

THE HIGHLY SPECIALISED DRUGS PROGRAM

Program overview

In addition to the drugs and medicinal preparations available under normal Pharmaceutical Benefits Schedule (PBS) arrangements, a number of drugs are also available as pharmaceutical benefits. However, these drugs are distributed under alternative arrangements that are considered more appropriate.

These alternative arrangements are provided for under Section 100 (s100) of the National Health Act 1953 (the Act). One of the programs under s100 is the Highly Specialised Drugs (HSD) Program. The Australian Government provides for certain specialised medications under the HSD Program.

HSD's are for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals that have appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units.

The HSD Program is administered by the Pharmaceutical Access and Quality Branch of the Australian Government Department of Health and Ageing, while the process of selecting and reviewing drugs and procedures is the responsibility of the Highly Specialised Drugs Working Party.

Subsidy for drugs under this program commences following recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), approval by the Australian Government and the States and Territories accepting the offer of subsidy.

The Australian Government also provides funding to the States and Territory Governments and through private hospitals for HSD's to be supplied to community based patients, that is non in-patients. Subsidy is available for the PBS approved clinical indications only.

To gain access to a Government funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge. Government subsidy is not available for hospital in-patients. Patients must also be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a HSD at a similar rate to the PBS.

Highly Specialised Drugs Working Party

The Australian Health Ministers' Advisory Council established the HSD Working Party in 1991. The Working Party consists of representatives from the Health Department of each of the States and Territories, the Australian Private Hospitals Association and the Commonwealth as chair.

The Working Party's terms of reference are:

- Selecting drugs proposed for inclusion in the funding arrangements for highly specialised drugs;
- referring proposed drugs with supporting information to the Pharmaceutical Benefits

Advisory Committee (PBAC) for consideration for listing as pharmaceutical benefits under section 100 supply arrangements;

- monitoring information on potential new highly specialised drugs which might come under the funding arrangements;
- monitoring the quality use of drugs supplied under these arrangements; and
- investigating and making recommendations on procedures to monitor drugs supplied by public hospitals under the section 100 arrangements to patients in community settings.

Criteria for selection of Highly Specialised Drugs

Drugs recommended for inclusion in the program must satisfy the following criteria:

- Ongoing specialised medical supervision required;
- treatment of longer term medical conditions not episodes of in-patient treatment or treatment of acute conditions;
- drugs highly specialised and an identifiable patient target group;
- Subject to marketing approval by the Therapeutic Goods Administration (TGA) and specific therapeutic indications covered by the terms of the marketing letter from TGA; and
- a high unit cost.

Program expenditure

During 2006-2007 there were 71 drugs subsidised under the HSD Program, compared to 2005-2006 when 69 were subsidised. The new drug listings are:

1. Epoprostenol Sodium
2. Sildenafil Citrate

The two new inclusions are both for the treatment of Pulmonary Arterial Hypertension.

Before reconciliation¹ the expenditure for 2006-2007 amounted to \$591,042,429². Drugs were categorised as follows:

Indications Grouping	Number of Drugs	Public Hospital	Private Hospital	Combined
Acromegaly Agents	3	\$13,509,148	\$8,406,561	\$21,915,709
Antiarthritic Agents	2	\$4,132,360	\$19,054,813	\$23,187,173
Bisphosphonates Agents	2	\$12,812,717	\$7,938,988	\$20,751,705
Haemopoietics Agents	2	\$96,510,208	\$23,709,932	\$120,220,140
Hepatitis B or C Agents	7	\$55,208,154	\$10,614,994	\$65,823,148
HIV/AIDS Antiretroviral Agent	23	\$115,107,014	\$1,600,672	\$116,707,686
Immunocompromised Conditions	9	\$7,862,582	\$202,138	\$8,064,720
Immunosuppressive Agents	7	\$56,106,636	\$5,156,480	\$61,263,117
Iron Overload Agents	2	\$5,878,152	\$699,584	\$6,577,736
Malignancy Agents	5	\$49,228,540	\$29,299,748	\$78,528,288
Other Conditions	5	\$45,584,195	\$3,442,673	\$49,026,868
Pulmonary Arterial Hypertension Agents	4	\$3,460,064	\$15,516,076	\$18,976,140
Grand Total	71	\$465,399,771	\$125,642,658	\$591,042,429

1. On receipt of a certified statement of acquittal, financial adjustments are made for each State/Territory to account for actual utilisation as compared to forecast usage.
2. 2006-2007 figures are based on payments, and are subject to reconciliation of expenditure.

**** Please note that 4th quarter utilisation figures are based on a forecast as actual usage figures are not available until early October 2007. Expenditure reported in the 06/07 Annual Report will differ from the figures provided above, as the Annual Report figures are the actual expenditure reported in SAP before the reconciliation process has taken place in October.**

The acquitted expenditure through the HSD program in 2005-2006 was \$526.3 million. Before reconciliation, 2006-2007 costs totalled \$591.1 million, an increase of 12.3 per cent from 2005-2006. At the end of the financial year, payments made to public hospitals via grants to the States and Territories will be reconciled against the actual drug usage.

Australian Government expenditure for HSDs is processed through two avenues; a grant process for public hospitals and through Medicare Australia for private hospital usage. For 2006-2007 the expenditure in public hospitals was \$465.4 million, an increase of 8.9 per cent from the 2005-2006 acquitted expenditure of \$427.5 million. HSD expenditure processed through Medicare Australia for private hospitals showed an increase of 27.5 per cent from the \$98.5 million in 2005-2006 to \$125.6 million in 2006-2007.

The increase in expenditure claimed through Medicare Australia (private hospitals) is also due to a number of factors. There has been a steady increase in the number of private hospitals participating in the program, due to the higher number of Australians accessing services through private hospitals. The factors for the increased supply through this mechanism are the transfer from State/Territory administration to the Medicare Australia

authority system, increased access to community pharmacies and changes in the way that some services are provided, particularly in oncology.

The Highly Specialised Drugs - Usage Expenditure chart outlines the program expenditure from 1991-1992 to 2006-2007 financial years.

