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| The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.  The PBAC agenda consists of the following:  **1 Minutes of Previous Meeting**  **2 Chairman’s report (verbal)**  **3 Matters arising from the minutes**  **4 Matters arising/outstanding**  **5 New drug applications**  **6 Requests for changes to listings**  **7 Resubmissions**  **8 Pricing Matters**  **9 Matters relating to PBS review**  **10 Subcommittee and Working Party reports**  **11 Other business**  **12 Correspondence**  **13 Further information**  **14 Late papers**  **15 Tabled papers**  Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.  Pharmaceutical benefits listed in the Schedule fall into three broad categories:  *Unrestricted benefits* – have no restrictions on their therapeutic uses;  *Restricted benefits* – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and  *Authority required benefits* – Authority required benefits fall into two categories:   * *Authority required benefits* require prior approval from Services Australia or the DVA (noted as Authority required) * *Authority required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).   Initial submissions are categorised broadly as:   * *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation. * *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.   Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the [Procedure Guidance](https://www.pbs.gov.au/industry/listing/procedure-guidance/files/Procedure-guidance-for-listing-medicines-on-the-Pharmaceutical-Benefits-Scheme-v2.0.pdf).  The PBAC meeting agenda will be published in week 3 - and updated in week 8 (to include early pathway resubmissions, and items for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants) in each PBAC cycle as per [PBS Calendar](https://www.pbs.gov.au/info/industry/useful-resources/pbs-calendar). |

| **Submission type** (new listing, change to listing) | **Drug Name, form(s), strength(s) and Sponsor** (Drug name, form, strength, Trade name®, Sponsor) | **Drug Type and Use** (What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
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| Change to listing | ACALABRUTINIB  Capsule 100 mg  Calquence®  Astrazeneca Pty Ltd | Relapsed and/or refractory mantle cell lymphoma (R/R MCL) | To request a General Schedule, Authority Required (online/telephone) listing for the treatment of patients with R/R MCL who have received at least one prior therapy or who have developed an intolerance to another Bruton’s tyrosine kinase (BTK). |
| Change to listing | 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  Abrilada®  Pfizer Australia Pty Ltd | Severe Crohn disease;  Moderate to severe ulcerative colitis;  Severe active juvenile idiopathic arthritis;  Complex refractory fistulising Crohn disease;  Severe active rheumatoid arthritis;  Severe psoriatic arthritis;  Ankylosing spondylitis;  Severe chronic plaque psoriasis;  Moderate to severe hidradenitis suppurativa. | To request both General Schedule and Section 100 (Highly Specialised Drug Program) listing of adalimumab biosimilar under the same conditions as its reference biologic. |
| Change to listing | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE  Sachets containing oral powder 25 g, 30  HCU express 15  Vitaflo Australia Pty Ltd | Pyridoxine non-responsive homocystinuria | To request HCU Express 15 with new formulation continue to be listed on the PBS under existing conditions. |
| Change to listing | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE  Sachets containing oral powder 34 g, 30  PKU express 20  Vitaflo Australia Pty Ltd | Phenylketonuria | To request PKU Express 20 with new formulation continue to be listed on the PBS under existing conditions. |
| Change to listing | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE  Sachets containing oral powder 25 g, 30  PKU express 15  Vitaflo Australia Pty Ltd | Phenylketonuria | To request PKU Express 15 with new formulation continue to be listed on the PBS under existing conditions. |
| Change to listing | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE  Sachets containing oral powder 25 g, 30  TYR express 15  Vitaflo Australia Pty Ltd | Tyrosinaemia | To request TYR Express 15 with new formulation continue to be listed on the PBS under existing conditions. |
