

# New drugs: transparency

Access to the information collected during clinical trials is important for preparing the new drug comments in *Australian Prescriber*. A lot of this information is unpublished, but is used by the Therapeutic Goods Administration (TGA) when it evaluates new drugs. *Australian Prescriber* routinely asks pharmaceutical companies to provide a copy of the clinical evaluation data which support the safety and efficacy of their products. Few companies provide this level of transparency.

Almost 10 years ago *Australian Prescriber* started to publish a rating of the companies' cooperation. This was called the T-score (see box). While some companies are willing to provide data, others do not even respond to the request for information (see Table).

In the last few years the TGA has started to publish information about what was considered when it evaluated a new drug for the Australian market. These Australian Public Assessment Reports (AusPARs) include information from the TGA's clinical evaluation. This then resulted in some companies, responding to requests for data, referring *Australian Prescriber* to the AusPAR rather than providing the data. As the AusPAR is a public document and does not contain the full clinical evaluation, the Editorial Executive Committee decided that companies which only provided an AusPAR would be given the minimum T-score.

To be advised to read the AusPAR is particularly unhelpful if the AusPAR has not been published before the drug is launched onto the Australian market. The TGA is working to reduce this delay in publishing AusPARs. In addition, the TGA has been providing extracts of its evaluations, as attachments to the AusPARs, since July 2013.

The transparency of drug regulation is gradually improving, but *Australian Prescriber* will continue to monitor the willingness of the pharmaceutical industry to provide information about clinical trials of new drugs.

### T-scores

- T T T** manufacturer provided the clinical evaluation
- T T** manufacturer provided additional useful information
- T** manufacturer provided the AusPAR and/or the product information
- X** manufacturer declined to supply data
- X** manufacturer did not respond to request for data

Table **Pharmaceutical company responses to requests for clinical evaluation data January 2011 - December 2013**

Company	Drug
<b>T T T manufacturer provided the clinical evaluation</b>	
AstraZeneca	vandetanib
Norgine	rifaximin
Sci Gen	zonisamide
Shire	lisdexamphetamine
Vifor Pharma	ferric carboxymaltose
<b>T T manufacturer provided additional useful information</b>	
Actelion	collagenase <i>Clostridium histolyticum</i>
Boehringer Ingelheim	linagliptin
Bristol-Myers Squibb	dapagliflozin, ipilimumab
Celgene	romidepsin

**Table** Pharmaceutical company responses to requests for clinical evaluation data January 2011 – December 2013 (continued)

Company	Drug
CSL	meningococcal vaccine
GlaxoSmithKline	dabrafenib
Janssen-Cilag	canagliflozin, prucalopride
Leo Pharma	ingenol mebutate
Merck Serono	sapropterin
Merck Sharp & Dohme	boceprevir, nomegestrol/oestradiol
Sanofi-Aventis	cabazitaxel, teriflunomide
Sanofi Pasteur	live Japanese encephalitis vaccine
Schering-Plough	corifollitropin alfa
Shire	velaglucerase
Specialised Therapeutics	fidaxomicin
Takeda	alogliptin
<b>T manufacturer provided the AusPAR and/or the product information</b>	
AstraZeneca	ceftaroline, ticagrelor
Bayer	aflibercept
Biogen	fampridine
Biogen Idec	dimethyl fumarate
Bristol-Myers Squibb	saxagliptin
CSL	tapentadol
GlaxoSmithKline	belimumab, eltrombopag, measles, mumps, rubella and varicella vaccine
Ikaria	terlipressin
Janssen-Cilag	abiraterone, rilpivirine, telaprevir
Lundbeck	rasagiline, sertindole
Merck Sharp & Dohme	tafluprost
MS Health	mifepristone
Novartis	canakinumab, fingolimod
Novo Nordisk	liraglutide
Pierre Fabre Medicament	vinflunine
Roche	pertuzumab, vemurafenib, vismodegib
Pfizer	axitinib
Specialised Therapeutics	palonosetron
<b>X manufacturer declined to supply data</b>	
Bristol-Myers Squibb	apixaban
Schering-Plough	asenapine
<b>X manufacturer did not respond to request for data</b>	
Link Medical Products	cyclizine
Novartis	ruxolitinib