

Question on notice no. 488

Portfolio question number: SQ18-000916

2018-19 Budget estimates

Community Affairs Committee, Health Portfolio

Senator Murray Watt: asked the Department of Health on 30 May 2018—

The Department has previously provided a list of medicines/vaccines that have been recommended by the PBAC but not yet listed on the PBS/NIP (SQ17-1115) . Please provide an updated list of medicines/vaccines that have been recommended by the PBAC but not listed on the PBS/NIP as of the date of the Department's response.

Answer —

Please see the attached answer.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2018 - 2019, 29 & 30 May 2018

Ref No: SQ18-000916

OUTCOME: 4 - Individual Health Benefits

Topic: PBAC recommendations

Type of Question: Written Question on Notice

Senator: Murray Watt

Question:

The Department has previously provided a list of medicines/vaccines that have been recommended by the PBAC but not yet listed on the PBS/NIP (SQ17-1115).

Please provide an updated list of medicines/vaccines that have been recommended by the PBAC but not listed on the PBS/NIP as of the date of the Department's response.

Answer:

The medicines and vaccines with a positive recommendation from the PBAC that are yet to be listed on the PBS are tabulated below. This information is current as of 9 October 2018.

- Please note – the information below is accurate as at 9 October 2018

PBAC Meeting July 2018		
MEDICINE	INDICATION	STATUS
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe; Injection 80 mg in 0.8 mL pre-filled pen Humira® AbbVie Pty Ltd	Severe active rheumatoid arthritis; Sever psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Sever active juvenile idiopathic arthritis; Sever Crohn disease; Refractory fistulating Crohn disease; Moderate to severe ulcerative colitis; Moderate to severe hidradenitis suppurativa	Negotiations with sponsor are continuing
ADALIMUMAB; Injection 20 mg in 0.4 mL pre-filled syringe; Injection 40 mg in 0.8 mL pre-filled syringe; Injection 40 mg in 0.8 mL pre-filled pen Amgevita® Amgen Australia Pty Limited	Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Severe active juvenile idiopathic arthritis; Severe Crohn disease; Refractory fistulating Crohn disease; Moderate to severe ulcerative colitis; Moderate to severe hidradenitis suppurativa	Sponsor advised that not currently progressing
ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled syringe; Injection 40 mg in 0.8 mL single dose autoinjector Hadlima® Merck Sharp & Dohme (Australia) Pty Ltd	Severe active rheumatoid arthritis (RA)	Sponsor advised that not currently progressing
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS, WITHOUT PHENYLALANINE AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID Oral powder 400 g ; Oral liquid 500 mL, 20 PKU Start®; PKU Baby®; VitaFlo Australia Pty Ltd Orpharma Pty Ltd	Phenylketonuria	Negotiations with sponsor are continuing
APOMORPHINE Injection containing apomorphine hydrochloride 30 mg in 3 mL cartridge Apomine® Intermittent Pfizer Australia Pty Ltd	Parkinson disease	Negotiations with sponsor are continuing
ARIPIPRAZOLE Powder for injection 400 mg (as monohydrate) with diluent, pre-filled syringe Abilify Maintena® Lundbeck Australia Pty Ltd	Schizophrenia	Negotiations with sponsor are continuing
AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® Merck Serono Australia Pty Ltd (with Pfizer Australia Pty Ltd)	Metastatic merkel cell carcinoma (MCC)	Negotiations with sponsor are continuing
BUDESONIDE Capsule (modified release) 3 mg Entocort® Emerge Health Pty Ltd	Mild to moderate Crohn disease	Negotiations with sponsor are continuing

