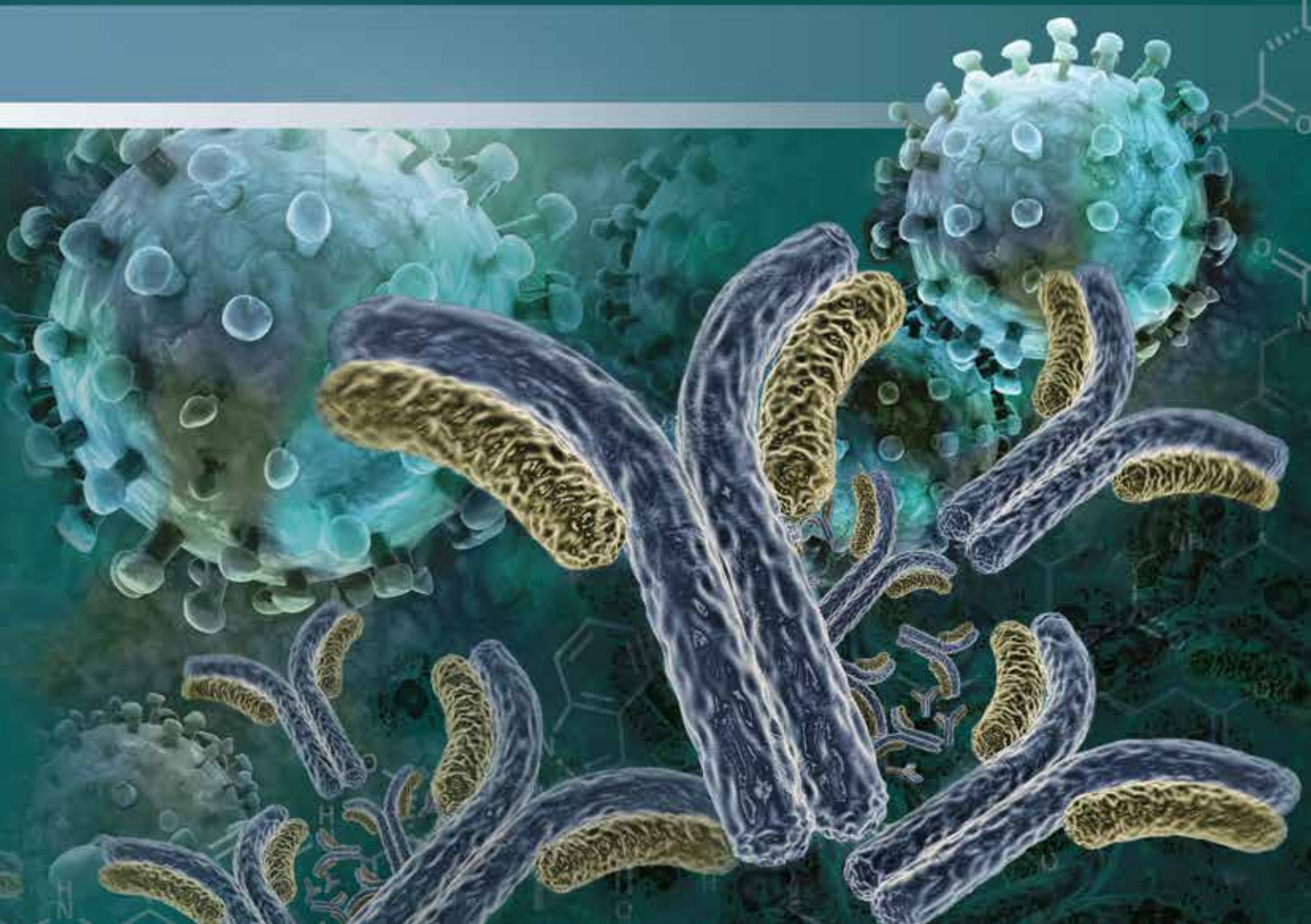
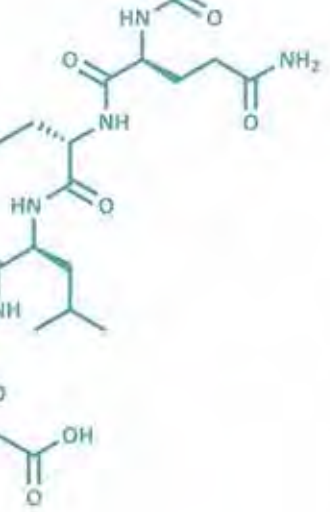
Australian Government

Department of Health

Therapeutic Goods Administration

Prescription medicines: annual summary 2015





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Prescription medicines: annual summary 2015

Each year, the Therapeutic Goods Administration (TGA) receives thousands of applications to register new and vary existing prescription medicines. This Annual Summary provides consolidated information on new medicines containing novel active ingredients, and significant variations that relate to new or extended therapeutic uses of a previously registered prescription medicine.

