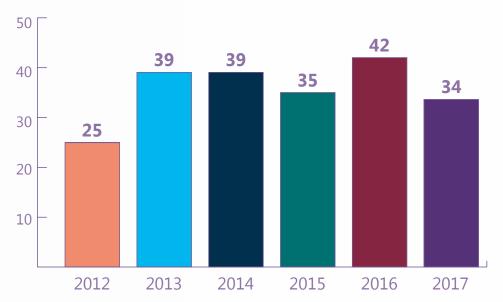


Prescription medicines and biologicals: TGA annual summary 2017





New chemical or biological entity registrations by year



New generic medicine registrations by year

In 2017

- 34 New chemical or biological entity registrations
- **46** New or extended uses, or new combination registrations
- 21 Orphan Drug registrations
- 101 New generic medicine registrations
- **69** AusPAR publications

Prescription medicines and biologicals: TGA annual summary 2017

The Therapeutic Goods Administration (TGA) is the regulator responsible for approving prescription medicines for human use in Australia through an evaluation of their quality, safety and efficacy. This includes entirely new medicines (termed 'new chemical or biological entities'), new uses ('extension of indications') or combinations of already-registered medicines, and new generic and biosimilar medicines. If approved, these medicines are added to the Australian Register of Therapeutic Goods (ARTG) and can be lawfully supplied in Australia, and prescribed by healthcare professionals for specific indications. In addition to evaluating prescription medicines, TGA's regulatory ambit includes complementary and over-the-counter medicines, medical devices, vaccines, cell and tissue products, blood and blood products, and other therapeutic goods such as sunscreens. As part of the Health Products Regulation Group (HPRG) within the Australian Commonwealth Department of Health, we contribute to the protection and promotion of public health by supporting timely access to this vast array of therapeutic goods.

This is TGA's fourth annual summary report on the registration of prescription medicines, which includes new generic and biosimilar medicines. The summary also showcases new biologicals, including human cell- and tissue-derived products; and Australian Public Assessment Reports (AusPARs) published on our website during 2017. For the first time, the summary contains Priority review determinations. Priority review involves a faster assessment of certain prescription medicines, with a 3-month shorter timeframe than the standard registration process.

This year's registrations covered a wide therapeutic base with new treatments for conditions that include cancers, schizophrenia and meningococcal disease. During this period, two new first-in-class treatments were approved for spinal muscular atrophy and liposomal acid lipase deficiency. Orphan drugs for the treatment of rare diseases were approved for haemophilia and Fabry disease. Notably, 2017 saw a large proportion of new registrations of immunotherapies and human monoclonal antibodies, while the listing of new 'first generic' medicines triggered a statutory 16% price reduction under the Pharmaceutical Benefits Scheme. The registration of these new medicines provides the Australian public with a broader and more affordable range of treatment options, which will serve to enhance public health. Today, TGA's approval times for prescription medicines are comparable with analogous registration processes in the US and Europe. As for 2016, these approval times have fallen in 2017 with continual business improvements, and are anticipated to further fall following the introduction of Priority review pathways.

It gives me great pleasure to publish the 2017 annual summary report. We hope this information is of interest and use to the public, healthcare professionals, government bodies, other medicines regulators, and industry as we work together towards better health outcomes for all Australians.

Adjunct Professor John Skerritt
Deputy Secretary, Health Products Regulation Group
Department of Health
January 2018

Some innovative and 'first-in-class' new registrations

Please note that the indication for which each prescription medication is approved may be more specific than as described in general terms in this summary. For the full approved indications, please consult the Australian Register of Therapeutic Goods (ARTG):

https://www.tga.gov.au/australian-register-therapeutic-goods

DARZALEX

Darzalex (daratumumab) is used in combination with other drugs for the treatment of multiple myeloma, a form of blood cancer arising from plasma cells in bone marrow. Darzalex is a human monoclonal antibody that works together with immune system cells to help clear myeloma from the body. By targeting and attaching to CD38, a molecule overexpressed on the surface of multiple myeloma cells, Darzalex instigates an immune reaction that ultimately causes these dangerous cells to die.

INTUNIV

Intuniv (guanfacine) is the first once-daily, extended-release, non-stimulant drug approved for the treatment of attention deficit hyperactivity disorder (ADHD) in children. As a highly selective agonist of the alpha-2A adrenergic receptor, a molecule with a critical role in regulating neurotransmitter release from sympathetic nerves and neurons in the central nervous system, Intuniv works by strengthening the regulation of attention and behaviour by the brain's prefrontal cortex. Because Intuniv is a non-stimulant drug, it alleviates the risk of addiction associated with other ADHD drugs.

KANUMA

Kanuma (sebelipase alfa) is a first-in-class recombinant human lysosomal acid lipase for liposomal acid lipase deficiency (LAL-D), a genetic and progressive ultra-rare metabolic disease associated with multi-organ damage in infant, paediatric and adult patients, and premature death in infants. LAL-D patients have genetic mutations that result in decreased or lost activity of the LAL enzyme, which leads to an accumulation of cholesteryl esters and triglycerides in the liver, blood vessel walls, and other tissues. Kanuma provides a recombinant form of the human lysosomal acid lipase (rhLAL) protein that functions in place of the absent or abnormal LAL protein.

REVESTIVE

Revestive (teduglutide) is a first-in-class medicine for the management of Short Bowel Syndrome (SBS) in adults. SBS is a malabsorption disorder caused by the lack of a functional small intestine, often due to surgical removal, which is most often required due to Crohn's disease or small intestine tumours. The naturally-occurring human glucagon-like peptide-2 (GLP-2) hormone plays a key role in maintaining the normal structure and function of the small intestine. Revestive is a GLP-2 analogue differing from natural GLP-2 by a single amino acid and treats SBS by promoting mucosal growth, increasing intestinal blood flow, and restoring gastric emptying and secretion.



Spinraza (nusinersen) is an antisense oligonucleotide for the treatment of 5q spinal muscular atrophy (SMA), which is a serious, debilitating, life-threatening, autosomal recessive neuromuscular disease. Until now, sufferers of SMA had few options, and babies with the most severe form of the genetic disease, SMA1, deteriorated until they couldn't swallow and breathe, usually by nine months of age. Spinraza works by causing the body to increase production of the survival motor neuron protein, which is critical to the function of muscles. It has been shown to extend and improve the life of babies with SMA1, which is the most common genetic cause of death in children under two years of age.

TECENTRIQ

Tecentriq (atezolizumab) is a human monoclonal antibody approved for use in non-small cell lung cancer. It is the first approved cancer immunotherapy against the programmed cell death-ligand 1 (PD-L1) protein and works by blocking the interaction of PD-L1 with the programmed cell death protein 1 (PD-1), which is highly expressed on tumour cells. By blocking this interaction, the body's normal immune response is restored, and immune cells are now able to recognise and attack the cancer.

TRUMENBA

Trumenba is the second meningococcal B vaccine approved for use in Australia. Meningococcal vaccines are used to prevent infection by Neisseria meningitides, which causes meningitis and other forms of meningococcal disease. Six Neisseria meningitidis serogroups – A, B, C, Y, W-135 and X – are responsible for virtually all cases of the disease in humans, with vaccines against serotype B having proven the most difficult to produce. Trumenba is approved for use in individuals 10 years and older and is composed of two recombinant lipidated factor H binding proteins (fHBPs). Trumenba prevents serogroup B disease by inducing broadly protective bactericidal antibody responses against epidemiologically diverse serogroup B strains. fHBP is found on the surface of meningococcal bacteria and is essential for bacteria to avoid host immune defences.

VENCLEXTA

Venclexta (venetoclax) is a first-in-class treatment for patients with relapsed or refractory chronic lymphocytic leukaemia (CLL), a type of cancer of the blood and bone marrow. It is approved for use in patients who have a chromosomal abnormality called 17p deletion, which is detected using a diagnostic kit. Venclexta works by targeting a specific protein called Bcl-2. When normal cells become damaged, the body tells them to self-destruct, a natural process called apoptosis. In CLL patients, Bcl-2 builds up and prevents cancer cells from undergoing this programmed cell death. By targeting Bcl-2, Venclexta restores the process of apoptosis, and allows abnormal cancer cells to naturally self-destruct.

Some new or extended uses for existing medicines

In addition the approval of new prescription medicines, patients will also benefit from the approval of new or extended therapeutic uses for existing medicines. For full information on the approved indications, please consult the ARTG:

https://www.tga.gov.au/australian-register-therapeutic-goods

ACTEMRA

Actemra (tocilizumab) was registered in 2009 for the treatment of rheumatoid arthritis in adults and later for juvenile idiopathic arthritis in children.

Actemra is now also indicated for the treatment of giant cell arteritis in adults.

JARDIANCE

Jardiance (empagliflozin) was registered in 2014 for the treatment of type 2 diabetes.

Jardiance is now also indicated to reduce the risk of cardiovascular death.

KEYTRUDA

Keytruda (pembrolizumab) was registered in 2016 for the treatment of metastatic melanoma.

Keytruda is now also indicated for metastatic non-small cell lung carcinoma, head and neck squamous cell carcinoma, and classical Hodgkin Lymphoma.

OPDIVO

Opdivo (nivolumab) was registered in 2016 for the treatment of metastatic melanoma and non-small cell lung cancer.

Opdivo is now also indicated for the treatment of head and neck squamous cell carcinoma and classical Hodgkin Lymphoma.

PEDEA

Ibuprofen was first marketed in Australia in 1969 and is used for temporary pain relief.

Pedea is a new ibuprofen formulation for the treatment of haemodynamically significant patent ductus arteriosus in pre-term newborn infants less than 34 weeks of gestational age.

STELARA

Stelara (ustekinumab) was registered in 2009 for the treatment of plaque psoriasis, and later approved for psoriatic arthritis in 2015.

Stelara is now also indicated for the treatment for Crohn's disease.

XALKORI

Xalkori (crizotinib) was registered in 2014 for the treatment of ALK-positive advanced non-small cell lung cancer.

Xalkori is now also indicated for patients with ROS1 non-small cell lung cancer.

Priority determinations and orphan drug designations

In 2017, the Government established a new Priority review pathway aimed at providing the expedited assessment of major therapeutic advances treating serious or life-threatening medical conditions. At the same time, the existing orphan drug program was reformed to create a fairer system that aligns more closely with international criteria but without impacting the availability of drugs for rare diseases.

Note that Priority **determinations** and orphan drug **designations** *do not* mean **approvals**; they merely reflect how the submission will be evaluated. Incentives for these submissions are: a 3-month shorter target timeframe for Priority review; and fees waived for orphan drugs.

Priority determinations

The Priority determination process considers whether a prescription medicine is eligible for the Priority review pathway and is the first step towards expedited registration on the ARTG. Approved Priority determinations from 1 July 2017 are shown below.

2017 chronological summary

August

ALECENSA

alectinib

Roche Products Pty Limited

Priority Indication: For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC).

Effective date: 21 August 2017

HEMLIBRA

emicizumab

Roche Products Pty Limited

Priority Indication: For routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors. Hemlibra can be used in all age groups.

Effective date: 29 August 2017

September

OPDIVO

nivolumab

Bristol-Myers Squibb Australia Pty Ltd

Priority Indication: For the adjuvant treatment of Stage III/IV melanoma in patients who have undergone complete resection.

Effective date: 28 September 2017

November

OPDIVO

nivolumab

Bristol-Myers Squibb Australia Pty Ltd

Priority Indication: Opdivo in combination with ipilimumab, is indicated for the treatment of patients with intermediate/poor risk advanced renal cell carcinoma (RCC).

Effective date: 10 November 2017

TAGRISSO

osimertinib

AstraZeneca Pty Ltd

Priority Indication: For the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.

Effective date: 24 November 2017

BRINEURA

cerliponase alfa

BioMarin Pharmaceuticals Australia Pty Ltd

Priority Indication: For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.

