.84%	\$ 69,384,867	15.23%	- 535,897	-25.39%	\$ 40,934,353	13.45%	92,373	2.19%
65 to 74 years	\$ 116.006.883	25.99%	1.765.180	63.39%	\$157.515.598	24.19%	3,225,060	30.69%	\$123.072.067	27.02%	894,954	42.39%	\$ 74,490,439	24.48%	1.390.856	32.92%
75 years and over	\$ 161,300,814	36.13%	2,767,409	99.38%	\$182,393,847	28.01%	4,074,109	38.77%	\$157,135,146	34.50%	1,565,021	74.13%	\$119,500,170	39.28%	2,407,737	56.98%
Age unknown	-\$ 23,093,037	-5.17%	- 775,301	-27.84%	\$ 1,646,539	0.25%	8,789	0.08%	\$ 292,561	0.06%	- 24,972	-1.18%	-\$ 2,621,881	-0.86%	- 78,396	-1.86%
Total	\$ 446,413,645	100.00%	2,784,684	100.00%	\$651,230,566	100.00%	10,508,290	100.00%	\$455,490,615	100.00%	2,111,062	100.00%	\$304,256,649	100.00%	4,225,347	100.00%

		2006	6/07			2007	//08			2008/	/09			2009/10				2010/1	1	
	Expenditure	e	Scripts		Expenditure	e	Scripts		Expenditure	è	Scripts		Expenditure		Scripts		Expenditure		Scripts	;
	s	%	Number	%	\$	%	Number	%	s	%	Number	%	\$	%	Number	%	\$	%	Number	%
General Copay	\$ 890,275,536	16%	19,871,669	12%	\$ 1,039,451,749	18%	19,607,454	11%	\$ 1,220,279,806	19%	20,746,777	11%	\$ 1,339,182,210	19%	21,226,750	12%	\$ 1,412,781,351.71	19%	21,032,398	11%
General SN	\$ 174,127,771	3%	4,710,422	3%	\$ 173,499,550	3%	4,553,340	3%	\$ 217,487,483	3%	5,580,636	3%	\$ 199,599,002	3%	4,763,435	3%	\$ 211,944,918.29	3%	4,943,233	3%
Concessional Copay	\$ 3,333,875,949	61%	110,917,202	66%	\$ 3,561,294,283	60%	113,118,234	66%	\$ 3,909,584,010	60%	119,906,347	66%	\$ 4,220,391,341	60%	122,832,364	67%	\$ 4,367,739,897.21	60%	125,446,923	67%
Concessional SN	\$ 1,067,478,074	20%	32,675,864	19%	\$ 1,137,925,393	19%	33,680,813	20%	\$ 1,216,050,241	19%	35,234,371	19%	\$ 1,259,719,602	18%	34,756,644	19%	\$ 1,330,682,635.72	18%	36,381,986	19%
Total (excl Drs Bag)	\$ 5,465,757,330	100%	168,175,157	100%	\$ 5,912,170,975	100%	170,959,841	100%	\$ 6,563,401,540	100%	181,468,131	100%	\$ 7,018,892,155	100%	183,579,193	100%	\$ 7,323,148,803	100%	187,804,540	100%
Drs Bag	\$10,698,205		360,362		\$ 13,468,779		336,182		\$ 14,533,302		367,996		\$ 13,571,776		332,344		\$ 14,228,519.83		337,715	
Total (incl Drs Bag)	\$ 5,476,455,535		168,535,519		\$ 5,925,639,754		171,296,023		\$ 6,577,934,842		181,836,127		\$ 7,032,463,931		183,911,537		\$ 7,337,377,323		188,142,255	

 Table 15: Trends in Government scripts and expenditure for S85 drugs by general/concessional status

Table 16: Contribution to total growth in Government expenditure on S85 drugs, by general/concessional status

