

## **THE HIGHLY SPECIALISED DRUGS PROGRAM**

### **Program overview**

In addition to the drugs available under usual PBS arrangements, a number of drugs are also made available under alternative arrangements where the normal supply arrangements are inadequate or where the drugs cannot be conveniently or efficiently supplied.

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

Highly Specialised Drugs are for the treatment of chronic conditions, which, because of their clinical use or other specialist requirements, 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 Access and Systems Branch, of the Pharmaceutical Benefits Division, administers the HSD Program while the process of selecting and reviewing drugs 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.

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 and funding for any in-patient use is provided by the state in public hospitals. 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 Highly Specialised Drug at a similar rate to the PBS.

### **Highly Specialised Drugs Working Party**

The Australian Health Ministers' Advisory Council established the Highly Specialised Drugs 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 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.

## Utilisation Based Government Expenditure on Highly Specialised Drugs

During 2008-2009 there were 83 drugs subsidised under the HSD Program, compared to 2007-2008 when there were 78. The new drug listings are:

1. Raltegravir Potassium
2. Natalizumab
3. Cinacalcet Hydrochloride
4. Telbivudine
5. Lanthanum Carbonate Hydrate

The Government<sup>1</sup> expenditure based on utilisation for 2008-2009 amounted to \$764.6 million. Drugs were categorised as follows:

<i>Indications Grouping</i>	<i>Number of Drugs</i>	<i>Public Hospital</i>	<i>Private Hospital<sup>2</sup></i>	<i>Combined</i>
Acromegaly Agents	2	\$15,307,661	\$7,717,918	\$23,025,578
Antiarthritic Agents	4	\$11,869,821	\$52,722,802	\$64,592,624
Bisphosphonate Agents	3	\$12,562,835	\$10,186,335	\$22,749,170
Haemopoietic Agents	6	\$103,865,666	\$27,620,170	\$131,485,836
Hepatitis B or C Agents	10	\$61,065,921	\$17,600,619	\$78,666,540
HIV/AIDS Antiretroviral Agents	24	\$145,598,142	\$581,446	\$146,179,588
Immunocompromised Conditions	10	\$10,356,629	\$355,935	\$10,712,564
Immunosuppressive Agents	7	\$64,069,569	\$5,625,927	\$69,695,495
Iron Overload Agents	3	\$11,291,622	\$3,315,426	\$14,607,048
Malignancy Agents	5	\$57,899,504	\$38,009,895	\$95,909,398
Other Conditions	4	\$64,590,179	\$9,817,214	\$74,407,393
Pulmonary Arterial Hypertension Agents	5	\$3,663,310	\$28,893,453	\$32,556,763
<b>Grand Total</b>	<b>83</b>	<b>\$562,140,859</b>	<b>\$202,447,139</b>	<b>\$764,587,997</b>

<sup>1</sup> All usage figures quoted in table refer to Government expenditure only, that is total expenditure minus the patient co-payment. Some figures in this table are subject to final reconciliation with each state and territory and may change slightly. Expenditure figures are based on utilisation reports provided by states and territories.

<sup>2</sup> Repatriation patients have been removed from Private hospital expenditure but cannot be removed from Public hospital expenditure as repatriation patients are not identified by public hospitals.

Government expenditure based on utilisation through the HSD program in 2007-2008 was \$663.2 million. In 2008-2009 costs totalled \$764.6 million, an increase of 15.3% from 2007-2008. At the end of the 2008-2009 financial year payments made to public hospitals via grants to the states and territories will be reconciled against the actual drug usage.