PBAC Meeting July 2018		
MEDICINE	INDICATION	STATUS
CARMELLOSE HYPROMELLOSE Eye drops containing carmellose sodium 5 mg per mL, 10 mL; Eye drops containing hypromellose 3 mg per mL, 10 mL; Evolve® carmellose Evolve® hypromellose Contact Lens Centre Australia	Severe dry eye syndrome	Negotiations with sponsor are continuing
CLADRIBINE Tablet 10 mg Mavenclad® Merck Serono Australia Pty Ltd	Relapsing remitting multiple sclerosis (RRMS)	Negotiations with sponsor are continuing
CLOZAPINE Oral liquid 50 mg per mL, 100 mL Versacloz® Pfizer Australia Pty Ltd	Schizophrenia	Negotiations with sponsor are continuing
CRIZOTINIB Capsule 200 mg; Capsule 250 mg Xalkori® Pfizer Australia Pty Ltd	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) with a ROS1 gene rearrangement confirmed by fluorescent in situ hybridisation (FISH) testing	The associated MBS test to facilitate access to crizotinib on the PBS has been recommended for listing by MSAC. The positive MSAC recommendation is now finalised and the Department is working towards a co-dependent listing for both the PBS and MBS. Negotiations with the sponsor are progressing.
DEFERASIROX Tablet 90 mg; Tablet 180 mg; Tablet 360 mg; Jadenu® Novartis Pharmaceuticals Australia Pty Ltd	Chronic iron overload	Negotiations with sponsor are continuing
DOLUTEGRAVIR WITH RILPIVIRINE Tablet containing dolutegravir 50 mg with rilpivirine 25 mg Juluca® ViiV Healthcare Pty Ltd	Human immunodeficiency virus (HIV) infection	Negotiations with sponsor are continuing
1) ERTUGLIFLOZIN WITH SITAGLIPTIN 2) ERTUGLIFLOZIN 3) ERTUGLIFLOZIN WITH METFORMIN 4) SITAGLIPTIN 5) SITAGLIPTIN WITH METFORMIN Steglujan®; Steglatro®; Segluromet®; Januvia®; Janumet®; Janumet XR® Merck Sharp & Dohme (Australia) Pty Ltd	Type 2 diabetes mellitus (T2DM)	Negotiations with sponsor are continuing
EVEROLIMUS Tablet, dispersible, 2 mg; Tablet, dispersible, 3 mg ;Tablet, dispersible, 5 mg Afinitor® Novartis Pharmaceuticals Australia	Tuberous sclerosis complex	Negotiations with sponsor are continuing
FERRIC DERISOMALTOSE Injection 500 mg (iron) in 5 mL Monofer® Pfizer Australia Pty Ltd	Iron deficiency anaemia (IDA)	Negotiations with sponsor are continuing
GOLIMUMAB Injection 50 mg in 0.5 mL single use pre-filled syringe; Injection 50 mg in 0.5 mL single use pre-filled pen Simponi® Simponi Smartject® Janssen Cilag Pty Ltd	Active non-radiographic axial spondyloarthritis (nr-axSpA)	Announced for listing from 1 December 2018
GUANFACINE Tablet containing guanfacine hydrochloride 1 mg Tablet containing guanfacine hydrochloride 2 mg Tablet containing guanfacine hydrochloride 3 mg Tablet containing guanfacine hydrochloride 4 mg Intuniv® Shire Australia Pty Limited	Attention deficit hyperactivity disorder (ADHD)	Negotiations with sponsor are continuing
GUSELKUMAB Injection 100 mg in 1 mL single use pre-filled syringe Tremfya® Janssen-Cilag Pty Ltd	Severe chronic plaque psoriasis	Negotiations with sponsor are continuing
HEPATITIS B SURFACE ANTIGEN RECOMBINANT VACCINE Injection 20 micrograms in 1 mL vial Engerix-B ® GlaxoSmithKline Australia Pty Ltd	Hepatitis B virus infection	Negotiations with sponsor are continuing
INSULIN GLARGINE Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 Semglee® Alphapharm Pty Ltd	Unrestricted (indicated for diabetes mellitus)	Negotiations with sponsor are continuing

