



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Prescription Medicines

## Meeting statement

**Meeting 296 - Wednesday 12 and Thursday 13 February 2014**

### **Role of the Advisory Committee on Prescription Medicines (ACPM) in the TGA's regulatory decision making process**

The ACPM is a statutory advisory committee established by the Therapeutic Goods Regulations 1990.

The TGA currently has nine statutory advisory committees from which it can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes. The ACPM provides advice to the TGA on, amongst other things, matters relating to the inclusion, variation or retention of prescription medicines on the Australian Register of Therapeutic Goods.

The advice provided by the ACPM is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only part of the information that is available to, for instance, a TGA delegate making a regulatory decision under the Therapeutic Goods Act. While appropriate consideration will be given to such advice, it is important to note that neither the TGA nor a TGA delegate is obliged to follow it.

It should also be noted that information about advice provided by the committee may not become publicly available for some time after a committee has provided that advice. The purpose of this Meeting Statement is to describe in general terms the matters considered by the committee at each meeting and for it to be available as soon as reasonably practical after the relevant meeting.

### **Update on matters where the Committee previously provided advice and a TGA decision has been made**

The following AusPAR's have been issued and are available on the website:  
<http://www.tga.gov.au/industry/pm-auspar-active.htm>

This list is an update from the beginning of 2013.

Meeting Number	Active	Sponsor
ACPM 288	Aflibercept rch	Sanofi-Aventis Australia Pty
ACPM 288	Apixaban	Bristol-Myers Squibb Australia Pty Ltd
ACPM 288	calcipotriol and betamethasone (as dipropionate)	LEO Pharma Pty Ltd
ACPM 288	Everolimus	Novartis Pharmaceuticals Australia Pty Ltd
ACPM 288	Fidaxomicin	Specialised Therapeutics Australia Pty Ltd
ACPM 288	Lixisenatide	Sanofi-Aventis Australia Pty Ltd
ACPM 288	Rivaroxaban	Bayer Australia Ltd
ACPM 288	Zonisamide	SciGen Australia Pty Ltd
ACPM 289	Azacitidine	Celgene Pty Ltd
ACPM 289	Eplerenone	Pfizer Australia Pty Ltd
ACPM 289	Mycafungin (as sodium)	Astellas Pharma Australia Pty Ltd
ACPM 289	Rituximab	Roche Products Pty Limited
ACPM 290	Cetuximab	Merck Serono Australia Pty Ltd
ACPM 290	Clobazam	Sanofi-Aventis Australia Pty Ltd
ACPM 290	Fentanyl citrate	Takeda Pharmaceuticals Australia Pty Ltd
ACPM 290	Filgrastim (rbe1)	Sandoz Pty Ltd
ACPM 290	Golimumab (rmc1)	Janssen-Cilag Pty Ltd
ACPM 290	Interferon beta-1a	Merck Serono Australia Pty Ltd
ACPM 290	Linagliptin	Boehringer Ingelheim Pty Ltd
ACPM 290	Linagliptin/Metformin HCl	Boehringer Ingelheim Pty Ltd
ACPM 290	Pertuzumab (rch1)	Roche Products Pty Limited
ACPM 290	Retigabine	GlaxoSmithKline Australia Pty Ltd
ACPM 290	Rivaroxaban	Bayer Australia Ltd
ACPM 290	Saxagliptin / metformin hydrochloride	Bristol-Myers Squibb Australia Pty Ltd
ACPM 290	Vismodegib	Roche Products Pty Limited
ACPM 291	Adalimumab (rch)	AbbVie Pty Ltd
ACPM 291	Amino acids (L-alanine, L-arginine, L-aspartic acid, L-glutamic acid, glycine, L-histidine, L-isoleucine, L-leucine, L-lysine (as L-lysine acetate), L-methionine, L-phenylalanine, L-proline, L-serine, L-threonine, L-tryptophan, L-tyrosine, L-valine) Lipids (refined soya oil, refined olive oil) Glucose (with or without calcium chloride dihydrate) With and without electrolytes (sodium glycerophosphate hydrate, magnesium chloride hexahydrate, potassium chloride, sodium acetate trihydrate).	Baxter Healthcare Pty Ltd
ACPM 291	Atazanavir	Bristol-Myers Squibb Australian Pty Ltd