Effective date: 30 November 2017

December

TAFINLAR

dabrafenib

Novartis Pharmaceuticals Australia Pty Ltd

Priority Indication: Tafinlar, in combination with trametinib, is indicated for the adjuvant treatment of patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

Effective date: 13 December 2017

MEKINIST

trametinib

Novartis Pharmaceuticals Australia Pty Ltd

Priority Indication: Mekinist, in combination with dabrafenib, is indicated for the adjuvant treatment of patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

Effective date: 13 December 2017

Orphan drug designations (from 1 July)

For full information on approved orphan drug designations from 1 July 2017, please consult: https://www.tga.gov.au/ws-designation-notices-index

Orphan drug designations prior to 1 July 2017 are available here: https://www.tga.gov.au/orphan-drugs

2017 chronological summary

August

HEMLIBRA

emicizumab

Roche Products Pty Limited

Designated Indication: For routine prophylaxis in patients with haemophilia A (congenital factor VIII deficiency).

Effective date: 25 August 2017

September

KUVAN

sapropterin dihydrochloride

BioMarin Pharmaceuticals Australia Pty Ltd

Designated Indication: For the treatment of HPA in patients with PKU or BH4 deficiency.

Effective date: 19 September 2017

November

BRINEURA

cerliponase alfa

BioMarin Pharmaceuticals Australia Pty Ltd

Designated Indication: For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.

Effective date: 8 November 2017

KEYTRUDA

pembrolizumab

Merck Sharp & Dohme (Australia) Pty Ltd

Designated Indication: For the treatment of adult and paediatric patients with primary mediastinal B-cell lymphoma.

Effective date: 28 November 2017

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December

SYMEDKO

tezacaftor / ivacaftor

Vertex Pharmaceuticals Australia Pty Ltd

Designated Indication: Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor based on in vitro data and/or clinical evidence.

Effective date: 14 December 2017

Biologicals

The Biologicals Regulatory Framework provides a comprehensive system of assessment and controls before products are allowed to be marketed in Australia, and also after registration approval through post-market vigilance.

For higher risk biologicals such as cell therapies, TGA evaluates their compliance with relevant standards relating to their quality, safety and efficacy.

For lower risk biologicals that have undergone no or only simple processing (called 'minimal manipulation'), such as products supplied by tissue banks, TGA evaluates their compliance with relevant quality standards.

All manufacturers of biologicals must also show that they comply with the manufacturing principles outlined in the Australian Code of Good Manufacturing Practice (GMP) for human blood and tissues.

For more information on the Biologicals Regulatory Framework, please consult: https://www.tga.gov.au/regulatory-framework-biologicals



Innovative and 'first-in-class' new biologicals registrations

Please note that the indication for which each biological is approved may be more specific than as described in general terms in this summary. For the full approved indications, please consult the ARTG: https://www.tga.gov.au/australian-register-therapeutic-goods

ORTHO-ACI

Orthocell Pty Ltd

Ortho-ACI is a suspension of cultured autologous chondrocytes. The chondrocytes are derived from a biopsy of the patient's cartilage and are expanded using in vitro cell culture. Ortho-ACI is indicated for use in treatment of cartilage lesions associated with the knee, patella and ankle in patients with cartilage damage caused by trauma, wear or degradation including cartilage lesions associated with chondromalacia patella or osteochondritis.

Evaluation commenced: 16 January 2014 Registration decision: 26 May 2017

Some new or extended uses for existing biologicals

In addition to the approval of new biologicals, patients will also benefit from the approval of existing biologicals for new or extended therapeutic uses. For the full approved indications, please consult the ARTG:

https://www.tga.gov.au/australian-register-therapeutic-goods

OCULAR TISSUE

Queensland Eye Bank

Approval was granted for 'Cornea, normothermic storage – L' for cornea allograft. This approval allows the sponsor to use an alternative organ culture system at physiological temperatures, which extends the storage and shelf life of the donated tissue. This tissue is intended for the treatment of ophthalmic disorder, disease or trauma.

Evaluation commenced: 20 April 2017 Registration decision: 18 October 2017

MUSCULOSKELETAL TISSUE

Australian Biotechnologies Pty Ltd

Approval was granted for new forms of bone allograft tissue including demineralised cortical fibres and malleable bone segments. These allografts have been demineralised through acid treatment to enhance malleability and are intended for restoring bone volume or filling voids or gaps in the skeletal system.

Evaluation commenced: 22 February 2017 Registration decision: 30 June 2017

W E

New registrations by therapeutic area

Antineoplastic & haematological agents

ADYNOVATE rurioctocog alfa pegol (antihaemophilic factor VIII Recombinant Coagulation Factor VIII rch)

AFSTYLA lonoctocog alfa (recombinant single-chain coagulation factor VIII)

ALECENSA alectinib

DARZALEX / JANSSEN DARATUMUMAB daratumumab

IBRANCE palbociclib

KISQALI ribociclib (as succinate)

LONSURF / ORCANTAS trifluridine / tipiracil hydrochloride

MONOFER ferric derisomaltose

ONCASPAR pegaspargase

TECENTRIQ atezolizumab (rch)

VENCLEXTA venetoclax

Neurological & neuromuscular agents

INTUNIV guanfacine (as hydrochloride)

OCREVUS ocrelizumab

REXULTI brexipiprazole

SPINRAZA nusinersen (as heptadecasodium)

Cardiovascular, gastrointestinal & reproductive agents

MONUROL fosfomycin trometamol

RANEXA ranolazine

REKOVELLE follitropin delta (rhu)

REVESTIVE teduglutide

UROREC silodosin



Endocrine, metabolic & respiratory agents

CINQAIR / CINQAERO reslizumab

GALAFOLD migalastat (as hydrochloride)

KANUMA sebelipase alfa rce

PHEBURANE sodium phenylbutyrate

RYZODEG 70/30 FLEXTOUCH and RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys)

TRESIBA FLEXTOUCH and TRESIBA PENFILL insulin degludec (rys)

VELTASSA patiromer sorbitex calcium

ZEMAIRA human alpha-1-proteinase inhibitor

Vaccines, anti-infectives & allergen immunotherapies

DENGVAXIA Dengue tetravalent vaccinelive, attenuated

FLUZONE HIGH-DOSE inactivated trivalent influenza vaccine (Split Virion)

GRAZAX standardised allergen extract of grass pollen from Timothy grass (Phleum pratense)

INFLUVACTETRA influenza virus haemagglutinin vaccine

TRUMENBA meningococcal group B vaccine

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ZINPLAVA bezlotoxumab



Registrations of new prescription medicines

Once an application has been accepted for evaluation by TGA, the **approval time** is defined as the **number of TGA working days between commencement of evaluation and registration decision**. This timeframe is underpinned by legislation (see *Therapeutic Goods Regulations 1990*) and excludes public holidays, weekends, the time allocated to the sponsor to respond to requests for information, 'mutual clock stop' periods agreed with the sponsor, or other review activities.

All products were approved within the statutory 255 working day period.



A medicine is designated as an orphan drug to provide an incentive to sponsors to bring medicines for a small population to market and make medicines available to patients who would not otherwise be able to access them.

2017 chronological summary

January

VENCLEXTA Approval time: 179 working days

venetoclax

Abbvie Pty Ltd

For the treatment of patients with relapsed or refractory chronic lymphocytic leukaemia (CLL) with 17p deletion, or patients with relapsed or refractory CLL for whom there are no other suitable treatment options.

Evaluation commenced: 29 February 2016 Registration decision: 15 December 2016 Entry onto ARTG: 5 January 2017

February

ZEMAIRA • Approval time: 177 working days

human alpha-1-proteinase inhibitor

CSL Behring Australia Pty Ltd

For maintenance treatment to slow the progression of emphysema in adults with documented severe A1-PI deficiency and progressive lung disease.

Evaluation commenced: 31 March 2016 Registration decision: 9 February 2017 Entry onto ARTG: 13 February 2017

March

GRAZAX Approval time: 231 working days

standardised allergen extract of grass pollen from Timothy grass (Phleum pratense) Seqirus Pty Ltd

For disease modifying treatment of grass pollen (Phleum pratense or allergens cross reacting with P. pratense) induced allergic rhinitis with or without conjunctivitis in adults, adolescents and children above the age of 5 years.

Evaluation commenced: 29 January 2016 Registration decision: 24 February 2017 Entry onto ARTG: 7 March 2017



Approval time: 210 working days

alectinib

Roche Products Pty Ltd

For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

Evaluation commenced: 4 April 2016 Registration decision: 10 March 2017 Entry onto ARTG: 14 March 2017

ADYNOVATE Approval time: 180 working days

rurioctocog alfa pegol (antihaemophilic factor VIII Recombinant Coagulation Factor VIII rch)

Baxalta Australia Pty Ltd

Adynovate is a long-acting antihaemophilic factor (recombinant) indicated in haemophilia A (congenital factor VIII deficiency) patients for:

- · control and prevention of bleeding episodes;
- routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
- perioperative management (surgical prophylaxis).

It is not indicated for the treatment of von Willebrand disease.

Evaluation commenced: 29 April 2016 Registration decision: 15 March 2017 Entry onto ARTG: 21 March 2017

REKOVELLE Approval time: 224 working days

follitropin delta (rhu)

Ferring Pharmaceuticals Pty Ltd

Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle.

Evaluation commenced: 29 February 2016 Registration decision: 24 March 2017 Entry onto ARTG: 31 March 2017

April

lonoctocog alfa (recombinant single-chain coagulation factor VIII) CSL Behring Australia Pty Ltd

Afstyla is indicated in adult and paediatric patients with haemophilia A (congenital FVIII deficiency) for:

- · control and prevention of bleeding episodes;
- routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
- perioperative management (surgical prophylaxis).

Afstyla is not indicated for the treatment of von Willebrand disease.

Evaluation commenced: 29 February 2016 Registration decision: 29 March 2017 Entry onto ARTG: 13 April 2017

May

IBRANCE Approval time: 182 working days

palbociclib

Pfizer Australia Pty Ltd

Ibrance is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

- · an aromatase inhibitor as initial endocrine-based therapy;
- fulvestrant in patients who have received prior therapy.

Evaluation commenced: 31 May 2016 Registration decision: 28 April 2017 Entry onto ARTG: 3 May 2017

KANUMA • Approval time: 220 working days

sebelipase alfa rce

Alexion Pharmaceuticals Australasia Pty Ltd

Kanuma is indicated for long-term enzyme replacement therapy (ERT) in patients of all ages with lysosomal acid lipase deficiency (LAL-D).

Evaluation commenced: 31 May 2016 Registration decision: 17 May 2017 Entry onto ARTG: 18 May 2017

REVESTIVE Approval time: 196 working days

teduglutide

Shire Australia Pty Ltd

Revestive is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support. Patients should be stable at least to 4 weeks on their parenteral support regimen before initiating teduglutide therapy.

Evaluation commenced: 31 May 2016 Registration decision: 17 May 2017 Entry onto ARTG: 19 May 2017

REXULTI Approval time: 231 working days

brexipiprazole

Lundbeck Australia Pty Limited

Rexulti is indicated in adult patients for the treatment of schizophrenia.

Evaluation commenced: 29 April 2016 Registration decision: 17 May 2017 Entry onto ARTG: 19 May 2017

UROREC Approval time: 197 working days

silodosin

Mayne Pharma International Pty Ltd

Urorec is indicated for the relief of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia in adult men.

Evaluation commenced: 31 May 2016 Registration decision: 18 May 2017 Entry onto ARTG: 23 May 2017

LONSURF/ORCANTAS

trifluridine/tipiracil hydrochloride

Servier Laboratories (Aust) Pty Ltd

Lonsurf/Orcantas is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with, or are not considered candidates for, fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.

Approval time: 232 working days

Approval time: 152 working days

Evaluation commenced: 2 February 2016 Registration decision: 19 May 2017 Entry onto ARTG: 23 May 2017

PHEBURANE Approval time: 225 working days

sodium phenylbutyrate

Orpharma Pty Ltd

Pheburane is indicated for the management of hyperammonaemia associated with urea cycle disorders. Pheburane should be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, and protein-free calorie supplements).

Evaluation commenced: 2 May 2016 Registration decision: 19 May 2017 Entry onto ARTG: 30 May 2017

June

There were no new entries for June.