PBAC Meeting July 2018		
MEDICINE	INDICATION	STATUS
IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen; Injection 80 mg in 1 mL single dose pre-filled syringe Taltz® Eli Lilly Australia Pty Ltd	Severe active psoriatic arthritis	Negotiations with sponsor are continuing
LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe. Somatuline® Autogel® Ipsen Pty Ltd	Non-functional gastroentero-pancreatic neuroendocrine tumours (GEP-NETs).	Negotiations with sponsor are continuing
LENVATINIB Capsule 4 mg (as mesilate); Capsule 10 mg (as mesilate); Lenvima® Eisai Australia Pty Ltd	Locally advanced or metastatic differentiated thyroid cancer	Negotiations with sponsor are continuing
MENINGOCOCCAL POLYSACCHARIDE SERO (GROUPS A, C, W-135 AND Y) OLIGOSACCHARIDE CONJUGATE VACCINE Injection 0.5mL combination pack Menveo® GlaxoSmithKline Australia Pty Ltd	Meningococcal disease	Sponsor advised not proceeding
MESALAZINE Tablet 1 g (enteric coated) Salofalk® Orphan Australia Pty Ltd	Ulcerative colitis; Crohn disease	Negotiations with sponsor are continuing
METHOTREXATE Injection 7.5 mg in 0.3 mL pre-filled syringe; Injection 10 mg in 0.4 mL pre-filled syringe; Injection 15 mg in 0.6 mL pre-filled syringe; Injection 20 mg in 0.8 mL pre-filled syringe; Injection 25 mg in 1 mL pre-filled syringe Methoblastin® PFS Pfizer Australia Pty Ltd	Severe active rheumatoid arthritis; Severe psoriasis	Negotiations with sponsor are continuing
MIDOSTAURIN Capsule 25 mg Rydapt® Novartis Pharmaceuticals Australia Pty Ltd	Acute myeloid leukaemia (AML)	Negotiations with sponsor are continuing
NIVOLUMAB and IPILIMUMAB nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Opdivo® and Yervoy® Bristol-Myers Squibb Australia Pty Ltd	Malignant melanoma	Negotiations with sponsor are continuing
OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® Roche Products Pty Ltd	Chronic lymphocytic leukaemia (CLL)	Negotiations with sponsor are continuing
OCTREOTIDE Injection (modified release) 10 mg (as acetate), vial and diluent syringe Injection (modified release) 20 mg (as acetate), vial and diluent syringe Injection (modified release) 30 mg (as acetate), vial and diluent syringe Sandostatin LAR® Novartis Pharmaceuticals Australia Pty Ltd	Functional carcinoid tumour; Acromegaly; Vasoactive intestinal peptide secreting tumour (VIPoma)	Negotiations with sponsor are continuing
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Locally advanced or metastatic urothelial cancer (LA or mUC)	Negotiations with sponsor are continuing
SOFOSBUVIR WITH VELPATASVIR AND VOXILAPREVIR Tablet containing sofosbuvir 400 mg with velpatasvir 100 mg and voxilaprevir 100 mg Vosevi® Gilead Sciences Pty Ltd	Chronic hepatitis C virus (HCV) infection	Negotiations with sponsor are continuing
SOMATROPIN Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) SciTropin A™ SciGen (Australia) Pty Ltd	Growth disturbance due to insufficient secretion of pituitary growth hormone, or growth disturbance associated with gonadal dysgenesis (Turner syndrome) or chronic renal insufficiency	Negotiations with sponsor are continuing
TENOFOVIR ALAFENAMIDE WITH EMTRICITABINE AND BICTEGRAVIR Tablet containing tenofovir alafenamide 25 mg with emtricitabine 200 mg and bictegravir 50 mg Biktarvy® Gilead Sciences Pty Ltd	Human immunodeficiency virus (HIV) infection	Negotiations with sponsor are continuing

PBAC Meeting July 2018		
MEDICINE	INDICATION	STATUS
TILDRAKIZUMAB Injection 100 mg in 1 mL single use pre-filled syringes Ilumya® Sun Pharma ANZ Pty Ltd	Severe chronic plaque psoriasis	Negotiations with sponsor are continuing
TOCILIZUMAB Injection 162 mg in 0.9 mL pre-filled pen Actemra® Subcutaneous Injection Roche Products Pty Ltd	Severe active rheumatoid arthritis	Negotiations with sponsor are continuing
TOLVAPTAN Pack containing 28 tablets 15 mg and 28 tablets 45 mg Pack containing 28 tablets 30 mg and 28 tablets 60 mg Pack containing 28 tablets 30 mg and 28 tablets 90 mg Jinarc® Otsuka Australia Pharmaceutical Pty Ltd	Autosomal dominant polycystic kidney disease (ADPKD)	Negotiations with sponsor are continuing
TRIFLURIDINE + TIPIRACIL Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride) Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride) LONSURF® Servier Laboratories (Australia) Pty Ltd	Metastatic colorectal cancer	Negotiations with sponsor are continuing
TRIGLYCERIDES MEDIUM CHAIN FORMULA Sachets containing oral powder 16 g, 30 (MCT Pro-Cal) MCT Pro-Cal VitaFlo Australia Pty Limited	Chylous ascites; Chylothorax; Fat malabsorption; Hyperlipoproteinaemia type 1; Long chain fatty acid oxidation disorders	Negotiations with sponsor are continuing
ZOLEDRONIC ACID Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL, 5 vials Clarix Lifesciences Zoledronic Acid® Medsurge Healthcare Pty Ltd	Multiple myeloma	Negotiations with sponsor are continuing

