

facilitate the lodgement of applications for the treatment of rare conditions, which may otherwise not be cost-effective, the TGA has introduced an Orphan Drug Scheme, whereby all evaluation fees are waived provided the sponsor obtains designation for the product for the indication. The usual criteria for determining a disease is rare are the orphan criteria that it is not likely to affect more than 2000 people. The TGA has also adopted a number of modifications to data packages to facilitate applications for older, off-patent

or orphan products. These include literature based submissions, whereby companies can submit published papers as the basis for an approval of a product or an extension of use of a product. Unfortunately, the TGA has no power to approve products for new indications in the absence of an application, but it is always happy to discuss with sponsors the modified data requirements for products where there is a demonstrated clinical need.

Top 10 drugs

These tables show the top 10 subsidised drugs in 2004–05. The tables do not include private prescriptions.

Table 1

Top 10 drugs supplied by DDD/1000 pop/day *

Drug	PBS/RPBS †
1. atorvastatin	98.173
2. simvastatin	55.967
3. ramipril	33.741
4. diltiazem hydrochloride	30.097
5. omeprazole	20.628
6. irbesartan	20.169
7. salbutamol	18.844
8. frusemide	18.775
9. aspirin	18.162
10. sertraline	17.604

Table 2

Top 10 drugs by prescription counts

Drug	PBS/RPBS †
1. atorvastatin	8,074,202
2. simvastatin	6,275,577
3. paracetamol	4,772,865
4. omeprazole	4,411,857
5. irbesartan	3,370,315
6. atenolol	3,247,475
7. salbutamol	3,062,355
8. esomeprazole	2,983,645
9. irbesartan with hydrochlorothiazide	2,938,448
10. ramipril	2,903,048

Table 3

Top 10 drugs by cost to Government

Drug	Cost to Government (\$A)	DDD/1000/day PBS/RPBS †	Prescriptions PBS/RPBS †
1. atorvastatin	460,930,251	98.173	8,074,202
2. simvastatin	369,659,052	55.967	6,275,577
3. omeprazole	177,075,832	20.628	4,411,857
4. fluticasone with salmeterol	165,690,424	– ‡	2,764,969
5. clopidogrel	151,235,466	7.551	1,925,546
6. olanzapine	149,497,256	2.892	710,453
7. esomeprazole	143,233,727	11.465	2,983,645
8. pravastatin	119,587,717	13.983	2,102,171
9. alendronic acid	108,587,183	8.543	2,115,898
10. pantoprazole	104,291,272	10.971	2,586,383

* The defined daily dose (DDD)/thousand population/day is a more useful measure of drug utilisation than prescription counts. It shows how many people, in every thousand Australians, are taking the standard dose of a drug every day.

† PBS Pharmaceutical Benefits Scheme, RPBS Repatriation Pharmaceutical Benefits Scheme

‡ Combination drugs do not have a DDD allocated

Source: Drug Utilisation Sub-Committee (DUSC) Drug Utilisation Database, as at 10 Oct 2005. © Commonwealth of Australia