

## **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 2005-2006 there were 69 drugs subsidised under the HSD Program, compared to 2004-2005 when 65 were subsidised. The new drug listings are:

1. Abacavir Sulfate with Lamivudine
2. Everolimus
3. Tenofovir Disporoxil Fumarate with Emtricitabine
4. Thalidomide

Of the four new inclusions, two are HIV/AIDS Antiretroviral Agents and two are Immunosuppressive Agents.

Before reconciliation<sup>1</sup> the expenditure for 2005-2006 amounted to \$526,289,872<sup>2</sup>. Drugs were categorised as follows:

Indications Grouping	Number of Drugs	Public Hospital	Private Hospital	Combined
Acromegaly Agents	3	\$12,471,398	\$5,321,007	\$17,792,405
Antiarthritic Agents	2	\$2,615,423	\$12,864,259	\$15,479,682
Bisphosphonates Agents	2	\$14,798,848	\$9,738,426	\$24,537,274
Haemopoietics Agents	2	\$95,024,756	\$19,542,954	\$114,567,710
Hepatitis B or C Agents	7	\$32,935,679	\$6,494,262	\$39,429,941
HIV/AIDS Antiretroviral Agent	23	\$107,314,892	\$402,767	\$108,093,760
Immunocompromised Conditions	9	\$7,815,866	\$315,156	\$8,069,351
Immunosuppressive Agents	7	\$54,110,434	\$3,562,748	\$57,673,182
Iron Overload Agents	2	\$3,862,919	\$192,518	\$4,055,437
Malignancy Agents	5	\$50,287,242	\$27,635,204	\$77,922,446
Other Conditions	5	\$42,982,905	\$3,039,676	\$46,022,581
Pulmonary Arterial Hypertension Agents	2	\$3,255,189	\$9,390,914	\$12,646,103
<b>Grand Total</b>	<b>69</b>	<b>\$427,475,552</b>	<b>\$98,499,890</b>	<b>\$526,289,872</b>

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. 2005-2006 figures are based on payments, and are subject to reconciliation of expenditure.

The acquitted expenditure through the HSD program in 2004-2005 was \$459.6 million. Before reconciliation, 2005-2006 costs totalled \$526.3 million, an increase of 14.5% from 2004-2005. 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 2005-2006 the expenditure in public hospitals was \$427.5 million, an increase of 12.1 per cent from the 2004-2005 acquitted expenditure of \$381.4 million. HSD expenditure processed through Medicare Australia for private hospitals showed an increase of 25.8 per cent from the \$78.3 million in 2004-2005 to \$98.5 million in 2005-2006.

The per cent increase in private hospital expenditure for the previous 3 financial years are as follows:

- 38.9 per cent in 2002-2003
- 37.7 per cent in 2003-2004
- 37.9 per cent in 2004-2005