		Growth 2006-0 2007-08	17 to		Growth 2007- 2008-09	08 to		Growth 2008-0 2009-10	09 to	Growth 2009- 2010-11	
		\$	%		\$	%		\$	%	\$	%
General Copay	\$	149,176,213	33.4%	\$	180,828,057	27.8%	\$	118,902,404	26.1%	\$ 73,599,142	24.2%
General SN Concessional Copay	-\$ \$	628,221 227,418,334	-0.1% 50.9%	\$ \$	43,987,933 348,289,727	6.8% 53.5%	-\$ \$	17,888,481 310,807,331	-3.9% 68.2%	\$ 12,345,916 \$ 147,348,557	4.1% 48.4%
Concessional SN	\$	70,447,319	15.8%	\$	78,124,848	12.0%	\$	43,669,361	9.6%	\$ 70,963,034	23.3%
Total (excl Drs Bag)	\$	446,413,645	100.0%	\$	651,230,565	100.0%	\$	455,490,615	100.0%	\$ 304,256,648	100.0%
Drs Bag	\$ 2,770,574		\$	1,064,523		-\$	961,526		\$ 656,744		
Total (incl Drs Bag)	\$	\$ 449,184,219		\$	652,295,088		\$	454,529,089		\$ 304,913,392	

		Gov't PBS expenditure	Patient contribution	Total Cost
	General PBS	\$ 1,064,403,307	\$ 618,637,888	\$ 1,683,041,195
2006-07	Concessional PBS	\$ 4,401,354,023	\$ 532,682,972	\$ 4,934,036,994
	Total	\$ 5,465,757,330	\$ 1,151,320,859	\$ 6,617,078,189
	General	\$ 1,212,951,299	\$ 629,506,417	\$ 1,842,457,716
2007-08	Concessional	\$ 4,699,219,676	\$ 559,962,883	\$ 5,259,182,559
	Total	\$ 5,912,170,974	\$ 1,189,469,300	\$ 7,101,640,274
	General	\$ 1,437,767,290	\$ 691,378,400	\$ 2,129,145,690
2008-09	Concessional	\$ 5,125,634,250	\$ 617,378,323	\$ 5,743,012,573
	Total	\$ 6,563,401,540	\$ 1,308,756,723	\$ 7,872,158,263
	General	\$ 1,538,781,212	\$ 727,215,106	\$ 2,265,996,318
2009-10	Concessional	\$ 5,480,110,943	\$ 656,949,638	\$ 6,137,060,581
	Total	\$ 7,018,892,155	\$ 1,384,164,743	\$ 8,403,056,898
	General	\$ 1,624,726,270	\$ 734,674,267	\$ 2,359,400,537
2010-11	Concessional	\$ 5,698,422,533	\$ 689,108,592	\$ 6,387,531,125
	Total	\$ 7,323,148,803	\$ 1,423,782,860	\$ 8,746,931,663

Table 17: Trends in patient contribution and Government contribution T

Table 18: Trends in Government scripts and expenditure for S85 drugs, by formulary

		F1				F2				Combination	n items		Ex	temporaneously p	repared item:	s		Total		
	Expen	diture	Scrip	ots	Expen	diture	Scrip	ts	Expe	nditure	Scrip	ots	Expe	enditure	Scr	ipts	Expen	diture	Scrip	its
Year	\$	% contrib to expenditure	Number	% contrib to scripts	\$	% contrib to expenditure	Number	% contrib to scripts	\$	% contrib to expenditure	Number	% contrib to scripts	\$	% contrib to expenditure	Number	% contrib to scripts	\$	% contrib. to expenditure	Number	% contrib to scripts
2007-08	3,131,954,896	53.0%	51,008,382	29.8%	2,239,971,926	37.9%	107,755,030	63.0%	537,020,886	9.1%	11,873,877	6.9%	3,223,266	0.1%	322,552	0.2%	5,912,170,974	100.0%	170,959,841	100.0%
2008-09	3,773,390,258	57.5%	57,328,494	31.6%	2,171,897,298	33.1%	110,021,628	60.6%	614,408,197	9.4%	13,803,861	7.6%	3,705,787	0.1%	314,148	0.2%	6,563,401,540	100.0%	181,468,131	100.0%
2009-10	4,084,877,974	58.2%	58,433,559	31.8%	2,288,530,142	32.6%	111,257,498	60.6%	641,059,689	9.1%	13,595,501	7.4%	4,424,349	0.1%	292,635	0.2%	7,018,892,155	100.0%	183,579,193	100.0%
2010-11	4,163,173,571	56.8%	58,630,063	31.2%	2,440,051,920	33.3%	113,981,101	60.7%	715,717,392	9.8%	14,902,034	7.9%	4,205,920	0.1%	291,342	0.2%	7,323,148,803	100.0%	187,804,540	100.0%

Source: PBS section 85 General and Concessional expenditure and scripts

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Gov't expenditure is PBS S85 general and concessional scripts and expenditure including drs bag, excluding extemporaneously prepared items.

