Two-way transparency

For several years there have been complaints about the transparency of the Australian drug regulatory system. Pharmaceutical companies complain about the transparency of decisions to approve or reject a product for marketing or subsidy, while clinicians complain that they cannot access the data used to make those decisions.

The Pharmaceutical Benefits Advisory Committee has been working with the pharmaceutical industry to address some of these criticisms. Greater transparency of the operation of the Pharmaceutical Benefits Scheme (PBS) was also a key feature of the free trade agreement between Australia and the USA.

While the pharmaceutical industry has achieved some of its goals, much of the clinical data it provides to government remains secret. The Editorial Executive Committee believes that clinical information which could be used to help patients should not be kept as 'commercial-in-confidence'.[1,2]

In view of the pharmaceutical industry's interest in greater transparency, the Editorial Executive Committee has been inviting companies to supply the information that supported the approval of their products in Australia. This information can then be used in the preparation of the New Drugs section of *Australian Prescriber* and enhances the evidence base for these comments.

While there has been a range of responses (Table 1), the Editorial Executive Committee is pleased that some companies are willing to provide information for independent review. Companies have also been supplying information to assist the National Prescribing Service in preparing its RADAR review of new listings on the PBS. We hope this is the beginning of a trend which will lead to increased transparency in drug regulation.

References

1. Eadie M. The secrecy of drug regulatory information. Aust Prescr 2002;25:78-9.
2. Marley J. Cost-effectiveness: the need to know. Aust Prescr 1996;19:58-9.

Table 1

T-Score: Pharmaceutical company responses to requests for clinical evaluation data July 2003 – June 2005

Company	Drug
Manufacturer provided all requested information T T T	
Abbott	adalimumab
Bristol-Myers Squibb	atazanavir
Ferring	carbetocin
Gilead Sciences	adefovir dipivoxil
Lundbeck	escitalopram
Pfizer	eplerenone
Roche	enfuvirtide
Specialites Septodont	articaine
Manufacturer provided some data T T	
CSL Ltd	bivalirudin
Eli Lilly	atomoxetine
Eli Lilly	pemetrexed
Genzyme	agalsidase beta
Laboratoires Fournier	fenofibrate
Merck Sharp & Dohme	aprepitant
Novartis	ketotifen hydrogen fumarate
Schering	iloprost
Servier	strontium ranelate
Manufacturer had no objection to providing data but did not actually provide it T	
AstraZeneca	rosuvastatin
Genzyme	laronidase-rch
Novartis	lumiracoxib
Orphan	treprostinil
Pharmion	thalidomide
Pfizer	pregabalin
Serono	efalizumab
Manufacturer declined to supply data T	
GlaxoSmithKline	ropinirole
Janssen Cilag	norelgestromin and ethinyloestradiol
Novo Nordisk	insulin detemir
Schering	disodium gadoxetate
Manufacturer did not respond to request X	
Amgen	cinacalcet
ANSTO Radiopharmaceuticals	iobenguane [^{123}i] sulphate
Aventis Pasteur	inactivated cholera vaccine
Aventis Pharma	insulin glulisine
Baxter Healthcare	iron sucrose
Baxter Healthcare	human protein C (plasma derived)
Baxter Healthcare	amotosalen
Biogen	alefacept
Bracco	gadobenate dimeglumine
Douglas	poractant alfa
Gilead Sciences	emtricitabine
GlaxoSmithKline	fosamprenavir
Novartis	everolimus
Novartis	darifenacin hydrobromide
Pfizer	tolterodine tartrate
Solvay	moxonidine