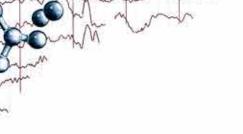


# Prescription medicines and biologicals:

TGA annual summary 2016

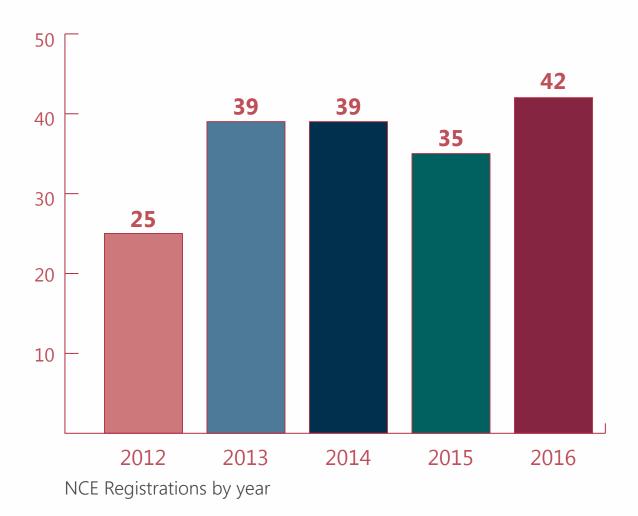




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- New Chemical Entity (NCE) registrations
- New or extended uses, or new combination registrations
- 18 Orphan Drug registrations
- AusPAR publications



# Prescription medicines and biologicals: TGA annual summary 2016

The Therapeutic Goods Administration (TGA) is a part of the Health Products Regulation Group (HPRG) within the Australian Commonwealth Department of Health. TGA contributes to the protection and promotion of public health as the regulator responsible for evaluating new therapeutic goods for human use in Australia; this includes pharmaceutical medicines, complementary medicines, biological products, and medical devices. TGA supports timely access to therapeutic products that achieve better health and wellbeing, while determining that these products do not pose an unacceptable risk to the health and safety of the Australian public.

This is TGA's third Annual Summary report on the registration of prescription medicines. Once approved, these medicines are added to the Australian Register of Therapeutic Goods (ARTG) and can be lawfully supplied in Australia. This report includes details of newly-registered prescription medicines, along with those already-registered medicines that have been approved for new uses (known as an 'extension of indications') and in new combinations. For the first time, the Annual Summary also details new biologicals and Australian Public Assessment Reports (AusPARs) published online.

The 2016 registrations covered a wide therapeutic base, with new treatments for a number of diseases including cancer, multiple sclerosis and cystic fibrosis. During this period, two new first-in-class treatments were approved for ovarian cancer and high cholesterol, along with whole regimen treatment options for HIV and hepatitis C virus infection. Orphan drugs for the treatment of rare diseases were approved for haemophilia and non-small cell lung cancer. Notably, TGA saw an increased number of new registrations of immunotherapies, including monoclonal antibodies. Today, TGA's approval times for prescription medicines are comparable – and, for standard approvals, often faster – with analogous registration processes in the US and Europe. In 2016, over 80% of TGA's registrations of prescription medicines were completed on time or before the planned date, which is well within legislated maximum timeframes. In 2017, an accelerated evaluation process for certain new prescription medicines will also be introduced.

I am pleased to share the 2016 Annual Summary report. We hope this information is of use to the Australian public, healthcare professionals, government agencies, other medicines regulators, and industry as we work together towards better health outcomes for all Australians.

# Adjunct Professor John Skerritt

Deputy Secretary
Therapeutic Goods Administration
Health Products Regulation Group
Department of Health
January 2017

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

Please note that the actual indication for which each prescription medication is approved may be more specific than described in this summary. For full indications, please consult the Australian Register of Therapeutic Goods (ARTG): <a href="https://www.tga.gov.au/australian-register-therapeutic-goods">www.tga.gov.au/australian-register-therapeutic-goods</a>

### **BRIVIACT**

Briviact (brivaracetam) is used for the treatment of seizures in patients with epilepsy. In the brain, Briviact binds to the synaptic vesicle protein 2A and inhibits presynaptic calcium channels; this in turn reduces neurotransmitter release, impedes impulse conduction across synapses, and brings about an anticonvulsant effect.

### **EMPLICITI**

Empliciti (elotuzumab) is a human monoclonal antibody used to treat multiple myeloma. Following intravenous injection, Empliciti specifically targets the cell surface SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) glycoprotein, which is expressed on myeloma cells and also Natural Killer (NK) cells. As a result, Empliciti facilitates the interaction of NK cells with myeloma cells to mediate the killing of the cancer through antibody-dependent cellular cytotoxicity (ADCC). Empliciti thereby works by activating the body's own immune system to attack and kill cancer cells.

## **ENTRESTO**

Entresto is a single drug for the treatment of chronic heart failure that combines two different medications: (1) sacubitril, which controls blood volume and lowers blood pressure, and (2) valsartan, which keeps blood vessels from narrowing and improves blood flow. Entresto helps lower the risk of hospitalisation when symptoms get worse, and helps lower the risk of death from heart failure.





Farydak (panobinostat) is used to treat patients with multiple myeloma, a form of blood cancer arising from plasma cells in bone marrow. Farydak is an innovative new drug that works by inhibiting the activity of enzymes known as histone deacetylases. This process slows the growth of plasma cells in multiple myeloma patients or causes these dangerous cells to die.