Table 19: Contribution to overall growth in Government scripts and expenditure for S85 drugs by formulary

		F1				F2	1			Combinat	ion items		Exte	emporaneousl	y prepared items			Tota	I	
¥	Gov't PBS exp	enditure	Scri	pts	Gov't PBS ex	penditure	Scrip	ots	Gov't PBS ex	kpenditure	Scri	pts	Gov't PBS ex	penditure	Scri	ots	Gov't P expend		Scrip	ots
Year	s	% contrib. to growth	Number	% contrib to arowth	\$	% contrib. to growth	Number	% contrib to growth	s	% contrib to growth	Number	% contrib to growth	\$	% contrib to growth	Number	% contrib to growth	s	% contrib to growth	Number	% contrib to growth
Growth 2007-08 to 2008-09	641,435,362	98.5%	6,320,112	60.1%	- 68,074,628	-10.5%	2,266,598	21.6%	77,387,311	11.9%	1,929,984	18.4%	482,521	0.1%	- 8,404	-0.1%	651,230,566	100.0%	10,508,290	100.0%
Growth 2008-09 to 2009-10	311,487,716	68.4%	1,105,065	52.3%	116,632,844	25.6%	1,235,870	58.5%	26,651,492	5.9%	- 208,360	-9.9%	718,562	0.2%	- 21,513	-1.0%	455,490,615	100.0%	2,111,062	100.0%
Growth 2009-10 to 2010-11	78,295,597	25.7%	196,504	4.7%	151,521,777	49.8%	2,723,603	64.5%	74,657,703	24.5%	1,306,533	30.9%	- 218,429	-0.1%	- 1,293	0.0%	304,256,648	100.0%	4,225,347	100.0%

Source: PBS section 85 General and Concessional expenditure and scripts

Gov't expenditure is PBS S85 general and concessional scripts and expenditure including drs bag, excluding extemporaneously prepared items.

Table 20: Percentage of PBS S85 expenditure on wholesale and pharmacy remuneration

	2006-07	2007-08	2008-09	2009-10	2010-11
Supply chain remuneration (Gov't expenditure)	\$ 1,421,487,089	\$1,532,288,649	\$1,787,426,187	\$1,935,062,247	\$2,054,986,221
Exman remuneration (Gov't expenditure)	\$ 4,044,270,241	\$4,379,882,325	\$4,775,975,353	\$5,083,829,908	\$5,268,162,582
Total S85 general and concessional Gov't PBS expenditure	\$ 5,465,757,330	\$5,912,170,974	\$6,563,401,540	\$7,018,892,155	\$7,323,148,803
Percentage of total Govt expenditure on supply chain remuneration	26.0%	25.9%	27.2%	27.6%	28.1%

Notes:

(1) Supply chain remuneration includes dispensing fee, pharmacy retail markup, wholesaler margin, dangerous drug fee, wastage fee and container fee.

(2) Government share of pharmacy remuneration estimated as (PBS expenditure/Total expenditure)*Total pharmacy remuneration.

Total expenditure = PBS expenditure + patient contribution.