July

OCREVUS Approval time: 215 working days

ocrelizumab

Roche Products Pty Ltd

Ocrevus is indicated for the treatment of patients with:

- relapsing forms of multiple sclerosis (RMS) to delay the progression of physical disability and to reduce the frequency of relapse;
- primary progressive multiple sclerosis (PPMS) to delay the progression of physical disability.

Evaluation commenced: 30 June 2016 Registration decision: 3 July 2017 Entry onto ARTG: 13 July 2017

DARZALEX / JANSSEN DARATUMUMAB

daratumumab

Janssen-Cilag Pty Ltd

Darzalex / Janssen Daratumumab is indicated:

- in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy;
- as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are refractory to both a PI and an immunomodulatory agent.

Evaluation commenced: 30 November 2016 Registration decision: 12 July 2017 Entry onto ARTG: 17 July 2017

DENGVAXIA Approval time: 236 working days

Dengue tetravalent vaccine-live, attenuated

Sanofi-Aventis Australia Pty Ltd

Dengvaxia is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals 9 through 45 years of age living in endemic areas.

Evaluation commenced: 30 June 2016 Registration decision: 13 July 2017 Entry onto ARTG: 20 July 2017

CINQAIR/CINQAERO

Approval time: 201 working days

reslizumab

Teva Pharma Australia Pty Ltd

Cingair/Cingaero is indicated as add-on therapy in adult patients with severe eosinophilic asthma (blood eosinophil count ≥400 cells/µL).

Evaluation commenced: 29 July 2016 Registration decision: 17 July 2017 Entry onto ARTG: 25 July 2017

TECENTRIQ Approval time: 210 working days

atezolizumab (rch)

Roche Products Pty Ltd

Tecentriq is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy. In patients with tumour EGFR or ALK genomic aberrations.

Evaluation commenced: 31 July 2016 Registration decision: 26 July 2017 Entry onto ARTG: 27 July 2017

August

GALAFOLD **C** Approval time: 221 working days

migalastat (as hydrochloride)

ERA Consulting (Australia) Pty Ltd

Galafold is indicated for long-term treatment of adult and adolescent patients 16 years and older with a confirmed diagnosis of Fabry disease (α -galactosidase A deficiency) and who have an amenable mutation.

Evaluation commenced: 30 June 2016 Registration decision: 9 August 2017 Entry onto ARTG: 11 August 2017

INTUNIV Approval time: 233 working days

quanfacine (as hydrochloride)

Shire Australia Pty Ltd

Intuniv is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old, as monotherapy (when stimulants or atomoxetine are not suitable, not tolerated or have been shown to be ineffective) or as adjunctive therapy to psychostimulants (where there has been a sub-optimal response to psychostimulants). Intuniv must be used as part of a comprehensive ADHD management program, typically including psychological, educational and social measures.

Evaluation commenced: 31 May 2016 Registration decision: 16 August 2017 Entry onto ARTG: 22 August 2017



MONUROL Approval time: 209 working days

fosfomycin trometamol

Mayne Pharma International Pty Ltd

Monurol is indicated only for the treatment of acute uncomplicated lower urinary tract infections (acute cystitis) in females above 12 years of age caused by the following susceptible pathogens: *Enterobacteriaceae* (including *Escherichia coli*), *Enterococcus faecalis*.

Evaluation commenced: 31 August 2016 Registration decision: 31 August 2017 Entry onto ARTG: 4 September 2017

TRUMENBA Approval time: 202 working days

meningococcal group B vaccine

Pfizer Australia Pty Ltd

Trumenba is indicated in individuals 10 years and older for active immunisation to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B.

Evaluation commenced: 29 July 2016 Registration decision: 12 September 2017 Entry onto ARTG: 14 September 2017

October

RANEXA Approval time: 197 working days

ranolazine

A. Menarini Australia Pty Ltd

Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of stable angina pectoris in patients taking maximum tolerated doses of a beta-blocker or a calcium channel blocker and have inadequate symptom control.

Evaluation commenced: 29 May 2015 Registration decision: 12 May 2016 Entry onto ARTG: 13 October 2017

KISQALI Approval time: 231 working days

ribociclib (as succinate)

Novartis Pharmaceuticals Australia Pty Ltd

Kisqali, in combination with an aromatase inhibitor, is indicated for the treatment of men and postmenopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer, as an initial endocrine-based therapy.

Evaluation commenced: 31 October 2016 Registration decision: 20 October 2017 Entry onto ARTG: 23 October 2017

ONCASPAR • Approval time: 226 working days

pegaspargase

Baxalta Australia Pty Ltd

Oncaspar is indicated as a component of antineoplastic combination therapy in patients with Acute Lymphoblastic Leukaemia (ALL).

Evaluation commenced: 30 September 2016 Registration decision: 19 October 2017 Entry onto ARTG: 31 October 2017



November

INFLUVACTETRA

influenza virus haemagglutinin vaccine

Mylan Health Pty Ltd

Influvac Tetra is indicated for the prevention of influenza caused by influenza virus, types A and B, in adults (18 years of age and older).

Approval time: 189 working days

Evaluation commenced: 30 November 2016 Registration decision: 1 November 2017 Entry onto ARTG: 2 November 2017

SPINRAZA C

Approval time: 167 working days

nusinersen (as heptadecasodium)

Biogen Australia Pty Ltd

Spinraza is indicated for the treatment of 5q Spinal Muscular Atrophy (SMA).

Evaluation commenced: 4 January 2017 Registration decision: 2 November 2017 Entry onto ARTG: 3 November 2017

ZINPLAVA Approval time: 192 working days

bezlotoxumab (rch)

Merck Sharp & Dohme Australia Pty Ltd

Zinplava is indicated for the prevention of recurrence of Clostridium difficile infection (CDI) in adult patients 18 years or older at high risk for recurrence of CDI who are receiving antibiotic therapy for CDI. Zinplava should only be used in conjunction with antibacterial drug treatment of CDI.

Evaluation commenced: 30 November 2016 Registration decision: 8 November 2017 Entry onto ARTG: 13 November 2017



TRESIBA FLEXTOUCH and TRESIBA PENFILL

insulin degludec (rys)

Novo Nordisk Pharmaceuticals Pty Ltd

Tresiba Flextouch and Tresiba Penfill are indicated to improve glycaemic control in adult patients with diabetes mellitus requiring insulin.

Evaluation commenced: 31 October 2016 Registration decision: 24 November 2017 Entry onto ARTG: 29 November

RYZODEG 70/30 FLEXTOUCH and RYZODEG 70/30 PENFILL Approval time: 228 working days

Approval time: 228 working days

70% insulin degludec (rys) / 30% insulin aspart (rys)

Novo Nordisk Pharmaceuticals Pty Ltd

Ryzodeg 70/30 Flextouch and Ryzodeg 70/30 Penfill are indicated to improve glycaemic control in adult patients with diabetes mellitus requiring basal and prandial insulin.

Evaluation commenced: 31 October 2016 Registration decision: 24 November 2017 Entry onto ARTG: 29 November 2017

December

MONOFER Approval time: 234 working days

ferric derisomaltose

Link Medical Products Pty Ltd

Monofer is indicated for the treatment of iron deficiency in adults, under the following conditions:

- · when oral iron preparations are ineffective or cannot be used;
- where there is a clinical need to deliver iron rapidly.

The diagnosis must be based on laboratory tests.

Evaluation commenced: 1 November 2016 Registration decision: 29 November 2017 Entry onto ARTG: 4 December 2017

VELTASSA Approval time: 231 working days

patiromer sorbitex calcium

Vifor Pharma Pty Ltd

Veltassa is indicated for the treatment of hyperkalaemia in adults.

Evaluation commenced: 31 October 2016 Registration decision: 5 December 2017 Entry onto ARTG: 12 December 2017

FLUZONE HIGH-DOSE

Approval time: 162 working days

inactivated trivalent influenza vaccine (Split Virion)

Sanofi-Aventis Australia Pty Ltd

Fluzone High-Dose is indicated for active immunisation against influenza disease caused by influenza virus types A and B contained in the vaccine for use in persons 65 years of age and older.

Evaluation commenced: 31 March 2017 Registration decision: 20 December 2017 Entry onto ARTG: 21 December 2017

Registrations of new or extended uses, or new combinations, of already-approved prescription medicines

Once an application has been accepted for evaluation by TGA, the **approval time** is defined as the **number of TGA working days between commencement of evaluation and registration decision**. This timeframe is underpinned by legislation (see *Therapeutic Goods Regulations 1990*) and excludes public holidays, weekends, the time allocated to the sponsor to respond to requests for information, 'mutual clock stop' periods agreed with the sponsor, or other review activities.

All products were approved within the statutory 255 working day period.



A medicine is designated as an orphan drug to provide an incentive to sponsors to bring medicines for a small population to market and make medicines available to patients who would not otherwise be able to access them.

2017 chronological summary

January

ACZONE Approval time: 214 working days

dapsone

Allergan Australia Pty Ltd

For the topical treatment of acne vulgaris in patients 12 years of age and older.

Evaluation commenced: 23 December 2015 Registration decision: 4 January 2017 Entry onto ARTG: 10 January 2017

VasoKINOX Approval time: 197 working days

nitric oxide

Biotech Regulatory Solutions

In conjunction with ventilator support and other appropriate active substances to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery.

Evaluation commenced: 31 March 2015 Registration decision: 18 March 2016 Entry onto ARTG: 16 January 2017

Approval time: 175 working days

AMOXICLAV JUNO and JUNOXICLAV

amoxicillin sodium and clavulanic acid

Juno Pharmaceuticals Pty Ltd

As an antibiotic alternative to narrow- and broad-spectrum antibiotics for the treatment of infections.

Evaluation commenced: 29 February 2016 Registration decision: 13 January 2017 Entry onto ARTG: 18 January 2017

JARDIANCE Approval time: 193 working days

empagliflozin

Boehringer Ingelheim Pty Ltd

To reduce the risk of cardiovascular death in patients with type 2 diabetes mellitus and established cardiovascular disease.

Evaluation commenced: 29 February 2016 Registration decision: 6 January 2017 Entry onto ARTG: 18 January 2017

AFINITOR Approval time: 224 working days

everolimus

Novartis Pharmaceuticals Aust Pty Ltd

For the treatment of progressive, unresectable or metastatic, well-differentiated, non-functional neuroendocrine tumours (NET) of gastrointestinal or lung origin in adults.

Evaluation commenced: 24 December 2015 Registration decision: 13 January 2017 Entry onto ARTG: 20 January 2017

EZETROL Approval time: 191 working days

ezetimibe

Merck Sharp & Dohme (Australia) Pty Limited

For administration in combination with the maximum tolerated dose of a statin with proven cardiovascular benefit in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS) in need of additional lowering of LDL-C in the expectation of a modest further reduction in the risk of cardiovascular events following at least one year of therapy.

Evaluation commenced: 31 July 2015 Registration decision: 17 January 2017 Entry onto ARTG: 20 January 2017

VYTORIN Approval time: 191 working days

ezetimibe/simvastatin

Merck Sharp & Dohme (Australia) Pty Limited

For use in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS) taking their maximum tolerated dose of simvastatin and in need of additional lowering of LDL-C in the expectation of a modest further reduction in the risk of cardiovascular events following at least one year of therapy.

Evaluation commenced: 31 July 2015 Registration decision: 17 January 2017 Entry onto ARTG: 20 January 2017

February

CIMZIA Approval time: 225 working days

certolizumab pegol (rbe)

UCB Australia Pty Ltd.

For use in combination with methotrexate (MTX) for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX or other disease-modifying antirheumatic drugs (DMARDs).

Evaluation commenced: 30 June 2015 Registration decision: 7 November 2016 Entry onto ARTG: 9 February 2017

ZYDELIG Approval time: 206 working days

idelalisib

Gilead Sciences Pty Ltd

For use, in combination with ofatumumab, for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) upon relapse in patients for whom chemo-immunotherapy is not considered suitable.

Evaluation commenced: 30 September 2015 Registration decision: 1 February 2017 Entry onto ARTG: 10 February 2017

VEMLIDY Approval time: 185 working days

tenofovir alafenamide (as fumarate)

Gilead Sciences Pty Ltd

For the treatment of chronic hepatitis B in adults.