The 2015 registrations covered a broad therapeutic base, with new treatments for a number of diseases including Hepatitis C, HIV and arthritis. During this period, a first-in-class treatment for hypercholesterolaemia was approved. Notably, almost one third of these new medicines were within the fields of oncological and haematological medicine, with eleven new registrations. The approval of these new prescription medicines provides prescribers with additional treatment options, which will ultimately serve to enhance public health in Australia.

It is imperative that Australians have timely access to therapeutic goods. To this end, we have endeavoured to streamline our registration processes for prescription medicines. Performance data collected over 2015 has shown that recent reforms have delivered greater overall timeliness and predictability with respect to pre-market registration activities. On average, it takes 12 months for the TGA to register a new prescription medicine, having assessed the scientific data available and established that the medicine meets appropriate standards of quality, safety and efficacy. The TGA's approval times for medicines containing new active ingredients are comparable with analogous processes in major jurisdictions such as the US and Europe. This Annual Summary has provided us with an opportunity to increase transparency around our approval times and includes key dates in relation to the registration process for each medicine.

Our work to safeguard the health of the Australian community will continue through our post market monitoring of these products to determine how they perform when they are used more widely in the Australian population.

I hope you enjoy reading the Annual Summary and that the information continues to be useful to the Australian public, prescribers, healthcare professionals, other government agencies and industry bodies, as we work together towards better health outcomes for all Australians.

Adjunct Professor John Skerritt

Deputy Secretary
Regulatory Services Group

April 2016

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

HARVONI

Harvoni is a combination of two anti-viral medicines (ledipasvir and sofosbuvir) used to treat hepatitis C. Harvoni is the first once-daily single tablet for the treatment of chronic hepatitis C.

ILEVRO

Ilevro (nepafenac) is a non-steroidal anti-inflammatory eye-drop that is used to reduce the pain and inflammation resulting from cataract surgery. Ilevro passes through the cornea where it is converted to its active metabolite by enzymes in the eye. Ilevro is administered as one drop per day, starting the day before surgery and continuing for up to two weeks following surgery.

IMBRUVICA

Imbruvica (ibrutininb) is used to treat patients with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) or mantle cell lymphoma (MCL). All of these diseases involve the proliferation of lymphocytes. Imbruvica acts by binding to a particular enzyme (Bruton's tyrosine kinase), which in turn inhibits the proliferation of B lymphocytes.

IMLYGIC

Imlygic (talimogene laherparepvec) is used to treat melanoma lesions in the skin and lymph nodes. Imlygic, a genetically modified live herpes virus, is used to treat melanoma lesions that cannot be removed completely by surgery. Imlygic is injected directly into the melanoma lesions, where it replicates inside cancer cells and causes the cells to rupture and die.

KEYTRUDA

Keytruda (pembrolizumab) is used to treat unresectable (inoperable) or metastatic melanoma. Keytruda works by targeting a protein on the surface of immune cells that stops them from attacking the melanoma cells.

OPTAFLU

Optaflu is a vaccine used to prevent influenza (flu). Unlike other flu vaccines, Optaflu is produced using cultured cells rather than chicken eggs. Therefore, Optaflu is free of chicken/egg protein and is safe for use in individuals with allergies to eggs. Also, because of the manufacturing method, Optaflu can be rapidly produced during times of need such as a potential pandemic.

VIEKIRA PAK and VIEKIRA PAK-RBV

Viekira Pak is a combination pack of two different tablets. One tablet contains ombitasvir, paritaprevir and ritonavir and the other contains dasabuvir. The combination is used to treat patients with chronic hepatitis C, including those with cirrhosis. Viekira Pak can also be used in combination with the nucleoside inhibitor ribavirin in some patients (Viekira Pak-RBV).

REPATHA

Repatha (evolocumab) is an injection that can be used in patients who are unable to control their low-density lipoprotein (LDL) cholesterol with current treatment options such as statins, diet and exercise. Repatha is an antibody that binds and blocks a specific protein (PCSK9), which reduces the ability of the liver to remove LDL cholesterol from the blood. By blocking PCSK9, the liver is more able to get rid of LDL cholesterol from the blood.

SELINCRO

Selincro (nalmefene) is used in association with counselling, to reduce high levels of alcohol consumption in patients with alcohol dependence. Selincro is a tablet that is taken once a day and works by affecting processes in the brain that are responsible for the urge to continue drinking.

TRULICITY

Trulicity (dulaglutide) is a once-weekly subcutaneous injection used, together with diet and exercise, to improve blood sugar levels in patients with type 2 diabetes. Trulicity acts by mimicking the naturally occurring peptide, glucagon, a hormone that helps to control blood sugar levels.

Some new or extended uses for existing medicines

Patients will also benefit from the approval of existing prescription medicines for new or extended therapeutic uses. From mid-2016, details relating to new or extended uses of registered prescription medicines will be published on the TGA website.

CORTIMENT

Cortiment (budesonide) is a corticosteroid available in different preparations for the treatment of various inflammatory diseases including ulcerative colitis (UC). Budesonide is absorbed relatively poorly from the gut when given orally which has the advantage of causing less systemic side-effects than other oral corticosteroids. Cortiment dissolves slowly in the gut and continues to release the active ingredient as it passes through the large intestine where it can act locally at the site of disease.