Table 21: Contribution of wholesale and pharmacy remuneration to growth in PBS S85 expenditure

	Growth in Gov't expenditure on Supply chain	Growth in total S85 Gov't PBS expenditure	Contribution of supply chain to total PBS increase
Change 2006-07 to 2007-08	\$ 110,801,560	\$ 446,413,644	24.8%
Change 2007-08 to 2008-09	\$ 255,137,538	\$ 651,230,566	39.2%
Change 2008-09 to 2009-10	\$ 147,636,060	\$ 455,490,615	32.4%
Change 2009-10 to 2010-11	\$ 119,923,974	\$ 304,256,648	39.4%

Table 22: Trends in concessional cardholders

	Card holder numbers	Card holder numbers (change YoY)	Growth in numbers of Concession card holder (%)
2000-01	4,957,984		
2001-02	5,039,346	81,362	1.6%
2002-03	5,060,705	21,359	0.4%
2003-04	5,011,322	-49,383	-1.0%
2004-05	4,937,298	-74,024	-1.5%
2005-06	4,916,273	-21,025	-0.4%
2006-07	4,951,158	34,885	0.7%
2007-08	4,936,791	-14,367	-0.3%
2008-09	5,234,695	297,904	6.0%
2009-10	5,389,025	154,330	2.9%
2010-11	5,466,022	76,997	1.4%

Table 23: Trends in concessional cardholders, by card types

Concessional Card Holders (,000)	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
Commonwealth Seniors Health Card	226	278	283	287	300	311	318	278	280	275	282.2
(Low Income) Health Care Card	354	369	330	315	308	332	364	358	381	404	435.7
Health Care Card	1,394	1,333	1,326	1,237	1,162	1,116	1,101	1,022	1,149	1,179	1,130.5
Pensioner Concession Card	2,985	3,060	3,122	3,172	3,167	3,158	3,167	3,278	3,425	3,531	3,617.6

Table 24: Highly Specialised Drugs expenditure in hospitals

	2006-07	2007-08	2008-09	2009-10	2010-11
Public hospitals	\$ 468,065,494	\$ 497,928,004	\$ 562,140,859	\$ 645,720,293	\$ 729,800,000
Private hospitals	\$ 135,238,636	\$ 174,911,640	\$ 213,659,194	\$ 235,026,943	\$ 248,900,000
Total	\$ 603,304,130	\$ 672,839,644	\$ 775,800,053	\$ 880,747,236	\$ 978,700,000

Table 25: Percent contribution to overall growth in HSD program expenditure

	2007-08	2008-09	2009-10	2010-11
Public hospitals	43%	62%	80%	86%
Private hospitals	57%	38%	20%	14%

Table 26: Percent contribution to expenditure in Highly Specialised Drugs Program by indications groupings

	2006-07	2008-09	2009-10
Other Conditions	8%	10%	10%
Immunocompromised Conditions	1%	1%	1%
Iron Overload Agents	1%	2%	2%
Bisphosphonate Agents	4%	3%	3%
Acromegaly Agents	3%	3%	3%
Pulmonary Arterial Hypertension Agents	3%	4%	5%
Antiarthritic Agents	4%	8%	8%
Hepatitis B or C Agents	11%	10%	10%
Immunosuppressive Agents	10%	9%	11%
Malignancy Agents	13%	12%	12%
Haemopoietic Agents	21%	18%	16%
HIV/AIDS Antiretroviral Agents	20%	19%	19%

Framework for the joint monitoring of PBS expenditure trends and growth drivers

Background

Paragraph 7 of the Memorandum of Understanding dated September 2010 between the Government and Medicines Australia (the MoU) states that:

Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.

The AMWG Sub-group established a Data Working Group (DWG) to progress the development of a framework. The DWG has representatives from the Department, Medicines Australia and industry.

At its 19 August 2010 meeting, the AMWG noted that a useful starting point in the development of a framework would be to identify a series of questions that could be answered through this exercise so that appropriate sources of data could be identified. The AMWG requested that the working group articulate, for consideration at the AMWG co-chairs teleconference on

28 October 2010, a set of questions/indicators against which PBS expenditure is to be analysed. An initial set of questions, indicators and possible data sources was provided to the co-chairs meeting and feedback has been incorporated in the lists at <u>Attachment A</u> and <u>Attachment B</u>.

<u>Scope</u>

It is proposed that trends in, and growth drivers of, PBS expenditure will be measured primarily using Medicare Australia PBS data, accessing other data sources (such as IMS and BEACH, see <u>Attachment A</u> and <u>Attachment B</u>) as appropriate to set a context for the Medicare Australia data.

Detailed PBS expenditure on prescriptions not processed through Medicare Australia will not be included in the framework. However, S100 expenditure (including expenditure on Highly Specialised Drugs) will be included at the national level, not disaggregated by drug.

Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions and expenditure are not included under this framework. The RPBS customer base has a significantly different profile to the general PBS population in terms of size, medicines use and demographic characteristics.

The 28 October co-chairs meeting included a request to expand the joint monitoring framework to include analyses of predicted versus actual expenditure for medicines listed on the PBS undertaken by the Drug Utilisation Sub-Committee (DUSC). It is noted that there is already work in progress in relation to this between Medicines Australia and the Department. The integration of this existing work into the joint monitoring work could be considered as part of this framework.

Governance

High level governance for the joint monitoring framework and the operation of the DWG will be provided by the AMWG. Direct advice for the DWG on operational matters relating to joint monitoring will be provided by the AMWG Sub-group. The DWG will be responsible for day-to-day decisions around the joint monitoring process.

Roles and Responsibilities

AMWG

- High level advice on the joint monitoring process.
- Final endorsement of joint monitoring reports.
- Final approving authority for any public release of reports.
- Resolution of issues referred by the DWG or AMWG Sub-group.

AMWG Sub-group

- Endorsement of joint monitoring reports before tabling to AMWG.
- Approval of requests made for additional analysis under this framework.
- Advising DWG on higher level policy matters related to joint monitoring.
- Resolution of issues referred by the DWG.

DWG

- Development and implementation of a joint monitoring framework.
- Joint production of joint monitoring reports.
- Resolution of day-to-day operational and policy matters related to joint monitoring.

Monitoring and Reporting

PBS expenditure trends and growth drivers will be monitored on a half-yearly basis. Half-yearly reporting provides a balance between responsiveness and administrative burden in ongoing monitoring and reporting. Reporting would occur each six months for the preceding 12 months. Reporting will occur at the next AMWG sub-group meeting after the end of a reporting period, providing at least two months after the end of a reporting period is available for data extraction, analysis and report production. It is proposed that the schedule of reporting be as follows:

Reporting period	Report due to AMWG
1 July – 30 June	First AMWG meeting after August
1 January – 31 December	First AMWG meeting after February

Monitoring will be undertaken against a list of key drivers, data and data sets that are mutually agreed between Medicines Australia and the Department. It is acknowledged that drivers and sources of data thought useful and appropriate could be considered for inclusion in the analysis. It is agreed that the primary data source for the joint monitoring is Medicare Australia prescription data. The list of possible drivers and data sets put forward for discussion is at <u>Attachment A</u> with more detail in <u>Attachment B</u>.

It is agreed that the Department will take primary responsibility for analysing data against the agreed list of drivers using an agreed methodology and that it will share the full workings with Medicines Australia (subject to privacy issues noted below) on a regular basis, with frequency to be agreed mutually.

Other issues

Forecasting

Under the monitoring framework there will be no forecasting of future PBS expenditure or measurement of future actual expenditure against such a forecast. Data shared with Medicines Australia under the MoU (or other existing arrangements with the Department) may allow Medicines Australia to forecast PBS expenditure, however the Department will not support nor endorse any such forecasts.

Interoperability of data and analysis

The Department and Medicines Australia will use their best efforts to ensure that, where data or analyses are transferred between the two organisations as part of this framework, the data are in a format that is compatible with the IT environment of the other organisation.

Reporting processes

The DWG will analyse the trends and drivers and prepare a joint report for the AMWG Sub-group's endorsement. After endorsement, the report will be tabled to the AMWG.

Protocols for requests from Medicines Australia for additional PBS data or tables

From time to time monitoring may highlight aspects of PBS expenditure or prescription volume that either the Department or Medicines Australia believe should be examined in more detail and which may require one or more separate additional data extractions.

The protocols will take into account issues such as:

- Privacy (ie, could highly disaggregated data be considered personal information under the *National Health Act 1953*?, is the data commercially sensitive?); and
- Resource capacity in the Department to undertake the data extraction or analysis work.

Additional analysis will only be undertaken after the AMWG Sub-group approves a formal request made to it. The request should include the reasons for, and the benefits of, such an analysis. The timeframes for such analysis are to be specified by the AMWG Sub-group.