Evaluation commenced: 29 April 2016 Registration decision: 21 February 2017 Entry onto ARTG: 22 February 2017

March

STELARA Approval time: 189 working days

ustekinumab

Janssen-Cilag Pty Ltd

For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, were intolerant to conventional therapy or a TNF alpha antagonist or have medical contraindications to such therapies.

Evaluation commenced: 31 March 2016 Registration decision: 27 February 2017 Entry onto ARTG: 1 March 2017

KEYTRUDA Approval time: 212 working days

pembrolizumab

Merck Sharp & Dohme (Australia) Pty Limited

For the first-line treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) whose tumours express programmed death-ligand 1 (PD-L1) with a \geq 50% tumour proportion score (TPS) as determined by a validated test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations.

Evaluation commenced: 1 April 2016 Registration decision: 3 March 2017 Entry onto ARTG: 6 March 2017

KEYTRUDA Approval time: 106 working days

pembrolizumab

Merck Sharp & Dohme (Australia) Pty Limited

For the treatment of patients with advanced non-small cell lung carcinoma (NSCLC) whose tumours express programmed death-ligand 1 (PD-L1) with a ≥1% tumour proportion score (TPS) as determined by a validated test and who have received platinum-containing chemotherapy. Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations should have received prior therapy for these aberrations prior to receiving Keytruda.

Evaluation commenced: 30 September 2016 Registration decision: 3 March 2017 Entry onto ARTG: 7 March 2017

EPIDUO FORTE

adapalene / benzoyl peroxide

Galderma Australia Pty Ltd

For the cutaneous treatment of acne vulgaris, when comedones, numerous papules and pustules are present in patients 12 years of age and older and the condition has not responded to first line treatment.

Approval time: 193 working days

Evaluation commenced: 31 March 2016 Registration decision: 2 March 2017 Entry onto ARTG: 10 March 2017

PEDEA ① Approval time: 197 working days

ibuprofen

Emerge Health Pty Ltd

For the treatment of haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age.

Evaluation commenced: 31 March 2016 Registration decision: 8 March 2017 Entry onto ARTG: 14 March 2017

KEYTRUDA Approval time: 163 working days

pembrolizumab (rch)

Merck Sharp & Dohme (Australia) Pty Limited

For the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. This indication is approved based on overall response rate and duration of response. Improvements in overall survival, progression-free survival or health-related quality of life have not been established.

Evaluation commenced: 30 June 2016 Registration decision: 20 March 2017 Entry onto ARTG: 21 March 2017

JINARC Approval time: 225 working days

tolvaptan

Otsuka Australia Pharmaceutical Pty Ltd

To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.

Evaluation commenced: 29 February 2016 Registration decision: 10 March 2017 Entry onto ARTG: 24 March 2017

April

VIEKIRA PAK Approval time: 230 working days

paritaprevir/ritonavir/ombitasvir & dasabuvir *AbbVie Pty Ltd*

For the treatment of genotype 1 chronic hepatitis C infection, including patients with compensated cirrhosis. Duration of therapy and addition of ribavirin are dependent on patient population.

Evaluation commenced: 29 February 2016 Registration decision: 21 March 2017 Entry onto ARTG: 21 April 2017

VIEKIRA PAK-RBV

paritaprevir/ritonavir/ombitasvir & dasabuvir & ribavirin *AbbVie Pty Ltd*

For the treatment of genotype 1 chronic hepatitis C infection, including patients with compensated cirrhosis. Duration of therapy and addition of ribavirin are dependent on patient population.

Evaluation commenced: 29 February 2016 Registration decision: 21 March 2017 Entry onto ARTG: 21 April 2017

JARDIAMETApproval time: 214 working days

Approval time: 230 working days

empagliflozin / metformin hydrochloride

Boehringer Ingelheim Pty Ltd

Empagliflozin is now also indicated in adults with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death. To prevent cardiovascular deaths, empagliflozin should be used in conjunction with other measures to reduce cardiovascular risk in line with the current standard of care.

Evaluation commenced: 29 April 2016 Registration decision: 26 April 2017 Entry onto ARTG: 28 April 2017

May

ATOZET/ZETEZE Approval time: 192 working days

ezetimibe and atorvastatin

Merck Sharp & Dohme (Australia) Pty Limited

Atozet/Zeteze is now also indicated in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS) taking their maximum tolerated dose of atorvastatin and in need of additional lowering of low-density lipoprotein cholesterol (LDL-C) in the expectation of a modest further reduction in the risk of cardiovascular events following at least one year of therapy.

Evaluation commenced: 29 February 2016 Registration decision: 19 May 2017 Entry onto ARTG: 24 May 2017

OPDIVO Approval time: 203 working days

nivolumab

Bristol-Myers Squibb Aust Pty Ltd

Opdivo, as monotherapy, is now also indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant and treatment with brentuximab vedotin.

Evaluation commenced: 31 May 2016 Registration decision: 26 May 2017 Entry onto ARTG: 30 May 2017

June

CEREZYME ⊕ Approval time: 185 working days

imiglucerase (rch)

Sanofi Aventis Australia Pty Ltd

Cerezyme is now also indicated for long-term enzyme replacement therapy for patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant non-neurological manifestations of the disease.

Evaluation commenced: 10 June 2016 Registration decision: 25 May 2017 Entry onto ARTG: 6 June 2017

XELJANZ Approval time: 193 working days

tofacitinib (as citrate)

Pfizer Australia

Xeljanz is now also indicated for the treatment of moderate to severe active rheumatoid arthritis in adults who have had an inadequate response or are intolerant to methotrexate. Xeljanz can be used alone or in combination with nonbiological DMARDs, including methotrexate.

Evaluation commenced: 6 June 2016 Registration decision: 1 June 2017 Entry onto ARTG: 6 June 2017

OZURDEX Approval time: 235 working days

dexamethasone

Allergan Australia Pty Ltd

Ozurdex is now also indicated for the treatment of macular oedema due to Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO), and also indicated for non-infectious uveitis affecting the posterior segment of the eye.

Evaluation commenced: 29 April 2016 Registration decision: 6 June 2017 Entry onto ARTG: 16 June 2017

July

MENVEO Approval time: 85 working days

meningococcal (Groups A, C, W-135 and Y) oligosaccharide CRM197 conjugate vaccines GlaxoSmithKline Australia Pty Ltd

Menveo is now also indicated for active immunisation of infants and children (from 2 months of age), adolescents and adults to prevent invasive disease caused by Neisseria meningitidis serogroups A, C, W135 and Y.

Evaluation commenced: 14 February 2017 Registration decision: 3 July 2017 Entry onto ARTG: 5 July 2017

TRAJENTA Approval time: 188 working days

linagliptin

Boehringer Ingelheim Pty Ltd

Trajenta is now also indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control in conjunction with diet and exercise, as add on to metformin plus a sodium-dependent glucose cotransporter-2 (SGLT2) inhibitor.

Evaluation commenced: 29 July 2016 Registration decision: 28 June 2017 Entry onto ARTG: 6 July 2017

TRAJENTAMETApproval time: 188 working days

linagliptin / metformin hydrochloride

Boehringer Ingelheim Pty Ltd

Trajentamet is now also indicated in combination with a sodium-dependent glucose co-transporter-2 (SGLT2) inhibitor (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximum tolerated dose of metformin and an SGLT2 inhibitor.

Evaluation commenced: 29 July 2016 Registration decision: 28 June 2017 Entry onto ARTG: 6 July 2017

OPDIVO Approval time: 189 working days

nivolumab

Bristol-Myers Squibb Australia Pty Ltd

Opdivo as monotherapy is now also indicated for the treatment of recurrent or metastatic squamous cell cancer of the head and neck in adults progressing on or after platinum based therapy.

Evaluation commenced: 2 September 2016 Registration decision: 7 July 2017 Entry onto ARTG: 11 July 2017

LENVIMA Approval time: 181 working days

lenvatinib

Eisai Australia Pty Limited

Lenvima is now also indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma whose disease has progressed following one prior vascular endothelial growth factor targeted therapy.

Evaluation commenced: 31 August 2016 Registration decision: 26 July 2017 Entry onto ARTG: 27 July 2017

BLINCYTO Approval time: 199 working days

blinatumomab

Amgen Australia Pty Ltd

Blincyto is now also indicated for the treatment of paediatric patients with Philadelphia chromosomenegative relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

Evaluation commenced: 31 August 2016 Registration decision: 19 July 2017 Entry onto ARTG: 28 July 2017

August

ALOXI Approval time: 161 working days

palonosetron as hydrochloride

Mundipharma Pty Ltd

Aloxi is now also indicated for prevention of post-operative nausea and vomiting (PONV) for up to 24 hours following surgery.

Evaluation commenced: 31 October 2016 Registration decision: 14 August 2017 Entry onto ARTG: 22 August 2017

LUCENTIS Approval time: 154 working days

ranibizumab (rbe)

Novartis Pharmaceuticals Australia Pty Ltd

Lucentis is now also indicated in adults for the treatment of visual impairment due to choroidal neovascularisation.

Evaluation commenced: 30 November 2016 Registration decision: 14 August 2017 Entry onto ARTG: 22 August 2017

FRAXIPARINE Approval time: 188 working days

nadroparin calcium

Aspen Pharmacare Australia Pty Ltd

Fraxiparine is now also indicated for the prophylaxis of venous thromboembolism in high-risk medical patients who are immobilised due to acute illness or hospitalised in an intensive care unit.

Evaluation commenced: 30 September 2016 Registration decision: 28 August 2017 Entry onto ARTG: 31 August 2017

September

ULTIBRO BREEZHALER 110/50

indacaterol (as maleate) / glycopyrronium (as bromide)

Novartis Pharmaceuticals Australia Pty Ltd

Ultibro Breezhaler 110/50 is now also indicated for the reduction of exacerbations of chronic obstructive pulmonary disease (COPD) in patients with a history of exacerbations.

Approval time: 193 working days

Evaluation commenced: 31 October 2016 Registration decision: 4 September 2017 Entry onto ARTG: 6 September 2017

KEYTRUDA Approval time: 195 working days

pembrolizumab (rch)

Merck Sharp & Dohme (Australia) Pty Limited

Keytruda as monotherapy is now also indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL) following:

- autologous stem cell transplant (ASCT); or
- at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.

Evaluation commenced: 31 October 2016 Registration decision: 1 September 2017 Entry onto ARTG: 7 September 2017

PRALUENTApproval time: 218 working days

alirocumab (rch)

Sanofi Aventis Australia Pty Ltd

Praluent is indicated as an adjunct to diet and exercise to reduce LDL-cholesterol (LDL-C) in adults with one or more of: heterozygous familial hypercholesterolaemia, clinical atherosclerotic cardiovascular disease, or hypercholesterolemia with high or very high cardiovascular risk

- in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with maximum tolerated dose of a statin; or
- in combination with other lipid lowering therapies in patients who are statin intolerant or for whom a statin is contraindicated who are unable to reach LDL-C goals.

Evaluation commenced: 31 August 2016 Registration decision: 12 September 2017 Entry onto ARTG: 26 September 2017

October

ELIGARD Approval time: 221 working days

leuprorelin

Tolmar Australia Pty Ltd

Eligard is now also indicated for the treatment of high-risk localised and locally advanced hormone-dependent prostate cancer in combination with radiotherapy.

Evaluation commenced: 30 September 2016 Registration decision: 6 October 2017 Entry onto ARTG: 12 October 2017

SOLIQUA Approval time: 178 working days

insulin glargine (rbe) and lixisenatide

Sanofi-Aventis Australia Pty Ltd

Soliqua is indicated in combination with metformin for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin.

Evaluation commenced: 30 November 2016 Registration decision: 23 October 2017 Entry onto ARTG: 27 October 2017

November

ACTEMRA Approval time: 194 working days

tocilizumab (rch)

Roche Products Pty Limited

Actemra is now also indicated for the treatment of giant cell arteritis (GCA) in adult patients.