A new, prolonged-release budesonide tablet has been approved for short term use which will now include induction of remission in patients with mild to moderate ulcerative colitis.

ELIQUIS

Eliquis (apixaban) has been registered since 2011 for the prevention of blood clots following hip and knee replacement surgery and for the prevention of blood clots and stroke in patients with atrial fibrillation.

Eliquis is now indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and for prevention of recurrent DVT and PE in adults.

ENBREL

Enbrel (etanercept) has been registered since 2003 for the treatment of inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, plaque psoriasis and ankylosing spondylitis.

Enbrel is now indicated for use in adult patients with active non-radiographic axial spondyloarthritis (a form of ankylosing spondylitis that cannot be detected on an X-ray) and is the first medicine to be specifically approved for this condition.

KINERET

Kineret (anakinra) has been registered since 2003, in combination with methotrexate, for the treatment of rheumatoid arthritis.

Kineret is now also indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in children aged two years and above.

PRADAXA

Pradaxa (dabigatran) has been registered since 2008 for the prevention of blood clots following major total hip or knee replacement and for prevention of stroke and blood clots in patients with atrial fibrillation.

Pradaxa is now indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT and PE in adults.

SAXENDA

Liraglutide has been registered since 2010, in combination with other medicines, for the treatment of patients with type 2 diabetes.

Saxenda is a new presentation of liraglutide that is approved for use in chronic weight management in obese or overweight patients, in conjunction with a reduced-calorie diet and increased physical activity.

SPIRIVA

Spiriva (tiotropium) has been registered since 2002 for the treatment and prevention of bronchospasms associated with chronic obstructive pulmonary disease.

Spiriva is now approved for use as an add-on bronchodilator in adult asthma patients, in addition to existing inhaled corticosteroids and β2-agonists.

STELARA

Stelara (ustekinumab) has been registered since 2009 for the treatment of plaque psoriasis.

Stelara is now approved for the treatment of psoriatic arthritis in adult patients where other treatments have been inadequate. Stelara may be used alone or in combination with methotrexate.

STRIBILD

Stribild has been registered since 2013 as a first line treatment for HIV infection. It is an oral antiviral medicine consisting of a combination of four active ingredients (tenofovir disoproxil fumarate, emtricitabine, elvitegravir and cobicistat).

Stribild can now be used in HIV infected patients who have already been stabilised on other antiviral treatments, thereby potentially replacing multiple medicines with a single, once-daily tablet.

New registrations by therapeutic area

Cardiovascular, Metabolic and Musculoskeletal disorders

CARBAGLU carglumic acid

CERDELGA eliglustat (as tartrate)

FOLOTYN pralatrexate

OTEZLA apremilast

RENVELA sevelamer carbonate

REPATHA evolocumab (rch)

XELJANZ tofacitinib (as citrate)

Immunomodulators, Antineoplastics and Antiemetic Agents

AKYNZEO netupitant/palonosetron (as hydrochloride)

BLINCYTO blinatumomab (rch)

COSENTYX secukinumab (rch)

CYRAMZA ramucirumab

IMBRUVICA ibrutinib

IMLYGIC talimogene laherparepvec

KEYTRUDA pembrolizumab

LONQUEX lipegfilgrastim (rbe)

ODOMZO sonidegib diphosphate

OFEV nintedanib (as esilate)

SYLVANT siltuximab (rmc)