Release of tables and data outside of the AMWG

While data and/or analysis may be provided by the Department to Medicines Australia under this joint monitoring framework, the Commonwealth retains ownership of this transferred data and/or analysis. Where data and/or analyses are provided by Medicines Australia to the Department under this framework Medicines Australia similarly retains ownership of the transferred material. It is proposed that Medicines Australia may not release any data or tables provided for the purpose of joint monitoring outside of the DWG without seeking written permission from the Department. The Department will use its best endeavours to respond to any such requests in a reasonable timeframe.

Release outside the DWG includes release to any of Medicines Australia's member organisations other than members that are already on the DWG. The Department commits not to release any in-confidence data it obtains from DWG members under this framework outside the Department or use it for any purpose other than the joint monitoring of PBS expenditure trends and growth drivers without consent from Medicines Australia.

It is proposed that a summary of the analysis may be released publicly via the DoHA and Medicines Australia websites, subject to the approval of the AMWG.

Dispute resolution

Members of the DWG will continue to work together in a spirit of collaboration and mutual respect.

In the highly unlikely event that an issue cannot be resolved in the DWG, it would be referred to the AMWG Sub-group for resolution. If the matter remains unresolved by the AMWG Sub-group, it would be referred to the AMWG.

Proposed high level guiding questions and possible PBS expenditure indicators to be analysed

Possible high level guiding questions and possible indicators to be analysed	Data sources	Possible other data sources ⁽²⁾⁽³⁾
	trend	
Are there particular groups of patients contributing more to PBS growth? eg is the aging population impacting on PBS growth?	Medicare Australia,	DUSC, BEACH
• Number of patients, expenditure and prescriptions by patient category (general/concessional).	FaHCSIA, ABS	
 Number of patients, expenditure and prescriptions by patient age (and perhaps further split by concessional status). 		
Number of persons covered by safety net cards.		
Number of persons covered by concession cards.		
Expenditure and prescription for specified chronic disease groups		
• Number of persons in the population (total and by age)		
Are there particular drugs or groups of drugs contributing more to PBS growth?	Medicare Australia	DUSC, IMS, BEACH
• Expenditure and prescription volume by Formulary.		
• Expenditure and prescription volume by ATC level 2.		
• For the top three ATC level two groups by expenditure, disaggregate by drug name.		
• Expenditure and prescriptions for the top 10 drug names by prescription volume.		
• Expenditure and prescriptions for the top 10 drug names by contribution to PBS growth.		
What is the contribution of newly listed medicines to PBS	Medicare	
expenditure growth in comparison to already listed medicines?	Australia	
• The contribution to expenditure of new medicines listed on the PBS in the previous 12 months.		
• The net contribution to expenditure of new medicines listing and medicines de-listing in the last 12 months		
• The contribution to expenditure of new medicines listed on the PBS in the previous 4 years.		
Are generic PBS medicines growing at a faster or slower rate than the general PBS?	Medicare Australia	DUSC, IMS
 Market share of generic medicines by PBS expenditure and prescription volume (noting that issues around the definition of a generic medicine will have to be resolved) 		

Additic	nal questions that may be considered -	
•	To what extent do economic factors (income, employment, hours worked) impact on PBS growth?	
•	To what extent to changes in pharmacy remuneration impact on PBS growth?	Available data sources and what
•	To what extent do changes to PBS pricing policy affect PBS growth?	might be possible measurable indicators will need to be more
•	To what extent do general Government policy changes affect PBS growth?	closely considered for these questions.
•	Do patient compliance programs have an impact on PBS growth?	
•	What is the contribution of S100 and HSD medicines to overall PBS growth?	