Evaluation commenced: 3 January 2017 Registration decision: 14 November 2017 Entry onto ARTG: 16 November 2017

AVASTIN Approval time: 223 working days

bevacizumab

Roche Products Pty Ltd

Avastin, in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, is now also indicated for the treatment of platinum-sensitive epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer.

Evaluation commenced: 30 November 2016 Registration decision: 16 November 2017 Entry onto ARTG: 23 November 2017

TASIGNA Approval time: 198 working days

nilotinib

Novartis Pharmaceuticals Australia Pty Ltd

Tasigna is indicated for the treatment of adult patients with:

- newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (CML) in chronic phase;
- chronic phase and accelerated phase Philadelphia chromosome positive CML that is resistant to or intolerant of prior therapy including imatinib.

Evaluation commenced: 30 November 2016 Registration decision: 16 November 2017 Entry onto ARTG: 24 November 2017



ABILIFY MAINTENA

aripiprazole (as monohydrate)

Lundbeck Australia Pty Ltd

Abilify Maintena is now also indicated for maintenance treatment to prevent the recurrence of manic or mixed episodes of bipolar I disorder in adult patients as monotherapy.

Approval time: 130 working days

Evaluation commenced: 31 March 2017 Registration decision: 5 December 2017 Entry onto ARTG: 5 December 2017

GAZYVA Approval time: 219 working days

obinutuzumab

Roche Products Pty Ltd

Gazyva, in combination with chemotherapy followed by Gazyva maintenance, is now also indicated for the treatment of patients with previously untreated advanced follicular lymphoma.

Evaluation commenced: 30 November 2016 Registration decision: 16 November 2017 Entry onto ARTG: 5 December 2017

MAVENCLAD Approval time: 176 working days

cladribine

Merck Serono Australia Pty Ltd

Mavenclad is now also indicated for the treatment of relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability. Following completion of the 2 treatment courses, no further treatment is required in years 3 and 4. Re-initiation of therapy after year 4 has not been studied.

Evaluation commenced: 31 January 2017 Registration decision: 5 December 2017 Entry onto ARTG: 11 December 2017

XALKORI • Approval time: 214 working days

crizotinib

Pfizer Australia Pty Ltd

Xalkori is now also indicated for the treatment of patients with ROS1-positive advanced non-small cell lung cancer (NSCLC).

Evaluation commenced: 3 January 2017 Registration decision: 12 December 2017 Entry onto ARTG: 13 December 2017

STIVARGA • Approval time: 179 working days

regorafenib

Bayer Australia Ltd

Stivarga is now also indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

Evaluation commenced: 28 February 2017 Registration decision: 18 December 2017 Entry onto ARTG: 21 December 2017

0

Generic prescription medicines

A generic medicine is an additional brand of an existing medicine. It contains the same 'active ingredient' as the existing medicine; the 'active ingredient' is the chemical that is biologically active in the body and makes the medicine work. Active ingredients can be manufactured and sold by other sponsors once the patent for the existing brand medicine has expired.

Apart from containing the same active ingredient, generic medicines must also be 'bioequivalent'. This means that the same amount of active ingredient is absorbed by the body over the same period of time for the same dose of generic or existing medicine.

Generic prescription medicines meet the same standards of quality, safety and efficacy as the existing medicine. TGA continually monitors the safety of registered medicines once they become available on the Australian market.

Registrations of chemical entities: first generics

Of the 101 generic prescription medicines registered during 2017, 29 submissions resulted in the registration of the 'first generic' version that contains a particular active ingredient. The term 'first generic' is the first registration approval by TGA which permits a sponsor to market a generic drug product in Australia. First generics are significant because they create more affordable treatment options for patients – the listing of a first generic triggers a 16% price reduction under the Pharmaceutical Benefits Scheme (PBS).



2017 chronological summary

Once an application has been accepted for evaluation by TGA, the **approval time** is defined as the **number of TGA working days between commencement of evaluation and registration decision**. This timeframe is underpinned by legislation (see *Therapeutic Goods Regulations 1990*) and excludes public holidays, weekends, the time allocated to the sponsor to respond to requests for information, 'mutual clock stop' periods agreed with the sponsor, or other review activities.

All products were approved within the statutory 255 working day period.

The sponsor name reflects the information in the ARTG at the time of registration. As sponsors may change over time, please consult the ARTG for full information in relation to these products, including full indications: https://www.tga.gov.au/australian-register-therapeutic-goods

January

APO-ZONISAMIDE, CHEMMART ZONISAMIDE, TERRY WHITE CHEMISTS ZONISAMIDE, ZONISAMIDE APOTEX Approval time: 197 working days

zonisamide

Apotex Pty Ltd

Zonisamide capsules are indicated as treatment of partial seizures in patients with epilepsy.

Dosage form: Capsule

Evaluation commenced: 24 December 2015 Registration decision: 12 December 2016 Entry onto ARTG: 11 January 2017

APO-DEXAMFETAMINE, DEXAMFETTABS, DEXAMFETAMINE GENPAR, DEXAMFETAMINE GPPL, DEXAMFETAMINE KINEDEXE, DEXAFET Approval time: 169 working days

dexamfetamine sulfate

Generic Partners Pty Ltd

Dexamfetamine sulfate tablets are indicated for narcolepsy and hyperkinetic behaviour disorders in children.

Dosage form: Tablet

Evaluation commenced: 29 February 2016 Registration decision: 6 January 2017 Entry onto ARTG: 18 January 2017

APO-RIVAROXABAN, RIVAROXABAN APOTEX

rivaroxaban

Apotex Pty Ltd

Rivaroxaban tablets are indicated for the treatment and/or prevention of venous thromboembolism, stroke, deep vein thrombosis, and pulmonary embolism.

Dosage form: Tablet

Evaluation commenced: 29 February 2016 Registration decision: 12 January 2017 Entry onto ARTG: 24 January 2017

Approval time: 172 working days

February

AMIKACIN SXP, AMIKACIN RMB, AMIKACIN AJS

amikacin sulfate

Southern Cross Pharma Pty Ltd

Amikacin sulfate injections are indicated for the treatment of serious infections and neonatal sepsis.

Dosage form: Solution for injection

Evaluation commenced: 30 November 2015 Registration decision: 17 October 2016 Entry onto ARTG: 7 February 2017

FLUOXETINE MLABS, FLUOXETINE MLPL, PROZET, FLUOXETINE B&B

fluoxetine hydrochloride

Micro Labs Pty Ltd

Fluoxetine hydrochloride capsules are indicated for treatment of depression, obsessive compulsive disorder (OCD), and premenstrual dysphoric disorder (PMDD).

Dosage form: Capsule

Evaluation commenced: 29 April 2016 Registration decision: 16 February 2017 Entry onto ARTG: 23 February 2017

March

DROPERIDOL SXP, DROPERIDOL AJS, DROPERIDOL RMB

Approval time: 183 working days

Approval time: 173 working days

Approval time: 176 working days

Approval time: 160 working days

droperidol

Southern Cross Pharma Pty Ltd

Droperidol injections are indicated for the treatment of nausea and vomiting in surgical and diagnostic procedures, and in the management of severe agitation or aggressiveness in psychotic disorders.

Dosage form: Solution for injection

Evaluation commenced: 31 August 2015 Registration decision: 28 July 2016 Entry onto ARTG: 6 March 2017

AL-CEFUROXIME, PHARMACOR CEFUROXIME

cefuroxime axetil

Pharmacor Pty Ltd

Cefuroxime axetil tablets are indicated for the treatment of mild to moderately severe infections in adults caused by sensitive bacteria.

Dosage form: Film-coated tablet

Evaluation commenced: 29 April 2016 Registration decision: 8 March 2017 Entry onto ARTG: 27 March 2017



MELATONIN MR GPPL, MELATONIN MR GXP, MELATONIN MR GENPAR,
MELATONTAB MR, MELOTIN MR, MELATONIN MR APOTEX,
CHEMMART MELATONIN MR, TERRY WHITE CHEMISTS MELATONIN MR,
BLOOMS THE CHEMIST MELATONIN MR

Approval time: 251 working days

melatonin

Generic Partners Pty Ltd

Melatonin tablets are indicated for the treatment of insomnia in patients aged 55 or over.

Dosage form: Tablet

Evaluation commenced: 31 July 2015 Registration decision: 22 December 2016 Entry onto ARTG: 4 April 2017

TIGECYCLINE JUNO, TIGECYCLE, TYGALINE, TYGACYCLINE Approval time: 154 working days tigecycline

Neo Health (Australia) Pty Ltd

Tigecycline injections are indicated for the treatment of complicated skin or intra-abdominal infections.

Dosage form: Powder for injection

Evaluation commenced: 30 June 2016 Registration decision: 7 April 2017 Entry onto ARTG: 11 April 2017

MUPIROCIN AJS, MUPIROCIN SCP, APO-MUPIROCIN

Approval time: 151 working days

mupirocin

Southern Cross Pharma Pty Ltd

Mupirocin ointment is indicated for the topical treatment of mild impetigo.

Dosage form: Ointment

Evaluation commenced: 5 July 2016 Registration decision: 11 April 2017 Entry onto ARTG: 12 April 2017

EVEROLIMUS-TEVA, TEVA-EVEROLIMUS

everolimus

Teva Pharma Australia Pty Ltd

Everolimus tablets are indicated for the treatment of breast cancer, neuroendocrine tumours of pancreatic origin, advanced renal cell carcinoma, subependymal giant cell astrocytoma, and tuberous sclerosis complex.

Dosage form: Tablet

Evaluation commenced: 11 July 2016 Registration decision: 6 April 2017 Entry onto ARTG: 20 April 2017

May

HOPE PHARMACEUTICALS SODIUM NITRITE INJECTION Approval time: 157 working days

sodium nitrite

Hope Pharmaceuticals Pty Ltd

Sodium nitrite injections are indicated as an antidote in the treatment of cyanide poisoning in conjunction with sodium thiosulfate.

Dosage form: Solution for injection

Evaluation commenced: 30 June 2016 Registration decision: 27 April 2017 Entry onto ARTG: 16 May 2017

Approval time: 109 working days

DARUNAVIR MYLAN

darunavir

Alphapharm Pty Ltd

Darunavir tablets are indicated for the treatment of HIV-1 infection, in combination with other antiretroviral agents.

Approval time: 158 working days

Approval time: 230 working days

Approval time: 220 working days

Dosage form: Tablet

Evaluation commenced: 31 March 2016 Registration decision: 13 January 2017 Entry onto ARTG: 26 May 2017

June

BUPRENORPHINE SDZ, BUPRENORPHINE SZ, BUPRENORPHINE SANDOZ

buprenorphine

Sandoz Pty Ltd

Buprenorphine sachets are indicated for the management of moderate to severe pain.

Dosage form: Transdermal drug delivery system sachet

Evaluation commenced: 29 February 2016 Registration decision: 11 April 2017 Entry onto ARTG: 16 June 2017

TWYNIPINE, TELMISARTAN/AMLODIPINE GXP, TELMISARTAN/AMLODIPINE APOTEX, TELMISARTAN/AMLODIPINE GPPL, TELMISARTAN/AMLODIPINE GENPAR, AMLO-TELMISARTAN, TELMISARTAN/AMLO Approval time: 182 working days

telmisartan and amlodipine (as besilate)

Generic Partners Pty Ltd

Telmisartan and amlodipine (as besilate) combination tablets are indicated for the treatment of hypertension.

Dosage form: Tablet

Evaluation commenced: 5 July 2016 Registration decision: 13 June 2017 Entry onto ARTG: 16 June 2017

July

MEFENAMIC ACID B&B, MEFENAMIC ACID MLABS, MEFENAMIC ACID MLPL, MENAMIC MLABS

mefenamic acid

Micro Labs Pty Ltd

Mefenamic acid capsules are indicated for the treatment of dysmenorrhea and menorrhagia, and for mild to moderate pain.

Dosage form: Capsule

Evaluation commenced: 31 May 2016 Registration decision: 16 June 2017 Entry onto ARTG: 7 July 2017



hyoscine butylbromide

Southern Cross Pharma Pty Ltd

Hyoscine butylbromide injections are indicated for spasm of the gastrointestinal tract, biliary spasm, renal spasm, diagnostic aid in radiology.