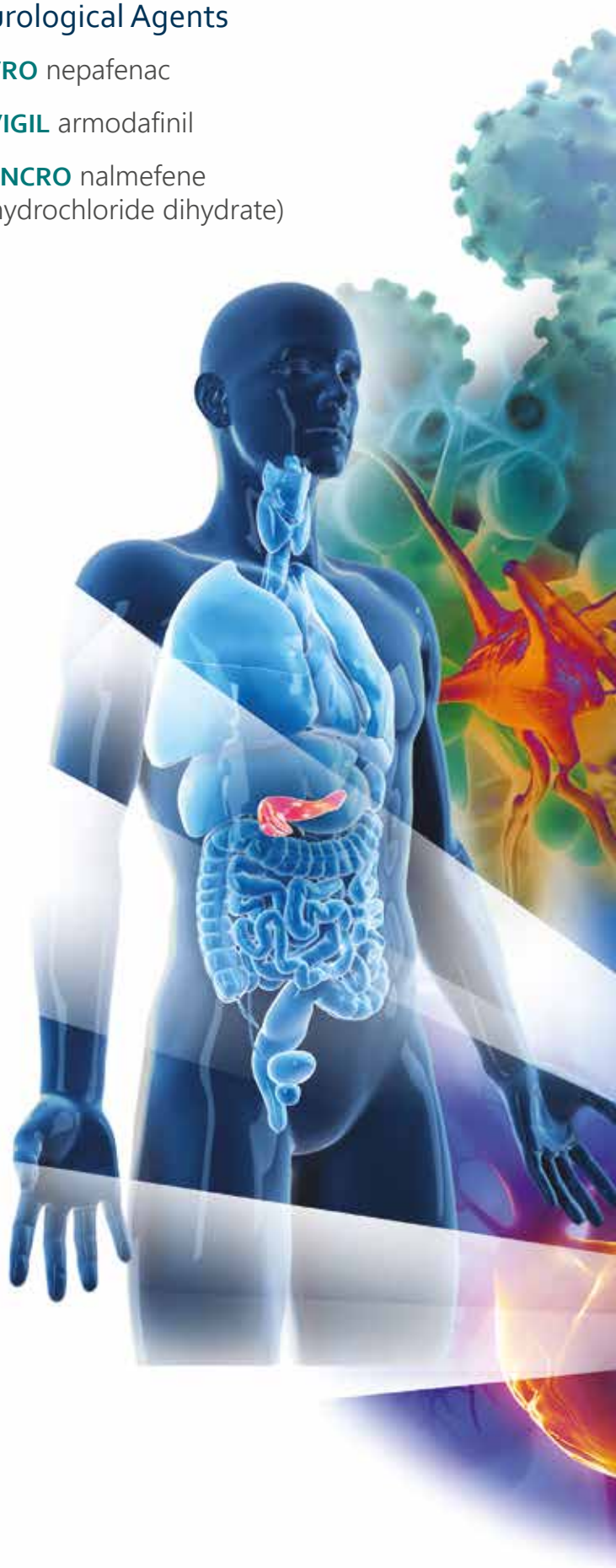
ZYDELIG idelalisib

Antidotes, Analgesics and Neurological Agents

ILEVRO nepafenac

NUVIGIL armodafinil

SELINCRO nalmefene (as hydrochloride dihydrate)



Endocrine, Gynaecological, Fluid and Electrolyte Agents

ALBUNATE 20 human albumin

DECAPEPTYL triptorelin acetate

ELLAONE ulipristal acetate

TRULICITY dulaglutide (rch)

Anti-Infectives and Vaccines

DAKLINZA daclatasvir (as dihydrochloride)

GARDASIL 9 human papillomavirus 9-valent vaccine

HARVONI ledipasvir/sofosbuvir

OPTAFLU inactivated influenza virus vaccine

SUNVEPRA asunaprevir

VIEKIRA PAK paritaprevir/ritonavir/ ombitasvir and dasabuvir (as sodium salt)

VIEKIRA PAK-RBV paritaprevir/ritonavir/ ombitasvir and dasabuvir (as sodium salt) and ribavirin

ZERBAXA ceftolozane sulfate/ tazobactam sodium

ZEVTERA ceftobiprole medocaril sodium

2015 Chronological summary

Orphan drug	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

COSENTYX

12 Jan 2015

secukinumab (rch)

Novartis Pharmaceuticals Australia Pty Ltd

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

Dossier received: 8/01/2014. Approved: 8/01/2015

TRULICITY

19 Jan 2015

dulaglutide (rch)

Eli Lilly Australia Pty Ltd

In addition to diet and exercise, to improve glycaemic control in adults with type 2 diabetes mellitus:

- as monotherapy or
- in combination with certain oral glucose-lowering medications or
- in combination with prandial insulin, with or without metformin.

Dossier received: 6/12/2013. Approved: 22/12/2014

February

XELJANZ

5 Feb 2015

tofacitinib (as citrate)

Pfizer Australia Pty Ltd

For the treatment of moderate to severe active rheumatoid arthritis in adults who have had an inadequate response or are intolerant to previous disease-modifying antirheumatic drug (DMARD) therapy. Can be used alone or in combination with DMARDS, including methotrexate.

For the treatment of the signs and symptoms of moderate to severe active rheumatoid arthritis in adults who have had an inadequate response or are intolerant to methotrexate. Can be used alone or in combination with nonbiological DMARDs, including methotrexate.

Dossier received: 4/05/2012. Approved: 13/01/2015

ZYDELIG

9 Feb 2015

idelalisib

Gilead Sciences Pty Ltd

For the treatment of patients with refractory follicular lymphoma, who have received at least 2 prior systemic therapies.

In combination with rituximab, for the treatment of patients with chronic lymphocytic leukaemia (CLL)/ small lymphocytic lymphoma (SLL) for whom chemo-immunotherapy is not considered suitable, either:

- upon relapse after at least one prior therapy or
- as first-line treatment in the presence of 17p deletion or TP53 mutation.

Dossier received: 8/01/2014 . Approved: 30/01/2015

CARBAGLU

12 Feb 2015

carglumic acid

Emerge Health Pty Ltd

For the treatment of hyperammonaemia due to N-acetylglutamate synthase primary deficiency and hyperammonemia due to organic acidaemias.

Dossier received: 8/10/2013. Approved: 30/01/2015

CERDELGA

17 Feb 2015

eliglustat (as tartrate)

Sanofi-Aventis Australia Pty Ltd

For the long-term treatment of adults with Gaucher disease type 1 (GD1).

