

Lessons for and from Australia

Canada can learn from the centralised national system of drug review in Australia. The process of review and evaluation appears to be well organised and resourced by Federal government. In Canada there is duplication of effort as each province conducts its own review of clinical evidence and cost-effectiveness. Discussions are ongoing in Canada about the establishment of a single Federal agency for drug review. One advantage of having a single buyer of medicines, similar to Australia, is that it affords what economists call monopsony power – the government having more power to negotiate the terms of price and reimbursement.

The main lessons for Australia relate to Ontario's experience with the limited use designation which attempts to direct drug usage to patients for whom a medicine is most cost-effective. A member of the DQTC has recently criticised the limited use mechanism saying that there is no evidence that the policy is effective.⁴ Producing 'evidence-based' prescribing guidance is the easy part – the difficulty is getting prescribers to comply. The related challenge is having the utilisation data systems in place to monitor how well the policy targets are being achieved. Ontario has made some progress in this respect and Australia needs to keep pushing for this necessary research infrastructure. Finally, whether you welcome or fear the 'brave new world' of the electronic medical record, it clearly holds great hope in the future as a means of real-time, office-based prescribing guidance and reimbursement adjudication. Concerns over

prescriber freedom and patient confidentiality will no doubt be voiced as this technological innovation becomes a reality in the doctor's office.

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REFERENCES

1. Top 10 drugs. Aust Prescr 2001;24:136.
2. The 2000/1 Report Card for ODBP including detailed statistics http://www.gov.on.ca/MOH/english/pub/ministry/odb_report01/drug_rep.html
3. Ontario guidelines for economic analysis of pharmaceutical products. Toronto: Ontario Ministry of Health and Long-term Care; 1994.
4. Laupacis A. Inclusion of drugs in provincial drug benefit programs: who is making these decisions, and are they the right ones? CMAJ 2002; 166:44-7.

FURTHER READING

The Ontario Drug Benefits Program homepage

http://www.gov.on.ca/health/english/program/drugs/drugs_mn.html

The ODBP formulary

http://www.gov.on.ca/health/english/program/drugs/odbf/odbf_mn.html

Ontario guidelines on economic analysis for drug submissions http://www.gov.on.ca/health/english/pub/drugs/drugpro/dsguide_mn.html

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Transparency and the Pharmaceutical Benefits Advisory Committee

Alan H. Evans, Chief Executive, Medicines Australia, Canberra

Comment on Professor M.J. Eadie's editorial 'The secrecy of drug regulatory information' (Aust Prescr 2002;25:78-9)

Medicines Australia, which represents the prescription medicines industry in Australia, welcomes discussion on transparency of the evaluation process for new medicines.

Medicines Australia wrote to the Therapeutic Goods Administration (TGA) earlier this year suggesting the establishment of an industry/TGA project team to look at the evaluation process, including the issue of transparency. While the terms of reference for that project team are yet to be established, it is anticipated that consumers will have representation on that team. The project team is expected to consider the level of information that could potentially be made publicly available, the depth and detail of that information and the timing of the release of that information.

Caution should however be taken in making direct comparisons with the types and level of information available to consumers in the USA. The evaluation systems that give rise to the release of the minutes of expert committee reports in the USA vary from those in Australia on some key issues. For example, the evaluation of a new product in the USA includes a public

hearing which both the public and the applicant are invited to attend. In Australia, the Australian Drug Evaluation Committee (ADEC) considers applications in closed sessions. Natural justice suggests that companies should have the opportunity to respond to the issues raised by the ADEC before the minutes are disclosed.

With respect to the release of pharmacological and clinical data, it should be noted that Article 39.3 of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), to which Australia is a signatory, states that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.