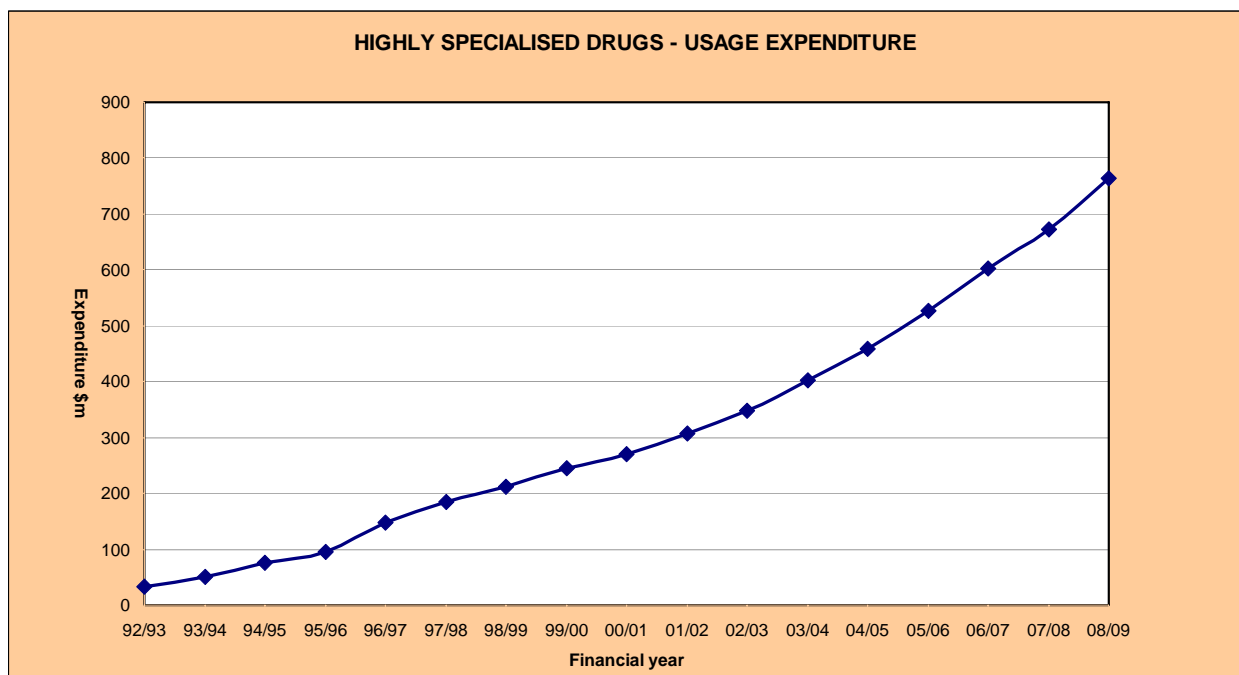
In 2008-2009 the Australian Government expenditure for HSDs was processed through two avenues: a grant process for public hospitals administered by the Department of Health and Ageing and a claims payment arrangement administered through Medicare Australia for private hospitals.

HSD expenditure based on utilisation in public hospitals in 2008-2009 was \$562.1 million, an increase of 12.9% from the 2007-2008 expenditure of \$497.9 million. The expenditure processed through Medicare Australia showed an increase of 22.2% from the \$165.6 million in 2007-2008 to \$202.4 million in 2008-2009.

The HSD program continues to increase at a steady rate across both public and private hospitals. The increase in expenditure over the last few years is due to the increase in number of drugs listed on the program and the increase of new private hospitals participating in the program.

**The Highly Specialised Drugs – Usage Government Expenditure Chart**

The Highly Specialised Drugs Usage Government Expenditure chart outlines the program’s Government expenditure from 1992-1993 to 2008-2009 financial years.



**Move from Special Purpose Payments to Commonwealth Own Purpose Expenditure Arrangements**

In 2008, the Council of Australian Government (COAG), in conjunction with the Department of Health and Ageing, agreed to cease funding public patient access to HSDs through Special Purpose Payments (SPPs) to states and territories, and fund these payments through an alternative Commonwealth Own Purpose Expenditure (COPE) mechanism.

As of 1 July 2009, payments for HSDs supplied through public hospitals moved from monthly advance payments by the Department of Health and Ageing, to payments in arrears by Medicare Australia following dispensing. This is consistent with the arrangements for private hospitals and community pharmacies.

Under the transition to COPE arrangements, payments for these claims are initially being made through an offline solution to state and territory health departments. Beginning in 2010, Medicare Australia will transition hospitals to PBS Online in a phased approach over a three year period. The utilisation of PBS Online in public hospitals will enable real-time claiming by hospital pharmacies direct to Medicare Australia.