Dossier received: 9/12/2013. Approved: 10/02/2015

FOLOTYN

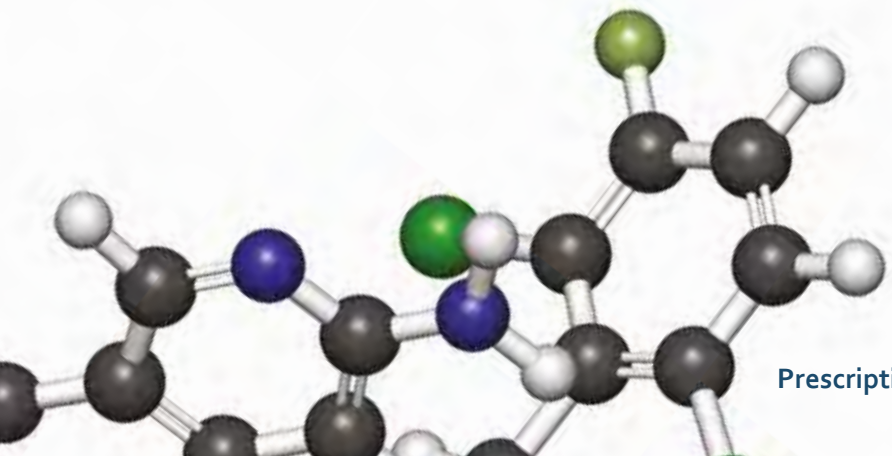
26 Feb 2015

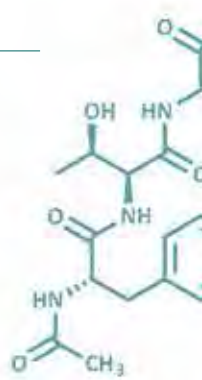
pralatrexate

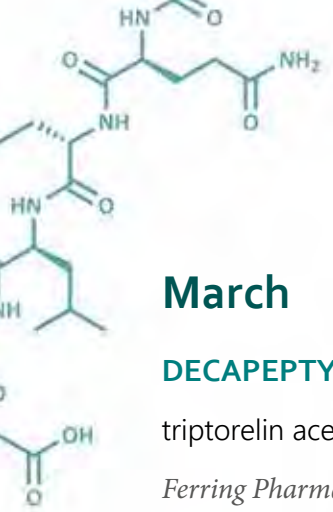
Mundipharma Pty Ltd

For the treatment of adult patients with peripheral T-cell lymphoma (nodal, extranodal, and leukaemic/disseminated) who have progressed after at least one prior therapy.

Dossier received: 8/04/2012. Approved: 22/01/2015







March

DECAPEPTYL

4 Mar 2015

triptorelin acetate

Ferring Pharmaceuticals Pty Ltd

For down-regulation and prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation for assisted reproductive technologies (ART).

Dossier received: 6/02/2014. Approved: 26/02/2015

ELLAONE

6 Mar 2015

ulipristal acetate

MS Health Pty Ltd

For emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

Dossier received: 6/02/2014. Approved: 25/02/2015

OPTAFLU

13 Mar 2015

inactivated influenza virus vaccine

bioCSL Pty Ltd

For the prevention of influenza caused by Influenza Virus Types A and B in adults over 18 years of age.

Dossier received: 7/03/2014. Approved: 3/03/2015

OTEZLA

19 Mar 2015

apremilast

Celgene Pty Ltd

For the treatment of:

- signs and symptoms of active psoriatic arthritis in adult patients
- adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Dossier received: 4/03/2014. Approved: 12/03/2015

April

KEYTRUDA

16 Apr 2015

pembrolizumab

Merck Sharp & Dohme (Australia) Pty Ltd

As monotherapy for the treatment of unresectable or metastatic melanoma in adults.

Dossier received: 6/08/2014. Approved: 15/04/2015

RENVELA

20 Apr 2015

sevelamer carbonate

Sanofi-Aventis Australia Pty Ltd

For the management of hyperphosphataemia in adult patients with stage 4 and 5 chronic kidney disease.

Dossier received: 11/03/2014. Approved: 14/04/2015

IMBRUVICA

20 Apr 2015

ibrutinib

Janssen-Cilag Pty Ltd

For the treatment of:

- patients with chronic lymphocytic leukaemia (CLL)/ small lymphocytic lymphoma (SLL) who have received at least one prior therapy or as first line in patients with CLL with 17p deletion
- patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

Dossier received: 1/10/2014. Approved: 15/04/2015

May

AKYNZEO

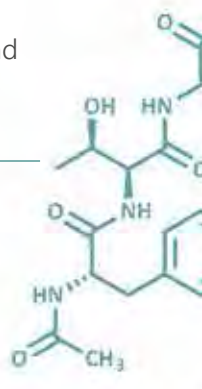
6 May 2015

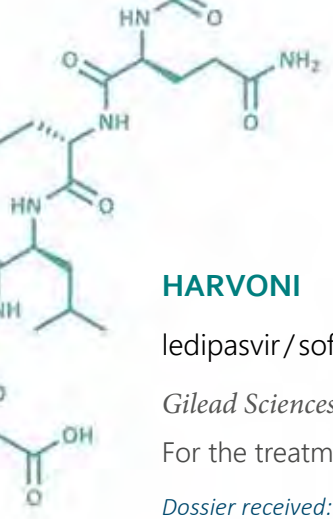
netupitant / palonosetron (as hydrochloride)

Specialised Therapeutics Pty Ltd

In adult patients for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy.