# **GENVOYA**

Genvoya is a complete regimen for the treatment of HIV-1 infection, containing four different medicines combined into one pill taken daily with food: (1) elvitegravir blocks an HIV enzyme called integrase, (2) cobicistat increases the effectiveness of elvitegravir, while (3) emtricitabine and (4) tenofovir alafenamide (as fumarate) block an HIV enzyme called reverse transcriptase. By blocking enzyme activity, Genvoya prevents HIV from multiplying in the body. Genvoya also contains a new form of tenofovir, which reduces side effects.

# **LENVIMA**

Lenvima (lenvatinib) is used to treat patients with differentiated thyroid cancer, a cancerous growth of the thyroid gland which is located in the neck and helps regulate the body's metabolism. Elevated levels of the protein vascular endothelial growth factor (VEGF), which stimulates the growth of new blood vessels, have been noted in thyroid tumours. Lenvima works as an anti-cancer drug by blocking the activation of VEGF receptors by VEGF, which in turn reduces the growth of cancer cells.

### **LYNPARZA**

Lynparza (olaparib) is used to treat patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer with a mutation in their BRCA genes. These genes play a role in DNA repair; mutations prevent this repair, which leads to uncontrolled cell growth and cancer. By inhibiting this defective repair process, Lynparza allows DNA to repair normally, and for cell growth to remain controlled. Lynparza is used with a companion diagnostic genetic test to identify BRCA mutations in suitable patients.

### **OPDIVO**

Opdivo (nivolumab) is a human monoclonal antibody used to treat patients with melanoma, non-small cell lung cancer, or advanced clear cell renal cell carcinoma. It is a form of cancer immunotherapy, which is a new way to treat cancer through the stimulation of an immune response. Opdivo works as a checkpoint inhibitor, blocking a signal that would have otherwise prevented activated T cells from secreting cytokines and attacking the cancer. The immune system is thus able to help clear the cancer from the body.

### **ORKAMBI**

Orkambi is a combination drug available in a single pill for the treatment of cystic fibrosis in people who have two copies of the F508del mutation in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR) protein. The F508del genetic mutation on chromosome 7 causes the CFTR protein to misfold; cells then destroy these defective proteins soon after they are made, which disrupts how water and chloride are transported in the body. In Orkambi, lumacaftor increases the number of CFTR proteins trafficked to the cell surface, while ivacaftor increases the probability the defective channel will open and allow chloride ions to pass through.

### **PRALUENT**

Praluent (alirocumab) is a human monoclonal antibody injected under the skin and used to treat patients who are unable to control their low-density lipoprotein (LDL) cholesterol in addition to diet, exercise, and other cholesterol-lowering drugs. Praluent targets a specific protein, proprotein convertase subtilisin kexin 9 (PCSK9), to reduce the number of receptors on the liver that remove LDL cholesterol from the blood. By blocking PCSK9's ability to work, more receptors are available to remove LDL cholesterol from the blood, which thereby lowers a patient's LDL cholesterol levels.



### **ZEPATIER**

Zepatier is a single drug for the treatment of genotype 1 and 4 chronic hepatitis C virus (HCV) infections that combines two different medications: (1) elbasvir, which prevents the transcription of the HCV RNA, and (2) grazoprevir, which blocks the action of viral replication. Zepatier provides an oral treatment option for patients with HCV infections without requiring the use of interferon.

### **ZINBRYTA**

Zinbryta (daclizumab) is a human monoclonal antibody used to treat multiple sclerosis (MS). It works by targeting the CD25 subunit of interleukin 2 (IL-2) receptors, which are highly expressed on reactive T cells in MS patients. By stopping and preventing the inflammation caused by CD25-positive T cells, Zinbryta reduces the symptoms of MS. Zinbryta is an injection administered by the patient under the skin on a monthly basis. The long-acting nature of Zinbryta means overall fewer injections for patients.

### **ZYKADIA**

Zykadia (ceritinib) is used to treat patients with non-small cell lung cancer (NSCLC) who have a genetic rearrangement in the anaplastic lymphoma kinase (ALK) gene. ALK gene rearrangement is found in about 2-7% of patients with NSCLC, which makes up about 85% of all lung cancer. Zykadia is an ALK tyrosine kinase inhibitor, and so blocks the proteins that promote the development of cancer cells.



# M. Janes

# Some new or extended uses for existing medicines

In addition to the approval of new prescription medicines, patients will also benefit from the approval of certain existing medicines for new or extended therapeutic uses. For full information on the indications, please consult the Australian Register of Therapeutic Goods (ARTG): <a href="https://www.tga.gov.au/australian-register-therapeutic-goods">www.tga.gov.au/australian-register-therapeutic-goods</a>

### **DESCOVY**

Descovy (emtricitabine / tenofovir alafenamide fumarate) is a combination drug containing a new form of tenofovir (as alafenamide fumarate). The earlier emtricitabine combination containing tenofovir disoproxil fumarate has been registered since 2005 for the treatment of HIV-1 infection and pre-exposure prophylaxis (PrEP) to prevent infection. Although Descovy is not for use in PrEP, this new combination will be an improved option in the treatment of HIV because it has better renal and bone safety.

### **ESMYA**

Ulipristal acetate has been registered since 2015 for emergency contraception.

Esmya is a new presentation of ulipristal acetate that is now also approved for the treatment of uterine fibroids in adult women of reproductive age. Previously, the treatment of uterine fibroids was with surgery.