Dosage form: Solution for injection

Evaluation commenced: 31 August 2016 Registration decision: 3 July 2017 Entry onto ARTG: 12 July 2017

BENZATROPINE INJECTION

benzatropine mesilate

Phebra Pty Ltd

Benzatropine mesilate injections are indicated for all forms of Parkinsonism including arteriosclerotic, postencephalitic, idiopathic, as well as drug induced extrapyramidal disorders (except tardive dyskinesia).

Dosage form: Solution for injection

Evaluation commenced: 30 June 2016 Registration decision: 27 June 2017 Entry onto ARTG: 18 July 2017

August

ANAGRELIDE MGH, ANAGRELIDE RMB, ANAGRELIDE SCP Approval time: 226 working days

Approval time: 165 working days

Approval time: 182 working days

anagrelide hydrochloride monohydrate

Southern Cross Pharma Pty Ltd

Anagrelide hydrochloride monohydrate capsules are indicated for the treatment of essential thrombocythaemia.

Dosage form: Capsule

Evaluation commenced: 30 June 2016 Registration decision: 27 July 2017 Entry onto ARTG: 3 August 2017

APO-FINGOLIMOD, FINGOLIMOD APOTEX

Approval time: 253 working days

Approval time: 146 working days

fingolimod hydrochloride

Apotex Pty Ltd

Fingolimod hydrochloride capsules are indicated for the treatment of multiple sclerosis.

Dosage form: Capsule

Evaluation commenced: 31 March 2016 Registration decision: 8 August 2017 Entry onto ARTG: 14 August 2017

APO-AZELASTINE/FLUTICASONE, AZELASTINE/FLUTICASONE APOTEX

azelastine (as hydrochoride) / fluticasone propionate

Apotex Pty Ltd

Azelastine/fluticasone nasal spray is indicated for the treatment of allergic rhinitis and rhino-conjunctivitis.

Dosage form: Nasal spray

Evaluation commenced: 29 July 2016 Registration decision: 9 August 2017 Entry onto ARTG: 22 August 2017

APO-FAMPRIDINE MR, FAMPRIDINE MR APOTEX

fampridine

Apotex Pty Ltd

Fampridine tablets are indicated for the symptomatic improvement of walking ability in adult patients with multiple sclerosis.

Approval time: 175 working days

Approval time: 219 working days

Approval time: 178 working days

Approval time: 143 working days

Approval time: 252 working days

Dosage form: Modified release tablet

Evaluation commenced: 31 August 2016 Registration decision: 18 August 2017 Entry onto ARTG: 25 August 2017

ATAZANAVIR CIPLA, ZANAVIR CA, CIPLA ATAZANAVIR

atazanavir

Cipla Australia Pty Ltd

Atazanavir capsules are indicated for the treatment of HIV-1 infection, in combination with other antiretroviral agents.

Dosage form: Capsule

Evaluation commenced: 31 May 2016 Registration decision: 18 August 2017 Entry onto ARTG: 30 August 2017

GANCICLOVIR JUNO, GANCICLOVIR HHH

ganciclovir sodium

Horizon Hospital Healthcare Pty Ltd

Ganciclovir sodium, administered by IV infusion, is indicated for the treatment of cytomegalovirus disease in immunocompromised individuals and bone marrow transplant patients.

Dosage form: Powder for injection

Evaluation commenced: 29 September 2016 Registration decision: 21 August 2017 Entry onto ARTG: 31 August 2017

September

AMBRICIP, AMBRIS, CIPLA AMBRISENTAN

ambrisentan

Cipla Australia Pty Ltd

Ambrisentan tablets are indicated for the treatment of pulmonary arterial hypertension.

Dosage form: Tablet

Evaluation commenced: 30 November 2016 Registration decision: 1 September 2017 Entry onto ARTG: 14 September 2017

APO-MELPHALAN, MELPHALAN APOTEX

melphalan hydrochloride

Apotex Pty Ltd

Melphalan hydrochloride injections are indicated for the treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

Dosage form: Powder for injection

Evaluation commenced: 30 June 2016 Registration decision: 6 September 2017 Entry onto ARTG: 15 September 2017



CIPLA ETORICOXIB, ETORICIP, E-COXIP

etoricoxib

Cipla Australia Pty Ltd

Etoricoxib tablets are indicated for the treatment of osteoarthritis, gouty arthritis, and period and dental pain.

Approval time: 190 working days

Approval time: 192 working days

Approval time: 192 working days

Dosage form: Tablet

Evaluation commenced: 31 October 2016 Registration decision: 3 October 2017 Entry onto ARTG: 18 October 2017

November

There were no new entries for November

December

LINCOMYCIN LWS, LINCOMYCIN SXP

lincomycin hydrochloride monohydrate

Southern Cross Pharma Pty Ltd

Lincomycin hydrochloride monohydrate injections are indicated in the treatment of serious infections due to susceptible strains of gram-positive aerobes such as streptococci, pneumococci and staphylococci.

Dosage form: Solution for injection

Evaluation commenced: 30 November 2016 Registration decision: 21 November 2017 Entry onto ARTG: 4 December 2017

DAPTOMYCIN PANPHARMA

daptomycin

Panpharma Australia Pty Ltd

Daptomycin injections are indicated for the treatment of complicated skin infections and bloodstream infections.

Dosage form: Powder for injection

Evaluation commenced: 31 May 2016 Registration decision: 8 December 2017 Entry onto ARTG: 14 December 2017

Registrations of chemical entities: other generics

2017 chronological summary

The sponsor name reflects the information in the ARTG at the time of registration. As sponsors may change over time, please consult the ARTG for full information in relation to these products, including full indications:

https://www.tga.gov.au/australian-register-therapeutic-goods

January

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
LINEZOLID SANDOZ, LINEZOLID SZ	linezolid	Sandoz Pty Ltd	Injection	4 January 2017	Infection
IRBESARTAN MLPL, IRBESARTAN MLABS, IRBESARTAN MLPL, IRBERAK MLABS, IRBESTRAZ MLABS	irbesartan	Micro Labs Pty Ltd	Film-coated tablet	10 January 2017	Hypertension
APO-DORZOLAMIDE /TIMOLOL, DORZOLAMIDE / TIMOLOL APOTEX	dorzolamide hydrochloride / timolol maleate	Apotex Pty Ltd	Eye drops	11 January 2017	Intraocular pressure
CASPOFUNGIN APOTEX	caspofungin acetate	Sandoz Pty Ltd	Powder for injection	17 January 2017	Fungal infection
MEDREICH CO- AMOXICLAV, AMOXICILLIN CLAVULANIC ACID MYLAN, APO-AMOXY/ CLAV, AMOXYCLAV GENERICHEALTH, AMOXYCLAV SANDOZ	amoxicillin and clavulanic acid	Medreich Australia Pty Ltd	Tablet	17 January 2017	Bacterial infection
GENRX DORZOLAMIDE, APO-DORZOLAMIDE	dorzolamide hydrochloride	Apotex Pty Ltd	Eye drops	17 January 2017	Intraocular pressure
LINEZOLID CA, CIPLA LINEZOLID, LINEZOLID CIP	linezolid	Cipla Australia Pty Ltd	Film-coated tablet	24 January 2017	Infection
APO-NALTREXONE, NALTREXONE-APOTEX	naltrexone hydrochloride	Apotex Pty Ltd	Film-coated tablet	24 January 2017	Alcohol dependence
NEVIRAPINE XR APOTEX	nevirapine	Apotex Pty Ltd	Modified release tablet	25 January 2017	HIV-1 infection

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
RIVASTIG PATCH, RIVASTIGMINE APOTEX PATCH, RIVASTIGMINE SG PATCH, RIVASTIGMINE GPPL PATCH, CHEMMART RIVASTIGMINE PATCH, RIVASTIGMINE GENPAR PATCH, APO- RIVASTIGMINE PATCH, RIVASTIGMINE PATCH, RIVASTIGMINE AML PATCH, RIVASTIGMINE GXP PATCH, TERRY WHITE CHEMISTS RIVASTIGMINE PATCH	rivastigmine	Generic Partners Pty Ltd	Transdermal drug delivery system sachet	25 January 2017	Alzheimer's disease
APO-TRANEXAMIC ACID, TRANEXAMIC ACID SCP, TRANEXAMIC ACID RMB	tranexamic acid	Southern Cross Pharma Pty Ltd	Tablet	30 January 2017	Angioneurotic oedema, hyphaema, menorrhagia
TENOFOVIR LUPIN, TENOFOVIR GH, TENOFOVIR LAPL	tenofovir disoproxil phosphate	Lupin Australia Pty Limited	Film-coated tablet	30 January 2017	HIV-1 infection, chronic hepatitis B
TENOFOVIR EMT LUPIN, TENOFOVIR EMT GH, TENOFOVIR EMT LAPL	tenofovir disoproxil phosphate / emtricitabine	Lupin Australia Pty Limited	Film-coated tablet	31 January 2017	HIV-1 infection

February

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
AKM-PREGABALIN, PHARMACOR PREGABALIN	pregabalin	Southern Cross Pharma Pty Ltd	Capsule	14 February 2017	Neuropathic pain
FLUAIR INHALER, FLUTICASONE CIPLA INHALER	fluticasone propionate	Cipla Australia Pty Ltd	Inhaler	21 February 2017	Asthma
IPCA-ALLOPURINOL, ALLOPURINOL APOTEX, PIP-ALLOPURINOL, MPI-ALLOPURINOL, CM ALLOPURINOL, TN-ALLOPURINOL, PTIN-ALLOPURINOL, TW ALLOPURINOL, GTA- ALLOPURINOL	allopurinol	Apotex Pty Ltd	Tablet	22 February 2017	Urate / uric acid deposition
FAMCICLOVIR GPPL, FAMCICLOVIR GENPAR, FCICLOVIR, FAMCICLO, FACLOVIR, FAMVEER, FAMCICLOVIR GXP, FAMCLOVIR	famciclovir	Generic Partners Pty Ltd	Tablet	24 February 2017	Herpes

March

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
MOMASONE	mometasone furoate	Aspen Pharma Pty Ltd	Ointment	6 March 2017	Dermatitis
ESTOPRAM, ESCITALOPRAM B&B, ESITAL, ESCIT	escitalopram oxalate	Micro Labs Pty Ltd	Tablet	14 March 2017	Depression, anxiety, obsessive- compulsive disorder
IRBESARTAN HCTZ MLABS, IRBESARTAN HCTZ MLPL	irbesartan and hydrochlorothiazide	Micro Labs Pty Ltd	Tablet	14 March 2017	Hypertension
LAPROSTIM, LATANOPROST / TIMOLOL GXP, LATANOMOL, LATANOPROST / TIMOLOL GENPAR, LATANOPROST / TIMOLOL GPPL, XATANOTIM, LAPROSTAMOL, LANTIM	latanoprost and timolol maleate	Generic Partners Pty Ltd	Eye drops	20 March 2017	Intraocular pressure
APO-MODAFINIL, MODAFINIL APOTEX	modafinil	Apotex Pty Ltd	Tablet	20 March 2017	Narcolepsy
VORIWOK, VORICONAZOLE WOCKHARDT	voriconazole	Geosun Pty Ltd	Powder for injection	21 March 2017	Fungal infection
PALOCIP, CIPLA PALONOSETRON, PALONOSETRON CIPLA	palonosetron hydrochloride	Cipla Australia Pty Ltd	Solution for injection	27 March 2017	Nausea, vomiting
TADACIP, TADALIS, CIPLA TADALAFIL,	tadalafil	Cipla Australia Pty Ltd	Film-coated tablet	27 March 2017	Erectile dysfunction, benign prostatic hyperplasia
PREGABALIN MYLAN, LYZALON	pregabalin	Alphapharm Pty Ltd	Capsule	30 March 2017	Neuropathic pain