Dossier received: 2/04/2014. Approved: 4/05/2015





HARVONI

13 May 2015

ledipasvir / sofosbuvir

Gilead Sciences Pty Ltd

For the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.

Dossier received: 2/05/2014. Approved: 8/05/2015

SUNVEPRA

25 May 2015

asunaprevir

Bristol-Myers Squibb Australia Pty Ltd

In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults with compensated liver disease (including cirrhosis).

Dossier received: 8/05/2014. Approved: 21/05/2015

June

SELINCRO

17 Jun 2015

nalmefene (as hydrochloride dihydrate)

Lundbeck Australia Pty Ltd

For the reduction of alcohol consumption in adult patients with alcohol use disorder who have an average daily consumption of alcohol of more than 60 g for men and more than 40 g for women.

Dossier received: 10/10/2013. Approved: 4/06/2015

DAKLINZA

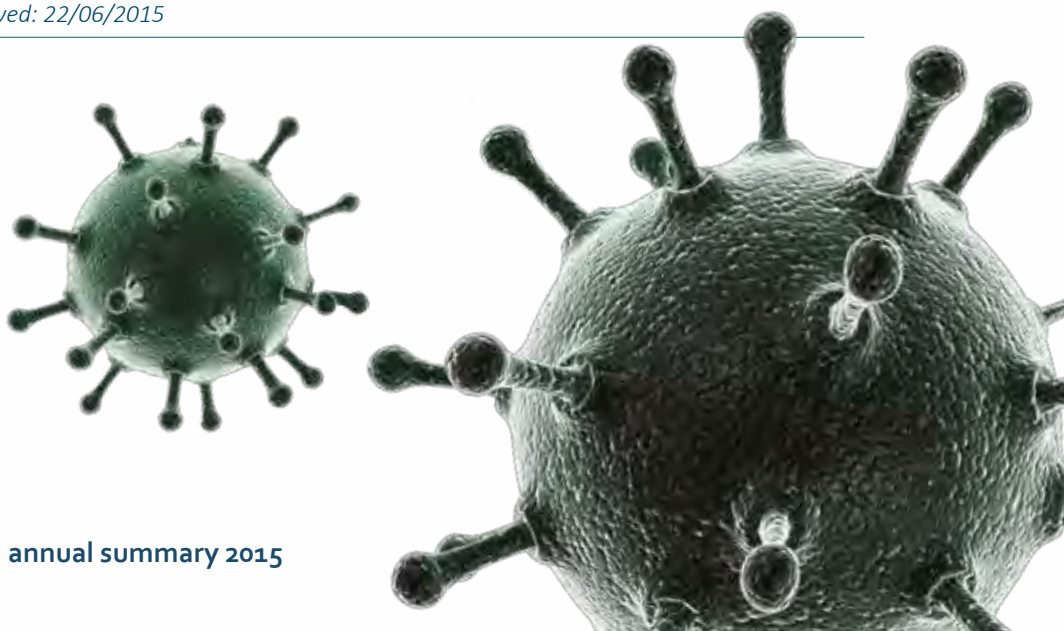
25 Jun 2015

daclatasvir (as dihydrochloride)

Bristol-Myers Squibb Australia Pty Ltd

In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults with compensated liver disease (including cirrhosis).

Dossier received: 7/05/2014. Approved: 22/06/2015



GARDASIL 9

29 Jun 2015

human papillomavirus 9-valent vaccine

Merck Sharp & Dohme Australia Pty Ltd

For use in females aged 9 through 45 years for the prevention of cervical, vulvar, vaginal and anal cancer, precancerous or dysplastic lesions, genital warts, and infection caused by Human Papillomavirus (HPV) Types 6, 11, 16, 18, 31, 33, 45, 52 and 58 (which are included in the vaccine).

For use in males 9 through 26 years of age for the prevention of anal cancer, precancerous or dysplastic lesions, external genital lesions and infection caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 (which are included in the vaccine).

Dossier received: 5/06/2014. Approved: 22/06/2015

July

VIEKIRA PAK

10 Jul 2015

paritaprevir / ritonavir / ombitasvir tablets
dasabuvir (as sodium salt) tablets

Abbvie Pty Ltd

For the treatment of genotype 1 chronic hepatitis C infection, including patients with compensated cirrhosis.

Dossier received: 4/07/2014. Approved: 1/07/2015

VIEKIRA PAK-RBV

21 Jul 2015

paritaprevir / ritonavir / ombitasvir tablets
dasabuvir (as sodium salt) tablets
ribavirin tablets

Abbvie Pty Ltd

For the treatment of genotype 1 chronic hepatitis C infection, including patients with compensated cirrhosis.