# **FYCOMPA**

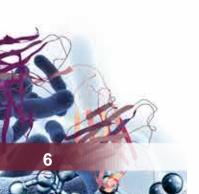
Fycompa (perampanel as hemisesquihydrate) has been registered since 2014 for the treatment of partial-onset seizures with or without secondarily generalised seizures in adult and adolescent patients from 12 years of age with epilepsy.

Fycompa is now also indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy.

# **HARVONI**

Harvoni (ledipasvir / sofosbuvir) has been registered since 2015 for the treatment of genotype 1 chronic hepatitis C virus (HCV) infection in adults.

Harvoni is now also indicated for the treatment of genotype 4, 5 and 6 HCV infections, and so provides more treatment options for patients with these rarer genotypes.







### **KALYDECO**

Kalydeco (ivacaftor) has been registered since 2013 for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have a G551D or other gating (class III) mutation or an R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Kalydeco is now also indicated for the treatment of CF in patients aged 2 years and older with these genetic abnormalities. The availability of the medicine for children at a younger age is important since CF is a congenital disorder. It is now also available as granules, not only tablets.

### **ODEFSEY**

Odefsey is a complete regimen for the treatment of HIV-1 infection, containing three different antiretroviral drugs combined into one pill taken daily with food: emtricitabine, rilpivirine, and tenofovir alafenamide.

### **PERJETA**

Perjeta (pertuzumab) has been registered since 2013 in combination with trastuzumab and docetaxel for patients with metastatic HER2-positive breast cancer who have not received prior anti-HER2 therapy or chemotherapy for their metastatic disease.

Perjeta is now also indicated in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of patients with inflammatory or locally advanced HER2-positive breast cancer as part of a complete treatment regimen. The change means Perjeta is available to a wider group of breast cancer patients.



Targin (oxycodone hydrochloride / naloxone hydrochloride) has been registered since 2010 for the management of moderate to severe chronic pain unresponsive to non-narcotic analgesia. The naloxone component is indicated for the therapy and/or prophylaxis of opioid-induced constipation.

Targin is now also indicated for second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome after failure of dopaminergic therapy.



### **TECHNIVIE**

The combination drug containing paritaprevir / ritonavir / ombitasvir has been registered since 2015 for the treatment of genotype 1 chronic hepatitis C virus (HCV) infection.

Technivie is a new presentation of this combination and is now also indicated for the treatment of patients with genotype 4 HCV infection, and so provides more treatment options for patients with this rarer genotype.

# **TRUVADA**

Truvada (emtricitabine / tenofovir disoproxil fumarate) has been registered since 2005 for the treatment of HIV-1 infected adults, in combination with other antiretroviral agents.

Truvada is now also indicated, in combination with safer sex practices, for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

# **VICTOZA**

Liraglutide has been registered as Victoza since 2010, in combination with metformin or a sulfonylurea, for the treatment of patients with type 2 diabetes. A second presentation in 2015 was approved for use in chronic weight management in obese or overweight patients, in conjunction with diet and exercise.

Victoza is now also indicated for combination therapy with basal insulin, with or without metformin, for the treatment of type 2 diabetes.

# **XIAFLEX**

Xiaflex (collagenase clostridium histolyticum) has been registered since 2013 for the treatment of Dupuytren's contracture in adult patients with a palpable cord.

Xiaflex is now also indicated for treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.



# Paediatric uses for registered medicines

A number of existing medicines were approved for extended therapeutic uses in children in 2016. These included some orphan drugs, which are intended to treat rare diseases, and which can be extended for use in children with congenital diseases existing at or before birth.

# **ALPROLIX & ELOCTATE**

Alprolix and Eloctate both containing the active ingredient efmoroctocog alfa have been registered since 2014 as long-acting anti-haemophilic factors in children older than 12 years and adults with haemophilia A and B, respectively.

Alprolix and Eloctate are now also indicated for use in children under the age of 12 years, which broadens their use to paediatric patients of all ages with haemophilia A or B.

### **REVOLADE**

Revolade (eltrombopag) has been registered since 2010 for the treatment of adult patients with chronic immune thrombocytopenic purpura (ITP) who have had an inadequate response or are intolerant to corticosteroids and immunoglobulins.

Revolade is now also indicated for the treatment of paediatric patients with chronic ITP, so can now be used in a wider population base.

# **XOLAIR**

Xolair (omalizumab) has been registered since 2002 for the management of adult and adolescent patients with moderate to severe allergic asthma.

Xolair is now also indicated for use in asthmatic children aged 6 to <12 years, which broadens its use to younger paediatric patients with severe allergic asthma.

# TGA's regulatory framework for biologicals

A new regulatory framework for biologicals was introduced in 2011. A 'biological' is defined as a substance that comprises, contains, or is derived from human cells or tissue; and is represented in any way to be, or is likely to be, for therapeutic use. The regulatory changes involved transitioning some human tissues and cell-based therapies to the ARTG to be listed alongside the 'new chemical entities' (e.g. pharmaceutical prescription medicines) and 'new biological entities' (e.g. vaccines). This will assure the public of the quality of the human cell and tissue-based therapeutic goods used in Australia, and increase the visibility of the types of cells and tissues approved for use.