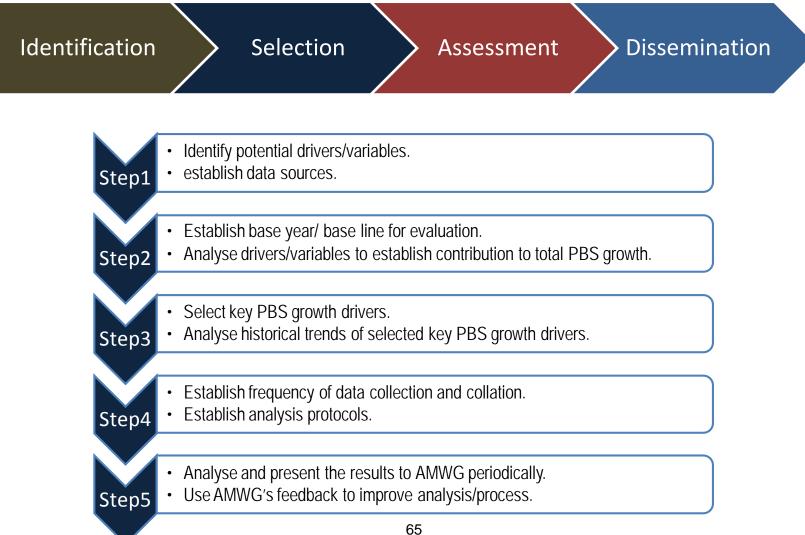
Notes:

(1) FaHCSIA = Department of Families, Housing, Community Services and Indigenous Affairs, ABS = Australian Bureau of Statistics.

(2) These data sources could add some context to the data obtained through Medicare Australia only. For example the undercopayment prescription data available from the DUSC data could further inform trends seen in subsidised medicines and help understand movements from above to below copay.

(3) DUSC = Drug Utilisation Sub-Committee dataset including Guild survey data on undercopay and private prescriptions, IMS = pharmaceutical industry data sourced through IMS Health, BEACH = data on GP prescribing from the Bettering the Evaluation and Care of Health survey.

Identification and reporting framework



Variables	Metric	Data required ⁽¹⁾	Source ⁽²⁾	Remarks
New listings ⁽³⁾ on the PBS in previous 12 months	% contribution to PBS expenditure growth attributable to new medicine listings in last 12 months	 New listings on the PBS in previous 12 months Expenditure on new listings (previous 12 months) on the PBS Reports on predicted vs actual expenditure for new PBS listings (4) 	 PBAC or pbs.gov.au - New Listings and Changes fact sheets (http://pbs.gov.au/html/healthpro/public ation/list) Medicare Australia data DUSC reports 	Where it is possible to identify the effect of a new or extended listing, examine expenditure of these new listings in relation to overall PBS growth
New listings ⁽³⁾ on the PBS in previous 4 years	% contribution to PBS expenditure growth attributable to new medicine listings in last 4 years	 New listings on the PBS in previous 4 years Expenditure on new listings (previous 4 years) on the PBS Reports on predicted vs actual expenditure for new PBS listings (4) 	 PBAC or pbs.gov.au - New Listings and Changes fact sheets (http://pbs.gov.au/html/healthpro/public ation/list) Medicare Australia data DUSC reports 	Where it is possible to identify the effect of a new or extended listing, examine expenditure of these new listings in relation to overall PBS growth
Prescriptions	% contribution total increase in PBS expenditure	 PBS expenditure and prescriptions by item code Change in script by item code average number of prescriptions per GP visit Number of GP visits 	 Medicare Australia data (PBS and MBS) DUSC under-copayment and private prescription data PBS schedule BEACH survey data 	Decompose total PBS expenditure growth into growth caused by prescription growth and growth caused by price changes
Price	% contribution total increase in PBS expenditure	 PBS expenditure and prescriptions by item code Change in average government remuneration by item code (at CDPMQ prices) Prices at ex-man level 	 Medicare Australia data DUSC data PBS schedule 	Decompose total PBS expenditure growth into growth caused by prescription growth and growth caused by price changes

