

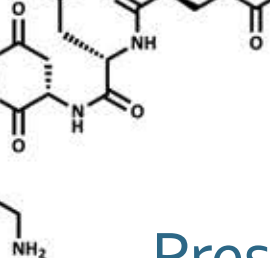


Australian Government  
Department of Health  
Therapeutic Goods Administration

# Prescription medicines: annual summary 2014

Registration of new chemical entities in Australia





# Prescription medicines: annual summary 2014

## Registration of new chemical entities in Australia

The Therapeutic Goods Administration (TGA) registered 39 new prescription medicines containing new active substances in 2014. These are called New Chemical Entities (NCEs) by the TGA.

Some of these NCE's are innovative or 'first-in-class', and have been made available for the first time outside the controlled environment of a clinical trial.

From mid-2015 these registrations will be published on a regular basis on the TGA website.

## Timeliness and predictability

All of the prescription medicine NCEs registered by the TGA in 2014 were approved within the legislated timeframe.

**In 2014**

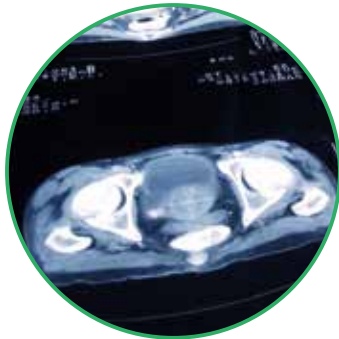
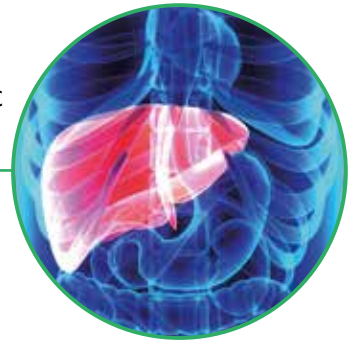
- 7 of the NCEs registered are considered to be innovative, for example, by having a new or unique mechanism of action over existing therapies (see list on following page).
- About one third of these medicines were designated to be orphan drugs by the TGA. A medicine, vaccine or in vivo diagnostic agent is designated as an 'orphan drug' if it:
  - is intended to treat, prevent or diagnose a rare disease; or
  - is not commercially viable to supply to treat, prevent or diagnose another disease or condition.

# Innovative or 'first-in-class' new prescription medicines



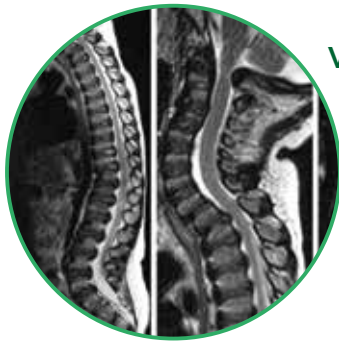
**FYCOMPA** – for the treatment of epilepsy

**SOVALDI** – for the treatment of chronic hepatitis C infection



**XOFIGO** – To treat men with castration-resistant prostate cancer

**ADEMPAS** – To treat certain types of pulmonary hypertension

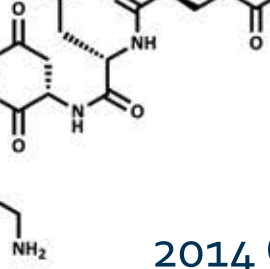


**VIMIZIM** – For the treatment of mucopolysaccharidosis IV, Type A (Morquio A syndrome, MPS IVA)

**MEKINIST** – For the treatment of patients with advanced melanomas




**JETREA** – For the treatment of vitreomacular traction (VMT)



# 2014 Chronological summary

 Orphan drug

## January

**NOVOEIGHT**  *Novo Nordisk Pharmaceuticals Pty Ltd* 8 Jan 2014  
turoctocog alfa  
Used to control or prevent bleeding in patients with haemophilia A.

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**LOTEMAX** *Bausch & Lomb Australia Pty Ltd* 16 Jan 2014  
loteprednol etabonate  
For the treatment of inflammation of the eye following cataract surgery or due to contact lens associated giant papillary conjunctivitis that is responsive to steroids.