Meeting Number	Active	Sponsor
ACPM 291	Botulinum toxin type A	Allergan Australia Pty Ltd
ACPM 291	Collagenase clostridium histolyticum	Actelion Pharmaceuticals Australia Pty Ltd
ACPM 291	Dimethyl Fumarate	Biogen Idec Australia Pty Ltd
ACPM 291	Fentanyl citrate	A. Menarini Australia Pty Ltd
ACPM 291	Ivacaftor	Vertex Pharmaceuticals Australia Pty Ltd
ACPM 291	Ivermectin	Merck Sharp Dohme (Australia) Pty Ltd
ACPM 291	Lisdexamfetamine dimesilate	Shire Australia Pty Limited
ACPM 291	Neisseria meningitidis Group B Factor H Binding Protein fusion protein, Neisseria meningitidis Group B Neisseria Adhesin A protein, Neisseria meningitidis Group B Neisseria Heparin Binding Antigen fusion protein, Neisseria meningitidis serogroup B outer membrane vesicles	Novartis Vaccines and Diagnostics Pty Ltd
ACPM 291	Nanoparticle albumin-bound (nab) paclitaxel	Abraxis Bioscience Australia Pty Ltd
ACPM 291	Olmesartan medoxomil, amlodipine (as besilate) and hydrochlorothiazide	Merck Sharp & Dohme (Australia) Pty Limited
ACPM 291	Retapamulin	GlaxoSmithKline Australia Pty Ltd
ACPM 291	Romidepsin	Celgene Australia Pty Ltd
ACPM 291	Tenofovir disoproxil fumarate	Gilead Sciences, Australia & New Zealand
ACPM 292	Alogliptin (as benzoate)	Takeda Pharmaceuticals Australia Pty Ltd
ACPM 292	Cobicistat	Gilead Sciences Pty Ltd
ACPM 292	Dabrafenib mesilate	GlaxoSmithKline Australia Pty Ltd
ACPM 292	Eltrombopag Olamine	GlaxoSmithKline Australia Pty Ltd (GSK)
ACPM 292	Elvitegravir	Gilead Sciences Pty Ltd
ACPM 292	Purified capsular polysaccharides of Neisseria meningitidis types A, C, W-135 and Y, each conjugated to tetanus toxoid carrier protein	GlaxoSmithKline Australia Pty Ltd
ACPM 292	Palonosetron hydrochloride	Specialised Therapeutics Australia Pty Ltd

## Overview of the therapeutic goods referred for advice

At this meeting, the committee's advice was sought on nineteen applications before the TGA, including: nine applications for new chemical entities; two applications for new combinations of active ingredients, three applications seeking extensions of indications, one application for a new strength, two applications for a new dose form and two applications for a new dosage regimen.

The committee's advice has now been provided to TGA delegates for consideration as part of the TGA's regulatory decision making process.

## **Other matters considered**

A celebration of 50 years of advice on the safety and efficacy of prescription medicines by the ACPM and its predecessor, the Australian Drug Evaluation Committee (ADEC), was held at Parliament House, hosted by Assistant Minister for Health, Senator the Honourable Fiona Nash.

The ACPM also noted the very impressive booklet produced by the TGA for the occasion.

## **Further information**

Meeting statements are made publicly available after each meeting.

For further information on the ACPM, please visit the [ACPM](#) web page or contact the ACPM Secretary by phone on 02 6232 8252 or email: [ACPM.Secretariat@tga.gov.au](mailto:ACPM.Secretariat@tga.gov.au).