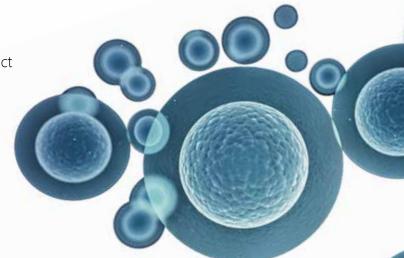
The Biologicals Regulatory Framework provides a comprehensive system of assessment and controls that must be completed before products are allowed to be marketed in Australia and follow-up and further controls after they are marketed. For lower risk biologicals that have undergone no or only simple processing (called 'minimal manipulation'), such as the products supplied by the tissue banks, TGA evaluates their compliance with relevant quality standards. For higher risk biologicals, such as cell therapies, TGA evaluates their compliance with relevant standards relating to quality, safety and efficacy. 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. Some examples of biologicals regulated by TGA are listed below, including their sources:

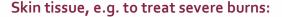
# Musculoskeletal tissue, e.g. bone products:

- Hunter New England Bone Bank
- PlusLife
- Metro South Hospital and Health Service T/A Queensland Bone Bank
- South Eastern Sydney Local Health District
- Victorian Institute of Forensic Medicine T/A Donor Tissue Bank of Victoria
- Sydney Local Health District T/A Rachel Forster Bone Bank
- SA Pathology
- Johnson & Johnson Medical Pty Ltd T/A DePuy Synthes
- Barwon Health Bone Bank
- Australian Biotechnologies Pty Limited

# Ocular tissue, e.g. cornea:

- South Eastern Sydney Local Health District
- Queensland Eye Bank
- Lions Eye Donation Service
- Eye Bank of South Australia
- Lions Eye Bank of Western Australia





- Metro South Hospital and Health Service T/A Queensland Bone Bank
- Skin (Dermis) Johnson & Johnson Medical Pty Ltd T/A DePuy
- Victorian Institute of Forensic Medicine T/A Donor Tissue Bank of Victoria

# Cardiovascular tissue, e.g. heart valves and arteries:

- Victorian Institute of Forensic Medicine T/A Donor Tissue Bank of Victoria
- Metro South Hospital and Health Service T/A Queensland Heart Valve Bank
- The Sydney Heart Valve Bank

# Demineralised bone products, e.g. mixed with a carrier to make it mouldable to the defect:

- DBX Putty
- Grafton DBM Orthoblend
- Grafton DBM Flex
- Grafton Plus DBM Paste
- Grafton DBM Matrix

# Biologicals clinical trials

Some novel therapies that use biologicals have also entered clinical trials over the past two years, including the following trials approved under the clinical trial exemption (CTX) scheme:

# Anti-Lewis Y gene modified T cells

12 August 2016

A Phase I study investigating the safety and tolerability of an infusion of T lymphocytes transduced with an anti-LewisY (LeY) chimeric receptor gene in patients with solid tumours expressing LeY.

# Human parthenogenetic stem cell-derived neural stem cells

10 December 2015

A Phase I study investigating the safety of human parthenogenetic-derived neural stem cells (ISC-hpNSC) when injected into patients with Parkinson's disease.

# Anti-GD2 gene modified T cells

20 April 2015

A Phase I study investigating the safety and tolerability of autologous peripheral blood T cells transfected with a retroviral construct to express a GD2-specific chimeric antigen receptor and an inducible caspase 9 (iCasp9) gene in patients with metastatic melanoma.

# New registrations by therapeutic area

Immunomodulators , gynaecological and cosmetic agents

**ESBRIET** pirfenidone

**ORKAMBI** lumacaftor/ivacaftor

**BELKYRA** deoxycholic acid

**PROLASTIN C** alpha-1-proteinase inhibitor (human, Alpha1-PI)

**DUAVIVE** conjugated estrogens/bazedoxifene

Antineoplastic and haematological agents

LYNPARZA olaparib

**OPDIVO** nivolumab

**LENVIMA** lenvatinib

FARYDAK panobinostat (as lactate)