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**TIVICAY** *ViiV Healthcare Pty Ltd* 17 Jan 2014  
dolutegravir (as sodium)  
Used in combination with other antiviral medicines to treat human immunodeficiency virus (HIV) infection in adults and children over 12 years of age.

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## February

**OPSUMIT**  *Actelion Pharmaceuticals Australia Pty Ltd* 5 Feb 2014  
macitentan  
As monotherapy or in combination with other medicines to treat certain types of pulmonary hypertension in adult patients.


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**RIXUBIS**  *Baxter Healthcare Pty Ltd* 5 Feb 2014  
nonacog gamma  
Used to control or prevent bleeding in adult patients with haemophilia B.

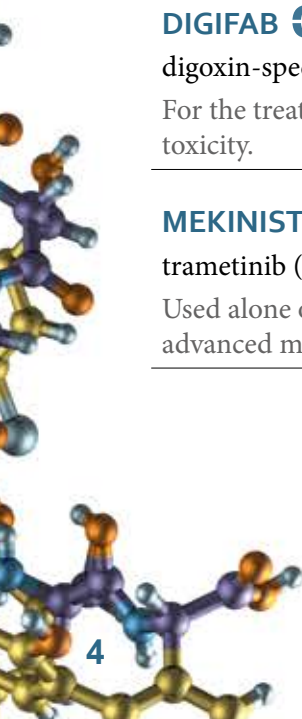
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**DIGIFAB**  *Phebra Pty Ltd* 14 Feb 2014  
digoxin-specific antibody fragment f(Ab) (ovine)  
For the treatment of known (or strongly suspected) life-threatening digoxin toxicity.

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**MEKINIST**  *GlaxoSmithKline Australia Pty Ltd* 14 Feb 2014  
trametinib (as dimethyl sulfoxide)  
Used alone or in combination with dabrafenib for the treatment of patients with advanced melanomas that express the BRAFV600 mutation.

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## March

**XEOMIN** *Merz Australia Pty Ltd*

21 Mar 2014

incobotulinum toxin A

For use in adults for the treatment of painful involuntary contraction of neck muscles, involuntary contraction of the eyelid muscles, post-stroke abnormal muscle rigidity affecting the arms, and frown lines between the eyes.

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**BRETARIS GENUAIR** *A. Menarini Australia Pty Ltd*

25 Mar 2014

acclidinium bromide

For use as maintenance therapy in adult patients with chronic obstructive pulmonary disease (COPD).

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**BRINTELLIX** *Lundbeck Australia Pty Ltd*

31 Mar 2014

vortioxetine hydrobromide

To treat major depression in adults.

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## April

**ADEMPAS**  *Bayer Australia Ltd*

14 Apr 2014

riociguat

As monotherapy or in combination with other medicines to treat certain types of pulmonary hypertension in adult patients.

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**LATUDA** *Commercial Eyes Pty Ltd*

16 Apr 2014

lurasidone hydrochloride

To treat symptoms of schizophrenia in adults.

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**BREO ELLIPTA** *GlaxoSmithKline Australia Pty Ltd*

17 Apr 2014

fluticasone furoate / vilanterol trifenate

For use as maintenance therapy in patients with chronic obstructive pulmonary disease (COPD) or moderate to severe asthma.

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**BOSULIF**  *Pfizer Australia Pty Ltd*

29 Apr 2014

bosutinib

For the treatment of chronic, accelerated or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia in adults previously treated with two or more tyrosine kinase inhibitors.

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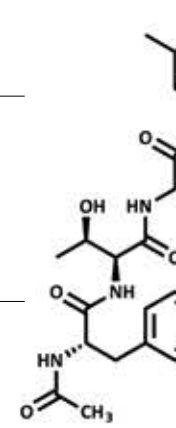
**JARDIANCE** *Boehringer Ingelheim Pty Ltd*

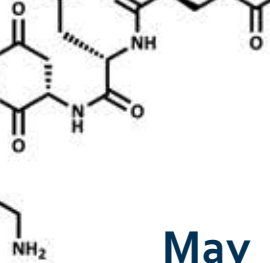
30 Apr 2014

empagliflozin



For use alone or in combination with other medicines to improve blood sugar control in adults with Type 2 diabetes.