April

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
MODAFINIL AN, MODAFINIL MYLAN, MODAFINIL SANDOZ, MODAFINIL CH	modafinil	Southern Cross Pharma Pty Ltd	Film-coated tablet	3 April 2017	Narcolepsy
DICLOFENAC MYLAN, MEDREICH DICLOFENAC, DICLOFENAC GH, GX DICLOFENAC	diclofenac sodium	Medreich Australia Pty Ltd	Modified release tablet	4 April 2017	Rheumatism
KNT-AMLODIPINE, TCW-AMLODIPINE, GTA-AMLODIPINE, BESIDEP, IPCA-AMLODIPINE, PIP-AMLODIPINE, TN-AMLODIPINE	amlodipine besilate	Ipca Pharma (Australia) Pty Ltd	Tablet	13 April 2017	Hypertension, angina
ВІМТОР	bimatoprost	Aspen Pharma Pty Ltd	Eye drops	18 April 2017	Intraocular pressure
CASFUNGIN, CASPODAS, CASPOFUNGIN JUNO, CANCIGIN	caspofungin acetate	Neo Health (Australia) Pty Ltd	Powder for injection	19 April 2017	Fungal infection
URSODEOXYCHOLIC ACID APOTEX, APO- URSODEOXYCHOLIC ACID	ursodeoxycholic acid	Apotex Pty Ltd	Capsule	20 April 2017	Chronic cholestatic liver disease
GABALEX MLABS, GABAPENTIN MLPL, GABAPENTIN MLABS, GABAPENTIN B&B	gabapentin	Micro Labs Pty Ltd	Capsule	28 April 2017	Seizures, neuropathic pain
KETOROLAC KABI	ketorolac trometamol	Fresenius Kabi Australia Pty Ltd	Solution for injection	28 April 2017	Pain following surgery

May

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
AZACCORD, AZACITIDINE ACCORD, AZACITIDINE INTAS	azacitidine	Accord Healthcare Pty Ltd	Powder for injection	8 May 2017	Leukaemia, myelodysplastic syndromes
LINEZOLID KABI	linezolid	Fresenius Kabi Australia Pty Ltd	Solution for injection	19 May 2017	Infection
TADALAFIL RRH, CIDALA, TADCIAL, TADALAFIL TIH, TADALAFIL ARW, TADALAFIL RRH PHT, CIDALA PHT, TADCIAL PHT, TADALAFIL TIH PHT, TADALAFIL ARW PHT	tadalafil	Arrow Pharma Pty Ltd	Film-coated tablet	26 May 2017	Erectile dysfunction, benign prostatic hyperplasia, pulmonary arterial hypertension

June

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
TEICOPLANIN SXP, TEICOPLANIN LWS, TEICOPLANIN MGH	teicoplanin	Southern Cross Pharma Pty Ltd	Powder for injection	7 June 2017	Serious infection
PHARMACOR EZETIMIBE, AKM EZETIMIBE	ezetimibe	Pharmacor Pty Ltd	Tablet	7 June 2017	High cholesterol, sitosterolaemia, cardiovascular disease

July

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
MEDICIANZ MUPIROCIN OINTMENT	mupirocin	Medicianz Healthcare Pty Ltd	Ointment	6 July 2017	Impetigo
IPCA-METFORMIN, PIP-METFORMIN, PTIN-METFORMIN, TN-METFORMIN, GTA- METFORMIN, METMIN, EMNORM	metformin hydrochloride	Ipca Pharma (Australia) Pty Ltd	Tablet	19 July 2017	Diabetes
ALIMETREX, PEMETREXED GENPAR, PEMETREXED GPPL, PEMETREXED GXP, PEMETREXED PFI	pemetrexed disodium	Generic Partners Pty Ltd	Powder for injection	19 July 2017	Mesothelioma, lung cancer
APO-TELMISARTAN / AMLODIPINE, GENRX TELMISARTAN / AMLODIPINE	telmisartan and amlodipine besilate	Apotex Pty Ltd	Tablet	26 July 2017	Hypertension

August

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
B. BRAUN PARACETAMOL	paracetamol	B Braun Australia Pty Ltd	Solution for infusion	1 August 2017	Pain
CYKLOTRANEXAMIC, TRANEXAMIC ACID GENPAR, TRANEXAMIC ACID MYLAN, TRANEXAMIC ACID GPPL, CYKLOTRAN, TRANEXAMIC ACID IV APOTEX	tranexamic acid	Generic Partners Pty Ltd	Solution for injection	7 August 2017	Blood loss
BOSENTAN AN, BOSENTAN CH, BOSENTAN CW, BOSENTAN AMNEAL	bosentan monohydrate	Amneal Pharma Australia Pty Ltd	Film-coated tablet	22 August 2017	Pulmonary arterial hypertension
OXYCODONE JUNO, OXYCONE	oxycodone hydrochloride	Juno Pharmaceuticals Pty Ltd	Solution for injection	31 August 2017	Pain
FENOFIBRATE SANDOZ	fenofibrate	Sandoz Pty Ltd	Film-coated tablet	31 August 2017	High cholesterol, dyslipidaemia

September

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
VORICONAZOLE MYX	voriconazole	Mayne Pharma International Pty Ltd	Powder for injection	1 September 2017	Fungal infection
CASPOFUNGIN APOTEX	caspofungin	Apotex Pty Ltd	Powder for injection	4 September 2017	Fungal infection
PHARMACOR ATORVASTATIN, AKM- ATORVASTATIN	atorvastatin calcium trihydrate	Pharmacor Pty Ltd	Film-coated tablet	11 September 2017	High cholesterol
PIPTAZ-AFT	piperacillin sodium and tazobactam sodium	AFT Pharmaceuticals Pty Ltd	Powder for injection	21 September 2017	Bacterial infection
CEFTAZIDIME-AFT	ceftazidime pentahydrate	AFT Pharmaceuticals Pty Ltd	Powder for injection	22 September 2017	Infection
HYDRALAZINE LINK	hydralazine hydrochloride	Link Medical Products Pty Ltd	Solution for injection	22 September 2017	Emergency hypertension

October

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
APO-NICORANDIL, NICORANDIL APOTEX	nicorandil	Apotex Pty Ltd	Tablet	3 October 2017	Angina
ABACAVIR / LAMIVUDINE LUPIN, ABACAVIR / LAMIVUDINE LAPL, ABACAVIR / LAMIVUDINE GH, ABACAVIR / LAMIVUDINE GENERIC HEALTH	abacavir hydrochloride monohydrate and lamivudine	Lupin Australia Pty Limited	Tablet	6 October 2017	HIV-1 infection
IRINOTECAN WOCKHARDT, IRINOTECAN WKT	irinotecan hydrochloride trihydrate	Wockhardt Bio Pty Ltd	Solution for infusion	13 October 2017	Colon or rectum cancer
OXALIPLATIN WOCKHARDT, OXALIPLATIN WKT	oxaliplatin	Wockhardt Bio Pty Ltd	Solution for infusion	13 October 2017	Colon or oesophago- gastric cancer

November

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
EZETIMIBE / SIMVASTATIN- MEDIS, EZETIMIBE / SIMVASTATIN SANDOZ, EZETIMIBE / SIMVASTATIN- AS, EZETIMIBE / SIMVASTATIN- ZP, EZETIMIBE / SIMVASTATIN-GX, APO EZETIMIBE SIMVASTATIN	simvastatin and ezetimibe	Medis Pharma Pty Ltd	Tablet	6 November 2017	High cholesterol, cardiovascular disease
GILENOFIR, FILENDYA, FINGOLIMOD-FBM, GILIMOD, GILMEDYA, FINGOLIMOD-SCP, FINGOLIMOD ARW, FINGOLIMOD GXP, FINGOLEYA	fingolimod hydrochloride	Arrow Pharma Pty Ltd	Capsule	7 November 2017	Multiple sclerosis
APO-TENOFOVIR / EMTRICITABINE, TENOFOVIR / EMTRICITABINE APOTEX	emtricitabine and tenofovir disoproxil fumarate	Apotex Pty Ltd	Film-coated tablet	10 November 2017	HIV-1 infection

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
FINGOLIMOD INTAS, FINGOLIMOD ASTRON, FINGOLINTAS, FINGOLIMOD AMEDA, FINGOLIMOD AN, FINGOLIMOD GH	fingolimod hydrochloride	Accord Healthcare Pty Ltd	Capsule	14 November 2017	Multiple sclerosis
HETINIB, HETLEVAC, HEVEC, IMATERO, NIBTERO, TERONIB, GILMAT	imatinib mesilate	Hetero Australia Pty Ltd	Film-coated tablet	14 November 2017	Cancer
MODAGIL, MODANIL, MVIGIL, MODAFINIL GXP, MFINIL, MODAFINIL GPPL, MOFINIL	modafinil	Generic Partners Pty Ltd	Tablet	15 November 2017	Narcolepsy
ABACAVIR / LAMIVUDINE	lamivudine and abacavir sulfate	Alphapharm Pty Ltd	Film-coated tablet	17 November 2017	HIV-1 infection

December

Trade name	Active ingredient	Sponsor	Dosage form	Entry onto ARTG	Therapeutic use
DOCETAXEL WOCKHARDT, DOCETAXEL WKT	docetaxel	Wockhardt Bio Pty Ltd	Solution for injection	4 December 2017	Cancer
QUETIAPINE XR KP, QUETIAPINE XR AN, QUETIAPINE XR CH, QUETIAPINE XR CW, QUETIAPINE XR AMNEAL	quetiapine fumarate	Amneal Pharma Australia Pty Ltd	Tablet	4 December 2017	Bipolar disorder, schizophrenia, depression, anxiety
EZETIMIBE KP, EZETIMIBE CW, EZETIMIBE ML, EZETIMIBE AN	ezetimibe	Amneal Pharma Australia Pty Ltd	Tablet	4 December 2017	High cholesterol, cardiovascular disease
CEFTRIX, CEFTRIXN, CEFTRIAXON, CFTRIAX	ceftriaxone sodium	Neo Health (Australia) Pty Ltd	Powder for injection	8 December 2017	Infection
GABAPENTIN B&B, GABAPENTIN MLABS, GABALEP, MIPENTINE	gabapentin	Micro Labs Pty Ltd	Film-coated tablet	5 December 2017	Seizures, neuropathic pain
TOBRAMYCIN SUN	tobramycin	Sun Pharma ANZ Pty Ltd	Solution for inhalation ampoule	15 December 2017	Infection associated with cystic fibrosis
APO-ACAMPROSATE, ACAMPROSATE APOTEX	acamprosate calcium	Apotex Pty Ltd	Enteric coated tablet	21 December 2017	Alcohol dependence

Biosimilar prescription medicines

A biosimilar medicine is a version of a biological prescription medicine that is already registered and is referred to as the 'reference medicine'.

Both the biosimilar and its reference medicine will have similar core characteristics such as physicochemical, biological, immunological, efficacy and safety, which are demonstrated using comprehensive comparability studies. Most biosimilar medicines are likely to contain biotechnology-derived proteins as the active substance.

Please note that the indication for which each prescription medication is approved may be more specific than as described in general terms in this summary. For the full approved indications, please consult the ARTG: https://www.tga.gov.au/australian-register-therapeutic-goods

Once an application has been accepted for evaluation by TGA, the **approval time** is defined as the **number of TGA working days between commencement of evaluation and registration decision**. This timeframe is underpinned by legislation (see *Therapeutic Goods Regulations 1990*) and excludes public holidays, weekends, the time allocated to the sponsor to respond to requests for information, 'mutual clock stop' periods agreed with the sponsor, or other review activities.





November

AMGEVITA Approval time: 245 working days

adalimumab

Amgen Australia Pty Ltd

Amgevita is indicated for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's Disease, ulcerative colitis, psoriasis, hidradenitis suppurativa, and uveitis.

Evaluation commenced: 3 May 2016 Registration decision: 18 October 2017 Entry onto ARTG: 9 November 2017

ERELZI Approval time: 195 working days

etanercept

Novartis Pharmaceuticals Pty Ltd

Erelzi is indicated for the treatment of:

- in adults: rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis;
- in children and adolescents: juvenile idiopathic arthritis, and paediatric plaque psoriasis.