PBAC meeting March 2018		
ITEM	INDICATION	STATUS
1) ERTUGLIFLOZIN 2) ERTUGLIFLOZIN WITH METFORMIN (1) Steglatro® (TBC) 2) Segluromet® (TBC)) Merck Sharp & Dohme (Australia) Pty Limited	Type 2 diabetes mellitus (T2DM)	Negotiations with sponsor are continuing
ADRENALINE (AdrenaJect) I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector Sun Pharma ANZ Pty Ltd	Anaphylaxis	Negotiations with sponsor are continuing
APOMORPHINE (Movapo Pen) Solution for subcutaneous infusion containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen Stada Pharmaceuticals Australia Pty Ltd	Parkinson disease	Negotiations with sponsor are continuing
BENRALIZUMAB (Fasenra®) 30mg in 1 mL solution for injection prefilled syringe AstraZeneca Pty Ltd	Uncontrolled severe eosinophilic Asthma	Negotiations with sponsor are continuing
BENRALIZUMAB (Fasenra®) 30mg in 1 mL solution for injection prefilled syringe AstraZeneca Pty Ltd	Eosinophilic asthma	Negotiations with sponsor are continuing
CETUXIMAB (Erbix®) Solution for I.V. infusion 100 mg in 20 mL Solution for I.V. infusion 500 mg in 100 mL Merck Serono Australia Pty Ltd	Recurrent or metastatic squamous cell carcinoma of the head and neck	Negotiations with sponsor are continuing
HYDROMORPHONE (Dilauid®) Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL Mundipharma Pty Ltd	Severe disabling pain	Negotiations with sponsor are continuing
MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE (Nimenrix®) Injection 0.5 mL in pre-filled syringe Pfizer Australia Pty Ltd	Meningococcal disease adolescents	Approved to be added to the NIP from April 2019
NICOTINE (Nicotinell Chewing gum® Nicotinell lozenge®) Gum 2 mg, Gum 4 mg, Lozenge 2 mg, Lozenge 4 mg Orion Laboratories Pty Ltd T/A Perrigo Australia	Nicotine dependence	Negotiations with sponsor are continuing

PBAC meeting March 2018		
ITEM	INDICATION	STATUS
OLAPARIB (Lynparza®) Tablet 100 mg Tablet 150 mg AstraZeneca Pty Ltd	High-grade serous ovarian, fallopian tube and primary peritoneal cancer	Negotiations with sponsor are continuing
OMALIZUMAB (Xolair®) Injection 150 mg in 1 mL single dose pre-filled syringe Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic spontaneous urticaria	Negotiations with sponsor are continuing
PALBOCICLIB (Ibrance®) Capsule 75 mg Capsule 100 mg Capsule 125 mg Pfizer Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	Sponsor not proceeding with listing
PEMBROLIZUMAB (Keytruda®) Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL Merck, Sharp and Dohme (Australia) Pty Limited	Melanoma	Sponsor not proceeding with listing
PNEUMOCOCCAL CONJUGATE VACCINE, 13 VALENT (Prevenar 13®) Injection 0.5 mL Pfizer Australia Pty Ltd	Prevention of pneumococcal disease	Cost-effectiveness review requested by the PBAC
RAMUCIRUMAB (Cyramza®) Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 500 mg in 50 mL Eli Lilly Australia Pty Ltd	Advanced gastric or gastro-oesophageal junction adenocarcinomas	Negotiations with sponsor are continuing
RANOLAZINE (Ranexa®) Tablet (modified release) 375 mg Tablet (modified release) 500 mg Tablet (modified release) 750 mg A. Menarini Australia Pty Ltd	Visual impairment due to choroidal neovascularisation (CNV)	Negotiations with sponsor are continuing
RITUXIMAB (Riximyo®) Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Sandoz Pty Ltd	CD20 positive follicular B-cell non-Hodgkin's lymphoma Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) CD20 positive non-Hodgkin's lymphoma Low-grade B-cell non-Hodgkin's lymphoma Chronic lymphocytic leukaemia Severe active rheuma	Listing currently not proceeding
TENECTEPLASE (Metalyse®)	Acute myocardial infarction	Sponsor not proceeding with listing