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## May

<p><b>ALPROLIX</b>  <i>Biogen Idec Australia Pty Ltd</i></p> <p>eftrenonacog alfa</p> <p>A long-acting anti-haemophilic factor to control or prevent bleeding in adults and children <math>\geq 12</math> years with haemophilia B.</p>	1 May 2014
<p><b>HIZENTRA</b> <i>CSL Behring Australia Pty Ltd</i></p> <p>normal human immunoglobulin</p> <p>Replacement therapy in adults and children with primary immunodeficiency disease (PID) and symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.</p>	8 May 2014
<p><b>GAZYVA</b> <i>Roche Products Pty Ltd</i></p> <p>obinutuzumab</p> <p>For use in combination with chlorambucil to treat patients with previously untreated chronic lymphocytic leukaemia.</p>	15 May 2014
<p><b>XOFIGO</b> <i>Bayer Australia Ltd</i></p> <p>radium (<math>^{223}\text{Ra}</math>) dichloride</p> <p>To treat men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastatic disease.</p>	20 May 2014
<p><b>ELELYSO</b>  <i>Pfizer Australia Pty Ltd</i></p> <p>taliglucerase alfa rpc</p> <p>For long-term enzyme replacement therapy in adults and children with Type 1 Gaucher disease.</p>	21 May 2014
<p><b>FYCOMPA</b> <i>Eisai Australia Pty Ltd</i></p> <p>perampanel (as hemisesquihydrate)</p> <p>For use in conjunction with other medicines to treat partial-onset seizures in patients with epilepsy aged 12 years and older.</p>	23 May 2014





## June

**ELOCTATE**  *Biogen Idec Australia Pty Ltd*

27 Jun 2014

efraloctocog alfa

A long-acting anti-haemophilic factor to control or prevent bleeding in adults and children  $\geq 12$  years with haemophilia A.

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**ENTYVIO** *Takeda Pharmaceuticals Australia Pty Ltd*

27 Jun 2014

vedolizumab (rch)

Treatment of adults with moderate to severe ulcerative colitis or Crohn's disease who have had an inadequate response with, lost response to, or are intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF $\alpha$ ) antagonist.

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**SOVALDI** *Gilead Sciences Pty Ltd*

30 Jun 2014

sofosbuvir

For use in combination with other antiviral medicines to treat chronic hepatitis C infection in adults.

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**RIBOMUSTIN** *Janssen-Cilag Pty Ltd*

30 Jun 2014

bendamustine hydrochloride

For treatment of certain types of chronic lymphocytic leukaemia, Non-Hodgkin's lymphoma, and Mantle Cell Lymphoma

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## July

**XTANDI** *Astellas Pharma Australia Pty Ltd*

1 Jul 2014

enzalutamide

For the treatment of men with metastatic castration-resistant prostate cancer who have previously received docetaxel.

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**POMALYST**  *Celgene Australia Pty Ltd*

1 Jul 2014

pomalidomide

Used in combination with dexamethasone for the treatment of patients with multiple myeloma whose disease has progressed despite treatment with other anticancer medicines.

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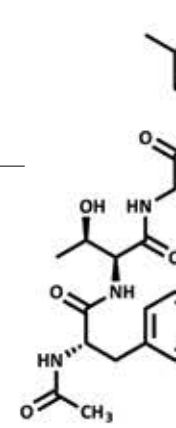
**ANORO ELLIPTA** *GlaxoSmithKline Australia Pty Ltd*

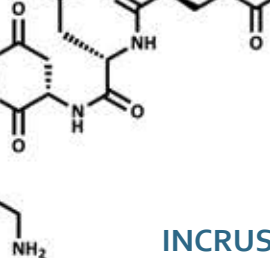
4 Jul 2014

umeclidinium bromide/ vilanterol trifenate

For use as maintenance therapy in adult patients with chronic obstructive pulmonary disease (COPD)

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**INCRUSE ELLIPTA** *GlaxoSmithKline Australia Pty Ltd*

8 Jul 2014

umeclidinium (as bromide)

For use as maintenance therapy in adult patients with chronic obstructive pulmonary disease (COPD)

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**OLYSIO** *Janssen-Cilag Pty Ltd*

18 Jul 2014

simeprevir (as sodium)

Used in combination with other antiviral medicines to treat chronic hepatitis C infection in adults.