Evaluation commenced: 30 November 2016 Registration decision: 18 October 2017 Entry onto ARTG: 30 November 2017

RIXIMYO Approval time: 209 working days

rituximab

Sandoz Australia Pty Ltd

Non-Hodgkin's Lymphoma (NHL)

Riximyo is indicated for treatment of B-cell non-Hodgkin's lymphoma, chronic lymphocytic leukaemia (CLL), rheumatoid arthritis, Wegener's granulomatosis, and microscopic polyangiitis.

Evaluation commenced: 30 November 2016 Registration decision: 21 November 2017 Entry onto ARTG: 30 November 2017

Australian Public Assessment Reports (AusPARs)

Each AusPAR outlines the outcome of TGA's pre-market registration process for prescription medicines – including new chemical/biological entities, extensions of indications, and generics – and provides a record of the scientific reasoning and risk-benefit considerations behind each regulatory decision.

In 2017, there were 69 AusPARs published. For full information on AusPARs, please see: https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

2017 chronological summary

January

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
FETZIMA	levomilnacipran	Pierre Fabre Australia	New chemical entity	Rejected	3 January 2017	N/A
GARDASIL 9	human papillomavirus 9 valent vaccine	Merck Sharp & Dohme	New biological entity	Approved	16 January 2017	Prevention of cancer and lesions caused by human papillomavirus (HPV)
KALYDECO	ivacaftor	Vertex Pharmaceuticals	Extension of indications	Approved	19 January 2017	Cystic fibrosis
TOUJEO / EDOMLUS / LAMBETO	glargine (rbe)	Sanofi Aventis	New strength	Approved	23 January 2017	Diabetes

February

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
GADOVIST 1.0	gadobutrol	Bayer Australia	Major variation	Approved	9 February 2017	Body imaging
MABTHERA	rituximab	Roche	Major variation	Approved	16 February 2017	Lymphoma
YERVOY / WINGLORE	ipilimumab (rch)	Bristol-Myers Squibb	Major variation (new indication)	Approved	23 February 2017	Melanoma

April

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
NUCALA	mepolizumab	GlaxoSmithKline Australia	New biological entity	Approved	5 April 2017	Severe refractory eosinophilic asthma
BRIVIACT	brivaracetam	UCB Australia	New chemical entity	Approved	11 April 2017	Epilepsy
HUMIRA	adalimumab	AbbVie	Extension of indications	Approved	12 April 2017	Enthesitis- related arthritis & psoriasis
ADDAVEN	nine trace elements including chromic chloride	Fresenius Kabi Australia	New chemical entity	Approved	20 April 2017	Nutritional deficiencies
VIEKIRA-PAK RBV	paritaprevir / ritonavir / ombitasvir and dasabuvir and ribavirin	AbbVie	New chemical entities in fixed dose combination	Approved	26 April 2017	Hepatitis C

May

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
VIEKIRA PAK	paritaprevir / ritonavir / ombitasvir and dasabuvir	AbbVie	New chemical entities in fixed dose combination	Approved	3 May 2017	Hepatitis C
BELKYRA	deoxycholic acid	Allergan Australia	New chemical entity	Approved	10 May 2017	Cosmetic treatment for submental fat
ZINBRYTA	daclizumab	Biogen Australia	New chemical entity	Approved	12 May 2017	Multiple sclerosis
TALTZ	ixekizumab	Eli Lilly	New chemical entity	Approved	23 May 2017	Plaque psoriasis
AVASTIN	bevacizumab (rch)	Roche	Major variation (new indication)	Approved	25 May 2017	Cervical cancer
ALBUNATE	albumin (human)	CSL	New biological medicine	Approved	29 May 2017	Blood circulation
INOMAX	nitric oxide	Ikaria Australia	Major variation (new indication)	Approved	31 May 2017	Pulmonary hypertension

June

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
STRIBILD	tenofovir disoproxil fumarate / emtricitabine / elvitegravir / cobicistat	Gilead Sciences	Extension of indications	Approved	7 June 2017	HIV-1 infection
ZEPATIER	grazoprevir / elbasvir	Merck Sharp & Dohme	New chemical entity	Approved	7 June 2017	Chronic hepatitis
BRILINTA	ticagrelor	AstraZeneca	New indication & strength	Rejected	9 June 2017	N/A *
TREXJECT, TREXJECT IN	methotrexate	Link Medical Products Pty Ltd	Major variation (new presentation, new route of administration)	Approved	15 June 2017	Rheumatoid arthritis & psoriasis arthritis
PROMETRIUM / UTROGESTAN	progesterone	Besins Healthcare Australia	Extension of indications	Approved	20 June 2017	Menstrual irregularities, hormone replacement therapy, luteal phase support
ANO-CREAM	diltiazem	AFT Pharmaceuticals	Major variation (new dosage form)	Rejected	22 June 2017	N/A **
TARGIN	oxycodone / naloxone	Mundipharma	Extension of indications	Approved	27 June 2017	Restless legs syndrome

July

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
EPHEDRINE HYDROCHLORIDE MYX	ephedrine	Mayne Pharma International	Major variation	Approved	12 July 2017	Hypotension
SIMPONI	golimumab (rmc)	Janssen Cilag	Extension of indications	Approved	13 July 2017	Axial spondyloarthritis
BRENZYS	etanercept (rch)	ERA Consulting	New biological entity	Approved	14 July 2017	Arthritis, psoriasis, ankylosing spondylitis
CIMZIA	certolizumab pegol	UCB Australia	Extension of indications	Approved	17 July 2017	Rheumatoid arthritis

^{*} Already approved in the treatment of atherothrombotic events;
** Already approved in the treatment of hypertension, angina and various cardiac rhythm disorders

August

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
VORCON	voriconazole	Aspen Pharma Pty Ltd	New generic medicine	Approved	10 August 2017	Fungal infections
ATOZET / ZETEZE	ezetimibe / atorvastatin	Merck Sharp & Dohme	Extension of indications	Approved	15 August 2017	Cardiovascular disease
EZETROL / VYTORIN	ezetimibe and ezetimibe / simvastatin	Merck Sharp & Dohme	Extension of indications	Approved	16 August 2017	Cardiovascular disease
AFLURIA QUAD	inactivated quadrivalent influenza vaccine (split virion)	Seqirus	New chemical / biological entity	Approved	16 August 2017	Influenza

October

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
ANTIZOL	fomepizole	AFT Pharmaceuticals	New chemical entity	Approved	5 October 2017	Ethylene glycol or methanol poisoning
ACTAIR	American house dust mite / European house dust mite	Stallergenes Australia	Major variation (new dosage form, new route of administration)	Approved	6 October 2017	House dust mite allergic rhinitis
VOLIBRIS	ambrisentan	GlaxoSmithKline Australia	Extension of indications	Approved	9 October 2017	Pulmonary arterial hypertension
ADCETRIS	brentuximab vedotin	Takeda Pharmaceuticals Australia	Extension of indications	Approved	11 October 2017	Hodgkin's lymphoma
IDELVION	albutrepenona- cog alfa (rch)	CSL Behring (Australia)	New biological entity	Approved	11 October 2017	Haemophilia B
ONIVYDE	irinotecan (as sucrosofate)	Baxalta Australia	New chemical entity	Approved	17 October 2017	Pancreatic cancer
QTERN	dapagliflozin / saxagliptin	AstraZeneca	New fixed dose combination	Approved	18 October 2017	Diabetes
EMPLICITI	elotuzumab	Bristol-Myers Squibb	New biological entity	Approved	31 October 2017	Multiple myeloma

November

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
PROLASTIN-C	alpha-1- proteinase inhibitor (human)	Grifols Australia Pty Ltd	New biological entity	Approved	1 November 2017	Alpha-1 antitrypsin deficiency and emphysema
HALAVEN	eribulin mesilate	Eisai Australia Pty Ltd	Extension of indications	Approved	1 November 2017	Unresectable liposarcoma
TECHNIVIE	paritaprevir / ritonavir / ombitasvir	AbbVie Pty Ltd	Extension of indications	Approved	1 November 2017	Hepatitis C
ODEFSEY	emtricitabine / rilpivirine / tenofovir alafenamide fumarate	Gilead Sciences Pty Ltd	New fixed dose combination	Approved	2 November 2017	HIV-1 infection
EPHEDRINE HYDROCHLORIDE SXP / EPHEDRINE HYDROCHLORIDE RMB / EPHEDRINE HYDROCHLORIDE AJS	ephedrine	Southern Cross Pharma Pty Ltd	Major variation (new dose form)	Approved	2 November 2017	Hypotension secondary to spinal anaesthesia
ACARIZAX	American house dust mite extract / European house dust mite extract	Seqirus Pty Ltd	New biological entity	Approved	2 November 2017	House dust mite allergic rhinitis & asthma
RENFLEXIS	infliximab	Samsung Bioepis AU Pty Ltd	New biosimilar	Approved	3 November 2017	Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis
STELARA	ustekinumab	Janssen-Cilag Pty Ltd	Extension of indications, new dosage strength and route of administration	Approved	6 November 2017	Crohn's disease
REKOVELLE	follitropin delta (rhu)	Ferring Pharmaceuticals Pty Ltd	New biological entity	Approved	7 November 2017	Controlled ovarian stimulation
ZYDELIG	idelalisib	Gilead Sciences Pty Ltd	Extension of indications	Approved	7 November 2017	Chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL)
JARDIANCE	empagliflozin	Boehringer Ingelheim Pty Ltd	Extension of indications	Approved	8 November 2017	Diabetes
OPDIVO	nivolumab	Bristol-Myers Squibb Australia Pty Ltd	Extension of indications	Approved	9 November 2017	Classical Hodgkin lymphoma

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
INVEGATRINZA, TREVICTA	paliperidone palmitate	Janssen-Cilag Pty Ltd	Major variation (extension of indications, new dose form and strength)	Approved	10 November 2017	Schizophrenia
UROREC	silodosin	Mayne Pharma International Pty Ltd	New chemical entity	Approved	14 November 2017	Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia
FLUMIST QUADRIVALENT	influenza virus	AstraZeneca Pty Ltd	New biological entity	Approved	14 November 2017	Influenza
OPDIVO	nivolumab	Bristol-Myers Squibb Australia Pty Ltd	Extension of indications	Approved	15 November 2017	Renal cell carcinoma
HARVONI	ledipasvir / sofosbuvir	Gilead Sciences Pty Ltd	Major variation, extension of indications	Approved	16 November 2017	Hepatitis C
NINLARO	ixazomib	Takeda Pharmaceuticals Australia Pty Ltd	New chemical entity	Approved	16 November 2017	Multiple myeloma
CRUSIA-AFT, CRUSIA AFT FORTE	enoxaparin	AFT Pharmaceuticals Pty Ltd	New biological entity	Withdrawn	17 November 2017	N/A
EPCLUSA	sofosbuvir / velpatasvir	Gilead Sciences Pty Ltd	New chemical entity	Approved	20 November 2017	Hepatitis C
VENCLEXTA	venetoclax	AbbVie Pty Ltd	New chemical entity	Approved	21 November 2017	Chronic lymphocytic leukaemia
KYLEENA	levonorgestrel	Bayer Australia Ltd	Major variation, new strength	Approved	21 November 2017	Contraception
PEDEA	ibuprofen	Emerge Health Pty Ltd	Extension of indications	Approved	22 November 2017	Ductus arteriosus
AFINITOR	everolimus	Novartis Pharmaceuticals Australia Pty Ltd	Extension of indications	Approved	29 November 2017	Neuroendocrine tumours (NET) of gastrointestinal or lung origin

December

Trade name	Active ingredient	Sponsor	Submission type	Decision	Publication date	Therapeutic use
ALECENSA	alectinib	Roche Products Pty Limited	New chemical entity	Approved	5 December 2017	Non-small cell lung cancer
ACZONE	dapsone	Allergan Australia Pty Ltd	New dose form, New route of administration, extension of indication	Approved	11 December 2017	Acne vulgaris
NOCDURNA	desmopressin	Ferring Pharmaceuticals Pty Ltd	Major variation (new strength)	Approved	12 December 2017	Nocturia