Variables	Metric	Data required ⁽¹⁾	Source ⁽²⁾	Remarks
Change in policy ⁽⁵⁾	% contribution to PBS expenditure growth attributable to changes in policy	 Identification of relevant policy changes (such as policies that affect PBS prices and patient access to PBS). 	1) Depends on policy change	Investigate associations between the timing of policy changes and PBS expenditure changes
Drugs/drug groups - Formulary	% contribution to PBS expenditure growth of each formulary	1) PBS expenditure and prescriptions by formulary	 Medicare Australia data Formulary allocation (pbs.gov.au) 	Decompose PBS growth into formularies to see which formularies contribute the most to PBS growth
Drugs/drug groups – ATC2 group	% contribution to PBS expenditure growth of each ATC2 group	 PBS expenditure and prescriptions by ATC2 group 	1) Medicare Australia data	Decompose PBS growth into ATC2 groups to see which groups contribute the most to PBS growth
Drugs/drug groups – drugs	% contribution to PBS expenditure growth of top 10 drugs within each of the top 5 ATC2 groups by contribution to PBS growth	1) PBS expenditure and prescriptions by drug name	1) Medicare Australia data	Decompose PBS growth in the top 5 ATC2 groups into drugs to see which drugs contribute the most to PBS growth
Ageing population	% contribution to PBS expenditure growth by patient age category	 PBS expenditure and prescriptions by patient age ⁽⁶⁾ number of PBS subsidised patients by patient age ⁽⁶⁾ 	1) Medicare Australia data	Decompose PBS growth into patient age groups to see which age groups contribute the most to PBS growth

Variables	Metric	Data required ⁽¹⁾	Source ⁽²⁾	Remarks
Concessional cards holders	% contribution to PBS expenditure growth by patient concessional category	 PBS expenditure and prescriptions by patient concessional status Number of persons covered by concession cards Number of persons covered by safety net cards 	 Medicare Australia expenditure and prescriptions data Medicare Australia safety net card coverage data FaHCSIA concessional card coverage data 	Decompose PBS growth into patient age groups to see which age groups contribute the most to PBS growth
Disease burden	% contribution to PBS expenditure growth for specified chronic disease groups	 PBS patients, expenditure and prescriptions by chronic disease group total incidence of chronic disease by chronic disease group 	 Medicare Australia expenditure and prescriptions data AIHW/ABS data on incidence of chronic disease 	Decompose PBS growth into DoHA defined chronic disease groups to see which groups contribute the most to PBS growth
Patient compliance	% contribution to PBS expenditure growth attributable to changing patterns of patient compliance	 PBS patients, expenditure and prescriptions (dispensed) average number of prescriptions prescribed per patient 	 Medicare Australia data BEACH survey data – this data is available to the Department under contract with the AIHW. The Department would need to investigate its ability to use the data for this purpose. 	Compare movements in "scripts dispensed per patient" to movements in "scripts prescribed per patient"
Below co-payment's market	% contribution to PBS expenditure growth attributable to medicines dropping from above to below the general copayment	 PBS expenditure and prescriptions PBS schedule 	 Medicare Australia data PBS schedule 	For each 12 month period consider the number and value of PBS drugs falling from above to below the general copayment
Supply chain remuneration	% contribution of change in remuneration to total PBS	 PBS expenditure (at CDPMQ prices versus ex-man prices) 	1) Medicare Australia data	Examine movements in the difference between total PBS expenditure at CDPMQ and

Variables	Metric	Data required ⁽¹⁾	Source ⁽²⁾	Remarks
	expenditure			ex-man prices.
Highly specialised drugs program	% contribution to PBS expenditure growth attributable to HSD expenditure	 Annual expenditure on HSDs PBS expenditure and prescriptions 	1) Department of Health and Ageing	Consider growth rates of HSD expenditure in relation to S85 expenditure

In the table above, where not further specified:

- 1. PBS expenditure and prescriptions relates to S85 PBS data processed through Medicare Australia.
- 2. Medicare Australia data is PBS scripts and expenditure data the Department of Health and Aging obtains from Medicare Australia. It contains information required for analysis, but not available on the Medicare Australia website (eg patient identifiers and patient date of birth).
- 3. 'New listings' to include extensions where possible
- 4. Reports on predicted vs actual expenditure for new listings will be integrated into this monitoring and reporting structure after appropriate consideration is given to the current process already underway between Medicines Australia and the Department looking at how these reports may be used in the future.
- 5. The focus of policy changes will be on changes that directly affect PBS prices and volume. However, the DWG recognises that from time-to-time, it may need to evaluate the impact of other policy measures on overall consumption of pharmaceuticals. In such cases, the DWG will make a recommendation to the AMWG Sub-group highlighting the benefits of investigating such policy measures.
- 6. Age categories to be based on an appropriate ABS or AIHW standard health classification.