**ZYKADIA** ceritinib

**KOVALTRY** octocog alfa (bhk)

**COTELLIC** cobimetinib as fumarate

**OBIZUR** susoctocog alfa (bhk)

**TAGRISSO** hexaminolevulinate (as hydrochloride)

**IDELVION** albutrepenonacog alfa

**EMPLICITI** elotuzumab

**NINLARO** ixazomib (as citrate)

**KYPROLIS** carfilzomib

**ONIVYDE** nanoliposomal irinotecan (as sucrosofate)

Cardiovascular, antidotes and endocrine agents

**STRENSIQ** asfotase alfa (rch)

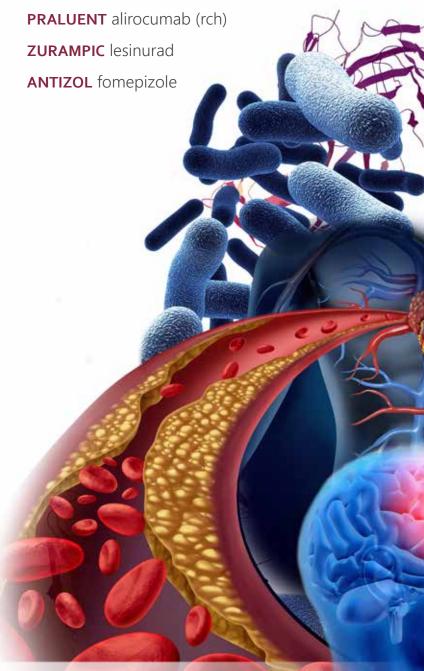
**NUCALA** mepolizumab

**ENTRESTO** sacubitril / valsartan

**UPTRAVI** selexipag

**SPEDRA** avanafil

**PRAXBIND** idarucizumab (rch)



# Neurological, disease-modifying, fluid/electrolyte and gastro-intestinal agents

**MOVANTIK** naloxegol (as oxalate)

**ADDAVEN** chromic chloride hexahydrate, cupric chloride dehydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride

**BRIVIACT** brivaracetam

**TALTZ** ixekizumab

**ZINBRYTA** daclizumab

**BELSOMRA** suvorexant

# Anti-infectives, vaccines and other agents

**GENVOYA** tenofovir alafenamide (as fumarate)/elvitegravir/cobicistat/emtricitabine

**HYQVIA** normal immunoglobulin (human)/vorhyaluronidase alfa

**AFLURIA QUAD** tenofovir alafenamide (as fumarate)/elvitegravir/cobicistat/emtricitabine

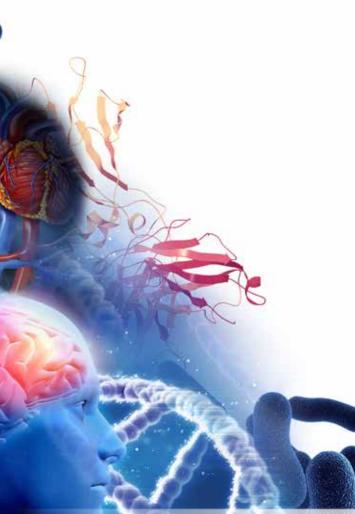
ACARIZAX dermatophagoides pteronyssinus and dermatophagoides farina (American house dust mite extract, European house dust mite extract)

**HEXVIX** hexaminolevulinate (as hydrochloride)

**ZEPATIER** elbasvir/grazoprevir

FLUMIST QUADRIVALENT influenza virus A (H1N1)/influenza virus A (H3N2)/influenza virus B (Yamagata lineage)/influenza virus B (Victoria lineage) quadrivalent vaccine (live attenuated)

**EPCLUSA** sofosbuvir/velpatasvir



# New registrations 2016 chronological summary

Note that all products were approved within the statutory 255 working day period (which equates to 12 calendar months). The overall approval periods for some products exceeded 12 calendar months for a range of reasons, including extended periods for sponsor responses for information or appeals of an initial decision by TGA (followed by provision of further information by the sponsor).



A medicine, vaccine or in vivo diagnostic agent that:

- is intended to treat, prevent or diagnose a rare disease; or
- is not commercially viable to supply to treat, prevent or diagnose another disease or condition.

# **January**

LYNPARZA O 07 Jan 2016

olaparib

# AstraZeneca Pty Ltd

As monotherapy for the maintenance treatment of patients with platinum-sensitive relapsed BRCA-mutated (germline or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) after platinum-based chemotherapy.

MOVANTIK 07 Jan 2016

naloxegol (as oxalate)

# AstraZeneca Pty Ltd

For the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s).

**OPDIVO** 11 Jan 2016

nivolumab

# Bristol-Myers Squibb Australia Pty Ltd

As monotherapy for the treatment of patients with unresectable (Stage III) or metastatic (Stage IV) melanoma, or locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy.

In combination with YERVOY (ipilimumab) for the treatment of patients with metastatic (Stage IV) melanoma with M1c disease or elevated lactic dehydrogenase (LDH).





14 Jan 2016

asfotase alfa (rch)

# Alexion Pharmaceuticals Australasia Pty Ltd

For enzyme replacement therapy in patients with paediatric-onset hypophosphatasia.

GENVOYA 15 Jan 2016

tenofovir alafenamide (as fumarate)/elvitegravir/cobicistat/emtricitabine

# Gilead Sciences Pty Ltd

A single tablet regimen for the treatment of HIV-1 infection in adults and adolescents aged 12 years of age and older with body weight at least 35 kg who are either treatment—naïve; or virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen.

ENTRESTO 20 Jan 2016

sacubitril/valsartan (combined as a sodium salt hydrate complex)

# Novartis Pharmaceuticals Australia Pty Limited

For the treatment of chronic heart failure (NYHA Class II-IV) with reduced ejection fraction in adult patients.

Dossier received: 02/03/2015 Approved: 15/01/2016

LENVIMA 🗘 28 Jan 2016

lenvatinib

# Eisai Australia Pty Ltd

For the treatment of patients with progressive, locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer.



Prescription medicines and biologicals: TGA annual summary 2016



# **February**

NUCALA 02 Feb 2016

mepolizumab

# GlaxoSmithKline Australia Pty Ltd

As an add-on treatment for severe refractory eosinophilic asthma in patients aged 12 years and over.

**ESBRIET** 29 Feb 2016

pirfenidone

Roche Products Pty Ltd

For the treatment of idiopathic pulmonary fibrosis (IPF).

Dossier received: 31/03/2015 Approved: 25/02/2016

# March

ORKAMBI • 08 March 2016

lumacaftor/ivacaftor

# Vertex Pharmaceuticals Australia Pty Ltd

For the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene.

UPTRAVI 🗘

selexipag

# Actelion Pharmaceuticals Australia Pty Ltd

For the treatment of:

- · idiopathic pulmonary arterial hypertension;
- heritable pulmonary arterial hypertension;
- pulmonary arterial hypertension associated with connective tissue disease;
- pulmonary arterial hypertension associated with congenital heart disease with repaired shunts;
- pulmonary arterial hypertension associated with drugs and toxins; in patients with WHO functional class II, III or IV symptoms.