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## September

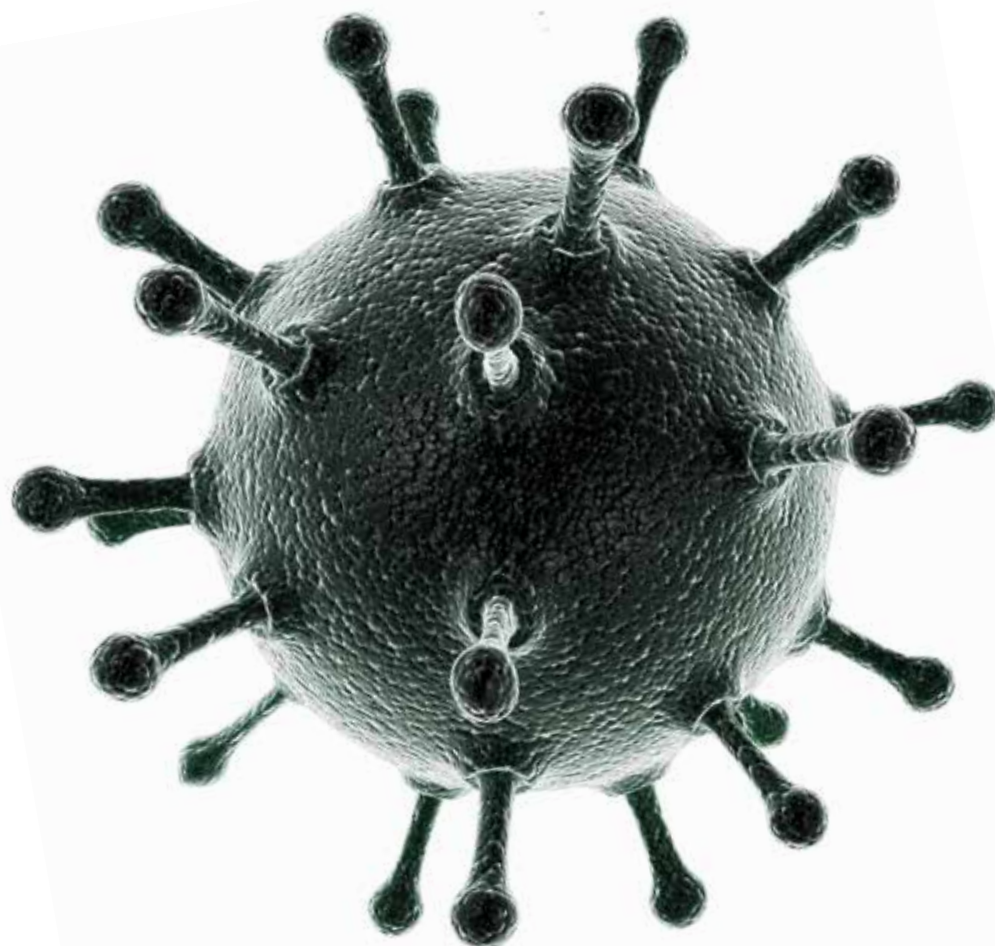
**HEXAXIM** *Sanofi-Aventis Australia Pty Ltd*

11 Sep 2014

diphtheria toxoid, haemophilus type B polysaccharide, hepatitis B surface antigen, pertussis filamentous haemagglutinin, pertussis toxoid, poliovirus, tetanus protein, tetanus toxoid

For vaccination of infants from six weeks of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b.

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## October

**JETREA** *Alcon Laboratories Australia Pty Ltd*

9 Oct 2014

ocriplasmin

For the treatment of vitreomacular traction (VMT) in adults, a condition where the vitreous gel sticks to the retina and can result in subsequent loss or distortion of vision and damage to the eye.

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## November

**PLEGRIDY** *Biogen Idec Australia Pty Ltd*

10 Nov 2014

peginterferon beta-1a (rch)

For the treatment of relapsing forms of multiple sclerosis.