Dossier received: 4/07/2014. Approved: 1/07/2015

CYRAMZA

23 Jul 2015

ramucirumab

Eli Lilly Pty Ltd

In combination with paclitaxel, for the treatment of adult patients with advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluropyrimidine chemotherapy.

As monotherapy, for the treatment of adult patients with advanced or metastatic gastric or gastro oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy when treatment in combination with paclitaxel is not appropriate.

Dossier received: 3/09/2014. Approved: 9/07/2015

ALBUNATE 20

30 Jul 2015

human albumin

CSL Behring Australia Pty Ltd

For the restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid is appropriate.

Dossier received: 6/06/2014. Approved: 15/07/2015

August

ODOMZO

10 Aug 2015

sonidegib diphosphate

Novartis Pharmaceuticals Australia Pty Ltd

For the treatment of adult patients with:

- locally advanced basal cell carcinoma (BCC) who are not amenable to curative surgery or radiation therapy
- metastatic BCC.

Dossier received: 7/08/2014. Approved: 6/08/2015

SYLVANT

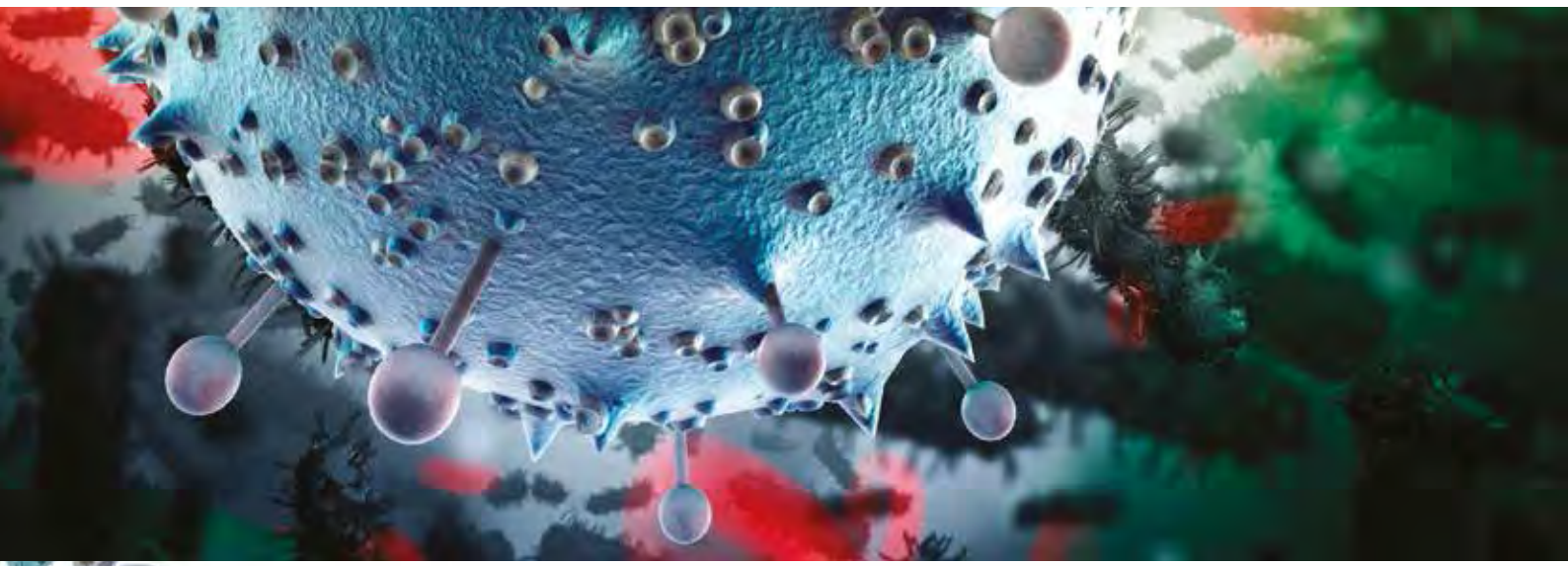
31 Aug 2015

siltuximab (rmc)

Janssen-Cilag Pty Ltd

For the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Dossier received: 4/11/2014. Approved: 27/08/2015



September

OFEV

1 Sep 2015

nintedanib (as esilate)

Boehriinger Ingelheim Pty Ltd

For use in combination with docetaxel for the treatment of patients with locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after failure of first line chemotherapy.

For the treatment of Idiopathic Pulmonary Fibrosis (IPF).

Dossier received: 1/08/2014. Approved: 27/08/2015

November

ZERBAXA

4 Nov 2015

ceftolozane sulfate / tazobactam sodium

Merck Sharp & Dohme (Australia) Pty Ltd

For the treatment of:

- complicated intra-abdominal infections in combination with metronidazole and
- complicated urinary tract infections, including pyelonephritis

in adults suspected or proven to be caused by designated susceptible microorganisms.

Dossier received: 29/10/2014. Approved: 29/10/2015

ILEVRO

4 Nov 2015

nepafenac

Alcon Laboratories Australia Pty Ltd

For the prevention and treatment of postoperative pain and inflammation associated with cataract surgery.