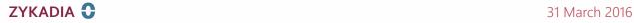
FARYDAK 31 March 2016

panobinostat (as lactate)

# Novartis Pharmaceuticals Australia Pty Ltd

In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.

Dossier received: 05/11/2014 Approved: 23/03/2016



ceritinib

# Novartis Pharmaceuticals Australia Pty Ltd

As monotherapy for the treatment of adult patients with ALK-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on or who are intolerant of crizotinib.

# **April**

KOVALTRY 01 April 2016

octocog alfa (bhk)

### Bayer Australia Ltd

For the treatment and prophylaxis of bleeding in patients of all ages with haemophilia A (congenital factor VIII deficiency).

COTELLIC 05 April 2016

cobimetinib (as fumarate)

# Roche Products Pty Ltd

For use in combination with ZELBORAF (vemurafenib) for the treatment of patients with unresectable or metastatic melanoma with BRAF V600 mutation.

SPEDRA 06 April 2016

avanafil

### A Menarini Australia Pty Ltd

For the treatment of erectile dysfunction in adult males.



HYQVIA 27 April 2016

normal immunoglobulin (human)/vorhyaluronidase alfa

# Baxalta Australia Pty Ltd

For replacement therapy in adults in:

- Primary Immunodeficiency Disease (PID); and
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.

OBIZUR C 29 April 2016

susoctocog alfa (bhk)

# Baxalta Australia Pty Ltd

For the treatment of bleeding episodes in adults with acquired haemophilia A.

Dossier received: 31/03/2015 Approved: 26/04/2016

# May

PRAXBIND 11 May 2016

idarucizumab (rch)

### Boehringer lngelheim Pty Ltd

For use as a specific reversal agent in patients treated with dabigatran etexilate (PRADAXA) when rapid reversal of the anticoagulant effects is required for emergency surgery/urgent procedures and in lifethreatening or uncontrolled bleeding.

PRALUENT 17 May 2016

alirocumab (rch)

# Sanofi-Aventis Australia Pty Ltd

For use as an adjunct to diet and exercise in adults with heterozygous familial hypercholesterolaemia or clinical atherosclerotic cardiovascular disease:

- in combination with a statin, or statin with other lipid-lowering therapies or;
- in combination with other lipid-lowering therapies in patients who are statin-intolerant.

Dossier received: 05/05/2015 Approved: 13/05/2016





**ZURAMPIC** 01 June 2016

lesinurad

# AstraZeneca Pty Ltd

For use in combination with a xanthine oxidase inhibitor for the treatment of hyperuricaemia associated with gout in patients who have not achieved target serum uric acid levels with an adequate dose of a xanthine oxidase inhibitor alone.

# July

BELKYRA 21 July 2016

deoxycholic acid

# Allergan Australia Pty Ltd

To be used for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

AFLURIA QUAD 22 July 2016

inactivated quadrivalent influenza vaccine (split virion)

### CSL Limited

For use in persons aged 18 years and over for the prevention of influenza caused by Influenza Virus. Types A and B contained in the vaccine.

ADDAVEN 29 July 2016

chromic chloride hexahydrate, cupric chloride dehydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride

# Fresenius Kabi Australia Pty Limited

For use to meet basal to moderately increased requirements of trace elements in parenteral nutrition in adults, when either oral or enteral nutrition is inappropriate.



ACARIZAX 01 August 2016

dermatophagoides pteronyssinus and dermatophagoides farina (American house dust mite extract, European house dust mite extract)

# Segirus Pty Ltd

For the treatment of adults diagnosed with house dust mite (HDM) allergic rhinitis not well controlled despite use of symptom relieving medication or HDM allergic asthma not well controlled by inhaled corticosteroids and associated with HDM allergic rhinitis.

TAGRISSO 03 August 2016

osimertinib mesilate

# AstraZeneca Pty Ltd

For the treatment of patients with locally advanced or metastatic EGFR T790M mutation-positive non-small cell lung cancer based on tumour response rate and duration of response.

BRIVIACT 04 August 2016

brivaracetam

# UCB Australia Pty Ltd T/A UCB Pharma Division of UCB Australia

For use as add-on therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients from 16 years of age with epilepsy.

HEXVIX 16 August 2016

hexaminolevulinate (as hydrochloride)

# Juno Pharmaceuticals Pty Ltd

For diagnostic use only, Hexvix blue light fluorescence cystoscopy is indicated as adjunct to standard white light cystoscopy to contribute to the diagnosis and management of bladder cancer in patients with known or high suspicion of bladder cancer.

**ZEPATIER** 29 August 2016

elbasvir/grazoprevir

Merck Sharp & Dohme (Australia) Pty Ltd

For the treatment of Chronic Hepatitis C genotype 1 or 4 infection in adults.

Dossier received: 10/09/2015 Approved: 25/08/2016



TALTZ 06 September 2016

ixekizumab

Eli Lilly Australia Pty Ltd

For the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IDELVION 😷

20 September 2016

albutrepenonacog alfa

CSL Behring Australia Pty Ltd

For use in all patients with haemophilia B for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
- Control and prevention of bleeding episodes;
- Control and prevention of bleeding in the perioperative setting.

