Challenges and opportunities for the Pharmaceutical Benefits Scheme

Price disclosure will only go part of the way to achieving lower prices for generic drugs

Philip M Clarke
BEc, MEc, PhD,
Professor of Health Economics

Centre for Health Policy, Programs and Economics, School of Population Health, University of Melbourne, Melbourne, VIC.

philip.clarke@unimelb.edu.au

doi: 10.5694/mja12.10092

The Pharmaceutical Benefits Scheme (PBS) faces both challenges and opportunities. The challenges, which are well known, come when listing new pharmaceuticals. The Pharmaceutical Benefits Advisory Committee (PBAC) determines the cost-effectiveness of new drugs and recommends whether or not they should be listed on the PBS. Although there is no capped budget for the PBS, any drug the PBAC recommends for listing that is expected to cost more than $10 million per year must be approved by Cabinet. Budget pressures that last year caused the listing of several therapies for conditions including schizophrenia, chronic pain and severe asthma to be deferred[1] are ongoing.

The opportunities, on the other hand, are less well known. They arise from patent expiry of drugs, especially major therapies such as atorvastatin,[2] which creates the potential for large reductions in manufacturers' prices and hence savings for the PBS. My purpose here is to examine these opportunities, using the cholesterol-lowering drugs, statins, as an example.

Pharmaceutical pricing in Australia is governed by an agreement between the Department of Health and Ageing and the peak industry body, Medicines Australia, dating from May 2010.[3] This agreement included a provision to reduce the price of older medications on the PBS, starting with regulated reductions of up to 5% for existing off-patent medications and a 16% reduction after expiry of a drug's patent. The price would then be determined through a policy known as "price disclosure", which requires pharmaceutical companies to reveal to the government the actual price at which they sell their products to pharmacies. Future prices are then set using a weighted average of these disclosed prices.[3]

The first round of these price disclosure reductions comes into effect in April this year. In some cases, the reductions are substantial (more than 50%), indicating that the real cost of many generics is well below the current PBS subsidy. The government pays a fixed fee to pharmacists each time a drug on the PBS is dispensed, which is intended to cover the cost to the pharmacist of the drug, a mark-up by the pharmacist, and dispensing and any other fees.[4] For example, the dispensed price of generic simvastatin 20 mg is $34, $22 of which is intended to cover its wholesale cost.[4] The results of the first round of price disclosures for simvastatin indicate that pharmacists have actually been paying, on average, $10 for this drug.[5]

Using data from Medicare Australia, it is possible to estimate that total PBS payments to cover the wholesale cost of simvastatin amounted to around $150 million between May 2010 and October 2011. Price disclosure data reveal that pharmacies only spent $70 million on the drug, due to discounts from manufacturers. While the disclosure of these discounts will reduce future prices, it is a slow adjustment mechanism, as a reduction in the supply price can take up to 18 months or more to produce savings for the PBS.

Even after these price reductions, Australia will continue to pay high prices for many of its generic drugs. An international price comparison of simvastatin 40 mg demonstrated that the Australian ex-manufacturer supply price was greater than that in any of 13 comparable Organisation for Economic Co-operation and Development countries.[6] After accounting for the price cuts slated for April 2012, Australia will still be paying more than twice the international average. Paying high prices relative to other countries comes at a substantial cost to the PBS. If Australia had paid English prices for simvastatin from

May 2010 to October 2011, PBS expenditure could have been reduced from $150 million to just $20 million.

The financial consequences are even greater for atorvastatin, the patent on which will expire in May 2012.[2] Since the mid 1990s, the total cost of subsidising atorvastatin on the PBS in current dollars has been in excess of $6.8 billion. After patent expiry, the supply price of generic atorvastatin 40 mg will be around $50 per script, compared with $16 in Canada[7] and $5 in New Zealand.[8] If Australians paid New Zealand prices, and assuming current levels of prescribing remained the same, savings in the order of $590 million would be attained in the first 18 months after patent expiry.

Another factor limiting savings from price reductions is that generics often constitute a small proportion of the drugs prescribed in major therapeutic classes in Australia.[2] PBS data indicate that prescriptions for off-patent simvastatin and pravastatin constituted only 22% of statins prescribed in Australia during 2011. In contrast, recent figures suggest these generic statins comprise more than 50% of prescriptions in the United States[9] and over 75% in England.[10] It is surprising that there is little published economic evidence on whether the much greater use of higher-cost patented statins in Australia represents a cost-effective use of PBS funds.

Although price disclosure will produce significant reductions in the price of some off-patent medications, these will be insufficient to bring the cost of drugs such as simvastatin and atorvastatin in line with prices overseas. Hence, there is scope for further price reductions that will directly benefit taxpayers and consumers. There is also a need to evaluate the costs and benefits of using patented therapies when generic alternatives are available, and for this to inform recommendations of the PBAC. Availing of these opportunities now will assist us in overcoming future challenges.

Acknowledgements: I was funded by a National Health and Medical Research Council Career Development Award (ID 571122).

Competing interests: No relevant disclosures.

Provenance: Not commissioned; externally peer reviewed.

1 Senate Finance and Public Administration References Committee. The Government's administration of the Pharmaceutical Benefits Scheme. Canberra: Commonwealth of Australia, 2011. http://www.aph.gov.au/Senate/committee/fapa_ctte/pharma_benefits_scheme/report/report.pdf (accessed Feb 2012).

2 Clarke PM, Fitzgerald EM. Expiry of patent protection on statins: effects on pharmaceutical expenditure in Australia. *Med J Aust* 2010; 192: 633-636.

3 Australian Government and Medicines Australia. Memorandum of understanding. September 2010. http://www.pbs.gov.au/industry/useful-resources/memorandum/MOU-MA-Sep2010.pdf (accessed Jan 2012).

4 Medicare Australia. Explanation of PBS pricing. June 2011. Canberra: Australian Government, 2011. http://www.medicareaustralia.gov.au/provider/pubs/program/files/2526-explanation-of-pbs-pricing.pdf (accessed Feb 2012).

5 Australian Government Department of Health and Ageing. National Health (Weighted average disclosed price – main disclosure cycle) Determination 2011 (No. PB 80 of 2011). http://www.comlaw.gov.au/Details/F2011L02702 (accessed Jan 2012).

6 Clarke PM, Fitzgerald EM. Expiry of patent protection on statins: effects on pharmaceutical expenditure in Australia [letter]. *Med J Aust* 2011; 194: 53-54.

7 Ontario Ministry of Health. Update ad: Ontario Drug Benefit Formulary/Comparative Drug Index No. 41. Effective January 19, 2012. http://www.health. gov.on.ca/english/providers/program/drugs/formulary/41_update_ad_20120111.pdf (accessed Jan 2012).

8 Pharmaceutical Management Agency (PHARMAC) (NZ). Notification: Approval of the listing of Dr Reddy's brand of atorvastatin. 14 September 2011. http://www.pharmac.govt.nz/2011/09/14/2011-09%20Dr%20Reddy%27s%20Atorvastatin%20notification.pdf (accessed Jan 2012).

9 Jackevicius CA, Chou MM, Ross JS, et al. Generic atorvastatin and health care costs. *N Engl J Med* 2012; 366: 201-204. Epub 2011 Dec 7.

10 Health and Social Care Information Centre, National Health Service (UK). Prescription cost analysis, England – 2010. 27 April 2011. http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-england--2010 (accessed Jan 2012). ❑