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**NUWIQ** *Octapharma Australia Pty Ltd*

10 Nov 2014

simoctocog alfa

Used to control or prevent bleeding in previously treated paediatric (< 2 years) and adult patients with haemophilia A.

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**ICLUSIG**  *ARIAD Pharmaceuticals Australia Pty Ltd*

26 Nov 2014

ponatinib hydrochloride

For the treatment of adult patients with certain types of leukaemia.

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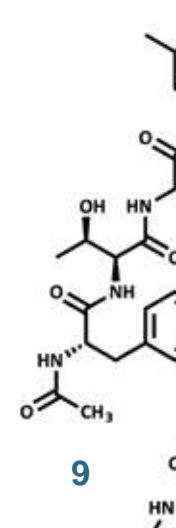
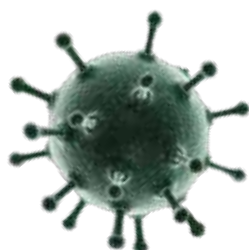
**VELPHORO** *Fresenius Medical Care Australia Pty Ltd*

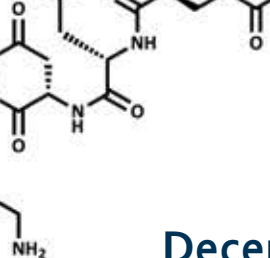
27 Nov 2014

sucroferric oxyhydroxide

To control serum phosphorus levels in adult patients with chronic kidney disease on dialysis.

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## December

**FLUQUADRI and FLUQUADRI JUNIOR** *Sanofi-Aventis Australia Pty Ltd*

2 Dec 2014

influenza virus haemagglutinin

FluQuadri and FluQuadri Junior are indicated for active immunisation of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

FluQuadri is indicated for use in adults and children 3 years and older.

FluQuadri Junior is indicated for use in children aged 6 months to 35 months inclusive.

**VIMIZIM**  *BioMarin Pharmaceutical Australia Pty Ltd*

9 Dec 2014

elosulfase alfa (rch)

An enzyme replacement therapy for the treatment of mucopolysaccharidosis IV, Type A (Morquio A syndrome, MPS IVA), a severely debilitating and progressive disease due to accumulation of certain polysaccharides in the body that can result in significant physical impairment, impaired quality of life, and early mortality.

**ADENURIC** *A. Menarini Australia Pty Ltd*

18 Dec 2014

febuxostat

Treatment of chronic symptomatic hyperuricaemia in adults with gout.

An Australian Public Assessment Report (AUSPAR) will be produced for each of these medicines and once available can be obtained from [www.tga.gov.au/browse-auspars-active-ingredient](http://www.tga.gov.au/browse-auspars-active-ingredient). The AUSPAR provides more information about the evaluation of the medicine and the considerations that led the TGA to register it.

The trade name, sponsor and active ingredient for each medicine reflects the information initially entered in the Australian Register of Therapeutic Goods (ARTG). The publicly accessible version of the ARTG is the reference database of the TGA. It provides current information on therapeutic goods that can be supplied in Australia.





### Image credit - VIMIZIM

Spinal involvement in mucopolysaccharidosis IVA (Morquio-Brailsford or Morquio A syndrome)

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National Center for Biotechnology Information, U.S. National Library of Medicine

[http://openi.nlm.nih.gov/detailedresult.php?img=3590412\\_10545\\_2013\\_9586\\_Fig4\\_HTML&req=4](http://openi.nlm.nih.gov/detailedresult.php?img=3590412_10545_2013_9586_Fig4_HTML&req=4)

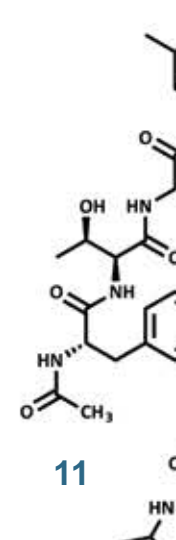
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The background features several faint, light-colored chemical structures. These include a complex heterocyclic molecule with a benzene ring fused to a five-membered ring containing nitrogen and oxygen, and another structure with a benzene ring and a nitrogen-containing side chain. The structures are rendered in a semi-transparent style, allowing the text to be legible.

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Therapeutic Goods Administration

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