**ZINBRYTA** 22 September 2016

daclizumab

Biogen Australia Pty Ltd

For the treatment of relapsing forms of multiple sclerosis (MS) to delay the progression of physical disability and to reduce the frequency of relapse.

**EMPLICITI** 22 September 2016

elotuzumab

Bristol-Myers Squibb Australia Pty Ltd

For use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.



# October

# **FLUMIST QUADRIVALENT**

18 October 2016

influenza virus A (H1N1)/influenza virus A (H3N2)/influenza virus B (Yamagata lineage)/influenza virus B (Victoria lineage) quadrivalent vaccine (live attenuated)

# AstraZeneca Pty Ltd

For the prevention of influenza in children and adolescents from 24 months to less than 18 years of age.

# **November**

PROLASTIN C 10 November 2016

alpha-1-proteinase inhibitor (human, Alpha1-PI)

# Grifols Australia Pty Ltd

Used to increase serum Alpha1-PI levels in adults with congenital deficiency of alpha-1 antitrypsin and with clinically significant emphysema (FEV1 <80%).

NINLARO 15 November 2016

ixazomib (as citrate)

# Takeda Pharmaceuticals Australia Pty Ltd

For use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

BELSOMRA 16 November 2016

suvorexant

# Merck Sharp & Dohme Australia Pty Ltd

For the treatment of insomnia, characterised by difficulties with sleep onset and/or sleep maintenance. Following initiation of treatment, continuation should be re-evaluated after 3 months.







01 December 2016

fomepizole

AFT Pharmaceuticals Pty Limited

For the treatment of ethylene glycol or methanol poisoning.

**DUAVIVE** 15 December 2016

conjugated estrogens/bazedoxifene

Pfizer Australia Pty Ltd

For the treatment of moderate to severe vasomotor symptoms associated with menopause in women with a uterus.

KYPROLIS 19 December 2016

carfilzomib

Amgen Australia Pty Ltd

For use in combination with dexamethasone or lenalidomide and dexamethasone, for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

**EPCLUSA** 19 December 2016

sofosbuvir/velpatasvir

Gilead Sciences Pty Ltd

For the treatment of chronic hepatitis C virus (HCV) infection (genotype 1, 2, 3, 4, 5 or 6) in adults.

**ONIVYDE** 19 December 2016

nanoliposomal irinotecan as sucrosofate

Baxalta Australia Pty Ltd

For the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil and folinic acid (leucovorin) in adult patients who have been previously treated with gemcitabine-based therapy.

# Australian Public Assessment Reports (AusPARs)

# 2016 chronological summary

Each AusPAR outlines the outcome of TGA's pre-market registration process for prescription medicines and provides a record of the scientific reasoning and risk-benefit considerations behind the regulatory decision. AusPARs have been published by TGA on our website since November 2009:

www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspar

# **January**

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Cervarix	human papillomavirus vaccine types 16 and 18 (recombinant AS04 adjuvanted)	GlaxoSmithKline Australia Pty Ltd	Approved	4 January 2016	Cervical lesions & cervical cancer
Pradaxa	dabigatran etexilate	Boehringer Ingelheim Pty Ltd	Approved	4 January 2016	Deep vein thrombosis & pulmonary embolism
Valcyte	valganciclovir	Roche Products Pty Ltd	Approved	5 January 2016	Cyto- megalovirus (CMV) retinitis
Cortiment	budesonide	Ferring Pharmaceuticals Pty Ltd	Approved	11 January 2016	Ulcerative colitis
Zerbaxa	ceftolozane (as sulfate)/ azobactam (as sodium salt)	Merck Sharp & Dohme Australia Pty Ltd	Approved	27 January 2016	Intra-abdominal & urinary tract infections



# February

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Imbruvica	ibrutinib	Janssen-Cilag Pty Ltd	Approved	2 February 2016	Leukaemia & lymphoma
Revlimid	lenalidomide	Celgene Pty Ltd	Approved	5 February 2016	Multiple myeloma
Ofev/Vargatef	nintedanib esilate	Boehringer Ingelheim Pty Ltd	Approved	8 February 2016	Lung cancer & idiopathic pulmonary fibrosis (IPF)
Zevtera	ceftobiprole medocaril sodium	JACE Pharma Pty Ltd	Approved	8 February 2016	Pneumonia
Lonquex	lipegfilgrastim (rbe)	Teva Pharma Australia Pty Ltd	Approved	23 February 2016	Neutropenia
Velcade	bortezomib	Janssen-Cilag Pty Ltd	Approved	26 February 2016	Mantle cell lymphoma

# March

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Saxenda	liraglutide	Novo Nordisk Pharmaceuticals Pty Ltd	Approved	23 March 2016	Weight management
Xtandi	enzalutamide	Astellas Pharma Australia Pty Ltd	Approved	23 March 2016	Prostate cancer
Revolade	eltrombopag	Novartis Pharmaceuticals Australia Pty Ltd	Approved	30 March 2016	Severe aplastic anaemia

# **April**

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Afoila/ Bemfola	follitropin alfa (rch)	Finox Biotech Australia Pty Ltd	Approved	8 April 2016	Infertility

# May

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Repatha	evolocumab (rch)	Amgen Australia Pty Ltd	Approved	3 May 2016	Cardiovascular disease
Nuvigil	armodafinil	Teva Pharmaceuticals Australia Pty Ltd	Approved	26 May 2016	Narcolepsy
Imlygic	talimogene laherparepvec	Amgen Australia Pty Ltd	Approved	31 May 2016	Melanoma