PBAC meeting December 2017		
ITEM	INDICATION	STATUS
ADALIMUMAB Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Humira® AbbVie Pty Ltd	All existing indications	Negotiations with sponsor are continuing

PBAC meeting November 2017		
ITEM	INDICATION	STATUS
CANAKINUMAB Powder for injection 150 mg with solvent Solution for injection 150 mg in 1 mL Ilaris® Novartis Pharmaceuticals Australia Pty Ltd	Cryopyrin associated periodic syndromes (CAPS)	Sponsor not proceeding with listing
DEFERIPRONE Tablet 1000 mg Ferriprox® Apotex Pty Ltd	Iron overload	Negotiations with sponsor are continuing

PBAC meeting November 2017		
ITEM	INDICATION	STATUS
INSULIN LISPRO Injections (human analogue), cartridges, 200 units per mL, 3 mL, 5 Humalog® U200 Kwikpen® Eli Lilly Australia Pty Ltd	Diabetes mellitus	Negotiations with sponsor are continuing
RADIUM (223Ra) Injection containing radium (223Ra) dichloride 6.6 MBq in 6 mL vial Xofigo® Bayer Australia Ltd	Metastatic castrate resistant prostate cancer (mCRPC)	New S100 program required to be developed
SEVELAMER Powder for oral liquid 2.4 g (as carbonate) Renvela® Sanofi-Aventis Australia Pty Ltd	Hyperphosphataemia in patients with chronic kidney disease	Negotiations with sponsor are continuing
VENETOCLAX Tablet 10 mg; Tablet 50 mg; Tablet 100 mg; Venclexta® AbbVie Pty Ltd	Monotherapy	Sponsor not proceeding with listing

PBAC meeting July 2017		
ITEM	INDICATION	STATUS
SOMATROPIN Multiple forms and strengths Multiple brands Endocrine Society of Australia and Australian Paediatric Endocrine Group	A S100 (Growth Hormone) Authority Required listing for the treatment of adults with severe growth hormone deficiency and substantially impaired quality of life at baseline.	Negotiations with sponsor are continuing
ADALIMUMAB Injection 40 mg in 0.8 mL vial Humira® AbbVie Pty Ltd New 40 mg vial form of adalimumab with the same Authority listings as for the currently listed forms of adalimumab (cartridge and syringe forms).	currently listed forms of adalimumab (cartridge and syringe forms).	Sponsor indicated not proceeding

PBAC meeting March 2017		
ITEM	INDICATION	STATUS
RITUXIMAB Solution for subcutaneous injection 1600 mg in 13.4 mL MabThera SC® Roche Products Pty Ltd	Chronic lymphocytic	Sponsor currently has no stock available
TENOFOVIR ALAFENAMIDE Tablet 25 mg Vemlidy® Gilead Sciences Pty Ltd	Chronic hepatitis B	Negotiations with sponsor are continuing

PBAC meeting November 2016		
ITEM	INDICATION	STATUS
PARITAPREVIR WITH RITONAVIR WITH OMBITASVIR Tablet containing 75 mg paritaprevir with 50 mg ritonavir with 12.5 mg ombitasvir Technivie® AbbVie Pty Ltd Hepatitis C	Chronic hepatitis C virus (HCV) infection	Sponsor indicated not proceeding

PBAC meeting July 2016		
ITEM	INDICATION	STATUS
ADRENALINE Adrenaline Auto Inject Sun-JV® Ranbaxy Australia (Sun Pharma)	Anaphylaxis	Sponsor indicated not proceeding
ALENDRONIC ACID Tablet, effervescent, 70 mg, Binosto® My Health 365 Pty Ltd	Osteoporosis	Sponsor indicated not proceeding
DENOSUMAB Injection 120 mg in 1.7mL, Xgeva® Amgen Australia Pty Ltd Hypercalcaemia of malignancy	Hypercalcaemia of malignancy	Sponsor indicated not proceeding
PNEUMOCOCCAL CONJUGATE VACCINE 13-Valent Adsorbed Pre-Filled Syringe, 0.5 mL, Prevenar 13® Pfizer Australia Pty Ltd	Prevention of pneumococcal disease	See March 2018 meeting