Dossier received: 7/11/2014. Approved: 3/11/2015

BLINCYTO

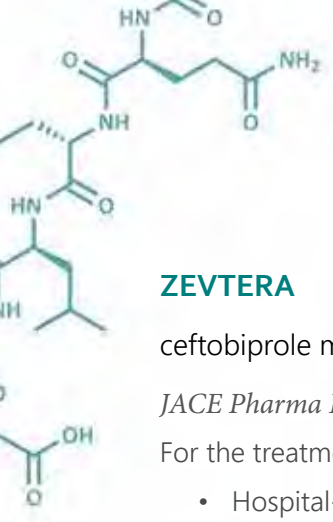
9 Nov 2015

blinatumomab (rch)

Amgen Australia Pty Ltd

For the treatment of adults with Philadelphia chromosome-negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).

Dossier received: 5/01/2015. Approved: 30/10/2015



ZEVTERA

10 Nov 2015

ceftobiprole medocaril sodium

JACE Pharma Pty Ltd

For the treatment of:

- Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP)
- Community-acquired pneumonia (CAP)

in adults suspected or proven to be caused by designated susceptible microorganisms.

Dossier received: 29/10/2014. Approved: 2/11/2015

LONQUEX

12 Nov 2015

lipegfilgrastim (rbe)

Teva Pharma Australia Pty Ltd

For the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Dossier received: 18/12/2014. Approved: 29/10/2015

NUVIGIL

26 Nov 2015

armodafinil

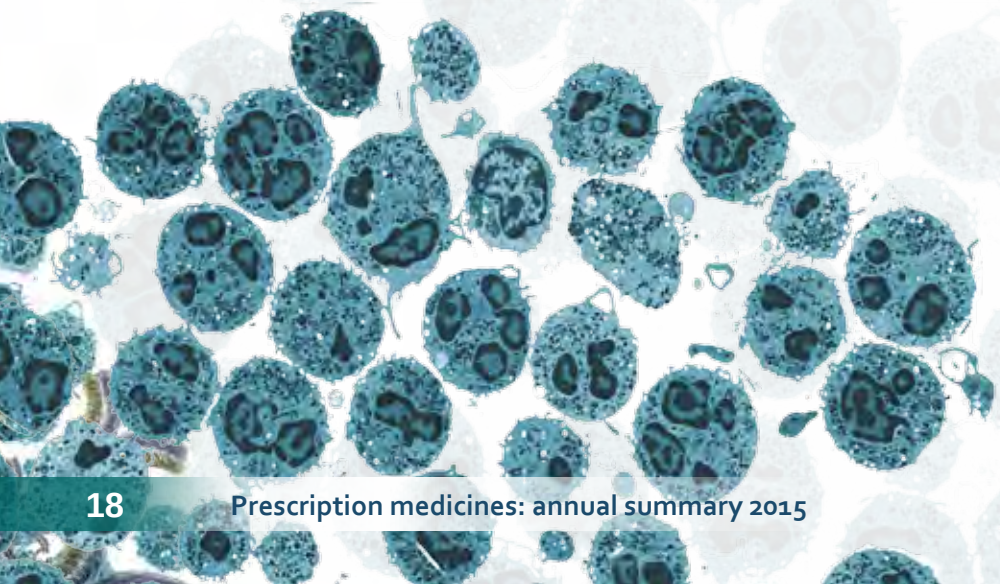
Teva Pharma Australia Pty Ltd

To improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.

To treat excessive sleepiness associated with moderate to severe chronic shift work sleep disorder where non-pharmacological interventions are unsuccessful or inappropriate.

As an adjunct to continuous positive airways pressure (CPAP) in obstructive sleep apnoea/hypopnoea syndrome in order to improve wakefulness.

Dossier received: 1/08/2014. Approved: 24/11/2015



December

REPATHA

9 Dec 2015

evolocumab (rch)

Amgen Australia Pty Ltd

As an adjunct to diet and exercise in:

- adults with heterozygous familial hypercholesterolaemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD):
  - 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
- adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid lowering therapies.

Dossier received: 17/11/2014. Approved: 4/12/2015

IMLYGIC

21 Dec 2015

talimogene laherparepvec

Amgen Australia Pty Ltd

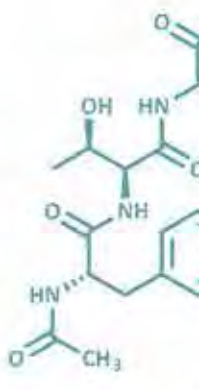
As monotherapy for the treatment of melanoma in patients with unresectable cutaneous, subcutaneous or nodal lesions after initial surgery.

Dossier received: 8/12/2014. Approved: 18/12/2015

Please refer to the Australian Register of Therapeutic Goods (ARTG) for the full wording of each indication.

The trade name, sponsor and active ingredient for each medicine reflects the information in the ARTG at the time of publication. The publicly accessible version of the ARTG is the reference database of the TGA. It provides current information on therapeutic goods that can be supplied in Australia.

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



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