# June

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Movantik	naloxegol oxalate	AstraZeneca Pty Ltd	Approved	1 June 2016	Opioid- induced constipation
Nuwiq	simoctocog alfa rhu	Octapharma Australia Pty Ltd	Approved	7 June 2016	Haemophilia A
Proshaeos	alprostadil	Commercial Eyes Pty Ltd	Withdrawn	9 June 2016	N/A *
Perjeta	pertuzumab	Roche Products Pty Limited	Approved	16 June 2016	Breast cancer
Xolair	omalizumab (rch)	Novartis Australia Pty Ltd	Approved	22 June 2016	Asthma
Genvoya	cobicistat/ emtricitabine/ tenofovir alafenamide (as fumarate)/ elvitegravir	Gilead Sciences Pty Ltd	Approved	28 June 2016	Human Immuno- deficiency Virus (HIV)

<sup>\*</sup> Already approved for use in erectile dysfunction



# July

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Strensiq	asfotase alfa (rch)	Alexion Pharmaceuticals Australia Pty Ltd	Approved	1 July 2016	Paediatric hypo- phosphatasia
Gliclazide GPPL MR 30	gliclazide	Generic Partners Pty Ltd	Withdrawn	19 July 2016	N/A
Humira	adalimumab (rch)	AbbVie Pty Ltd	Approved	12 July 2016	Hidradenitis suppurativa (acne inversa)

# August

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Xiaflex	collagenase clostridium histolyticum	Actelion Pharmaceuticals Australia Pty Ltd	Approved	2 August 2016	Peyronie's disease
Esbriet	pirfenidone	Roche Products Pty Ltd	Approved	9 August 2016	Idiopathic pulmonary fibrosis (IPF)
Selincro	nalmefene (as hydrochloride dihydrate)	Lundbeck Australia Pty Ltd	Approved	9 August 2016	Alcohol use disorder
Opdivo	nivolumab	Bristol-Myers Squibb Australia Pty Ltd	Approved	23 August 2016	Melanoma & lung cancer
Lenvima	lenvatinib mesilate	Eisai Australia Pty Ltd	Approved	30 August 2016	Thyroid cancer

# September

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Orkambi 200/125	ivacaftor/ lumacaftor	Vertex Pharmaceuticals Australia Pty Ltd	Approved	8 September 2016	Paediatric cystic fibrosis
Zurampic	lesinurad	AstraZeneca Pty Ltd	Approved	20 September 2016	Hyper- uricaemia & gout
Entresto/ Novartis Sacubitril/ Valsartan	sacubitril/ valsartan salt complex	Novartis Pharmaceuticals Australia Pty Ltd	Approved	23 September 2016	Chronic heart failure
Actemra	tocilizumab (rch)	Roche Products Pty Ltd	Approved	29 September 2016	Rheumatoid arthritis



# October

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Keytruda	pembrolizumab (rch)	Merck Sharp & Dohme (Australia) Pty Ltd	Approved	14 October 2016	Melanoma
Esmya	ulipristal acetate	Vifor Pharma Pty Ltd	Approved	19 October 2016	Uterine fibroids
Cosentyx/ Zafrez	secukinumab	Novartis Pharmaceuticals Australia Pty Ltd	Approved	25 October 2016	Psoriatic arthritis & ankylosing spondylitis
Ozurdex	dexamethasone	Allergan Australia Pty Ltd	Approved	25 October 2016	Diabetic macular oedema (DME)
Praxbind	idarucizumab	Boehringer Ingelheim Pty Ltd	Approved	25 October 2016	Bleeding
Spedra	avanafil	A Menarini Australia Pty Ltd	Approved	27 October 2016	Erectile dysfunction
Akynzeo	netupitant/ palonosetron (as hydrochloride)	Specialised Therapeutics Australia Pty Ltd	Approved	28 October 2016	Nausea & vomiting associated with cancer chemotherapy

# November

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Uptravi	selexipag	Actelion Pharmaceuticals Pty Ltd	Approved	8 November 2016	Pulmonary arterial hypertension
Truvada	emtricitabine/ tenofovir disoproxil fumarate	Gilead Sciences Pty Ltd	Approved	10 November 2016	Human Immuno- deficiency Virus (HIV)
Spiriva Respimat/ Favint Respimat	tiotropium bromide	Boehriger Ingelheim Pty Limited	Approved	25 November 2016	Bronchodilator treatment

# December

Trade name	Active ingredient	Sponsor	Decision	AusPAR date	Therapeutic use
Seasonique	levonorgestrel /ethinyl- oestradiol	Teva Pharma Australia Pty Ltd	Approved	9 December 2016	Oral contraceptive
Transtec	buprenorphine	Mundipharma Pty Ltd	Rejected	13 December 2016	N/A *
Praluent (Golyra/ Eliriduc)	alirocumab (rch)	Sanofi-Aventis Australia Pty Ltd	Approved	13 December 2016	Cholesterol management
Descovy	emtricitabine/ tenofovir alafenamide (as fumarate)	Gilead Sciences Pty Ltd	Approved	20 December 2016	Human Immuno- deficiency Virus (HIV)

<sup>\*</sup> Already approved for use in the treatment of pain and opiate dependence.



ISSN: 2204-9843 (print)

ISSN: 2207-6840 (online)

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