| Change to listing | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE  Sachets containing oral powder 25 g, 30  MSUD express 15  Vitaflo Australia Pty Ltd | Maple syrup urine disease | To request MSUD Express 15 with new formulation continue to be listed on the PBS under existing conditions. |
| Change to listing | BARICITINIB  Tablet 2 mg  Tablet 4 mg  Olumiant®  Eli Lilly Australia Pty Ltd | Severe atopic dermatitis | To request a General Schedule, Authority Required (written) listing for the treatment of patients with severe atopic dermatitis. |
| Change to listing | BORTEZOMIB  Powder for injection 2.5 mg  Bortezomib Juno  Juno Pharmaceuticals Pty Ltd | Multiple Myeloma | To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand. |
| Change to listing | BORTEZOMIB  Powder for injection 1 mg  Powder for injection 2.5 mg  Powder for injection 3 mg  Powder for injection 3.5 mg  DBL Bortezomib  Pfizer Australia Pty Ltd | Multiple Myeloma | To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand. |
| New listing | BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL  Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms (as bromide) and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses  Breztri Aerosphere  Astrazeneca Pty Ltd | Moderate to severe chronic obstructive pulmonary disease (COPD) | To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of moderate to severe COPD. |
| Change to listing | DAPAGLIFLOZIN  Tablet 10 mg  Forxiga®  AstraZeneca Pty Ltd | Chronic kidney disease | To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease. |
| Change to listing | DAPAGLIFLOZIN  Tablet 10 mg  Forxiga®  AstraZeneca Pty Ltd | Heart failure | Resubmission to request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of heart failure with reduced ejection fraction. |
| Change to listing | DARATUMUMAB  Solution for subcutaneous injection  1,800 mg in 15 mL vial  Darzalex®  Janssen-Cilag Pty Ltd | Relapsed and/or refractory multiple myeloma (RRMM) | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing of a new 1,800 mg subcutaneous flat dosing regimen in addition to the current 16 mg/kg intravenous weight-based dosing regimen for the treatment of RRMM. |
| New listing | ELOTUZUMAB  Powder for I.V. infusion 300 mg  Powder for I.V. infusion 400 mg  Empliciti®  Bristol-Myers Squibb Australia Pty Ltd | Relapsed and/or refractory multiple myeloma (RRMM) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (telephone/online) listing, in combination with lenalidomide and dexamethasone, for the treatment of RRMM. |
| New listing | ESKETAMINE  Nasal spray solution 28 mg  Spravato®  Janssen-Cilag Pty Ltd | Treatment resistant depression | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (telephone) listing for the treatment of treatment resistant depression, in combination with a newly initiated oral antidepressant. |
| Change to listing | ETANERCEPT  Injection 50 mg in 1 mL single use dose-dispenser cartridge, 4  Enbrel®  Pfizer Australia Pty Ltd | Rheumatoid arthritis;  Plaque psoriasis;  Ankylosing spondylitis;  Psoriatic arthritis;  Juvenile idiopathic arthritis;  Paediatric plaque psoriasis. | To request both General Schedule and Section 100 (Highly Specialised Drugs Program) listings of etanercept in dose dispenser cartridges under the same conditions as the currently listed pre-filled syringes. |
| Change to listing | FOLLITROPIN ALFA  Injection 300 I.U. in 0.5 mL multi-dose cartridge  Injection 450 I.U. in 0.75 mL multi-dose cartridge  Injection 900 I.U. in 1.5 mL multi-dose cartridge  Ovaleap®  Theramex Australia Pty Ltd | Assisted Reproductive Technology;  Anovulatory infertility;  Infertility. | To request both General Schedule and Section 100 (IVF Program) listings of a biosimilar under the same conditions as its reference biologic. |
| Change to listing | HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE  Oral liquid 250 mL, 30  KetoVie® Peptide 4:1  Cortex Health Pty Ltd | Ketogenic diet | To present additional data to progress the November 2020 recommended listing for KetoVie Peptide 4:1. |
| Change to listing | HYDROCORTISONE  Capsule 0.5 mg  Capsule 1 mg  Capsule 2 mg  Capsule 5 mg  Alkindi®  Chiesi Australia Pty Ltd | Adrenal Insufficiency | To request an Authority Required (STREAMLINED) listing for replacement therapy of adrenal insufficiency for patients aged six or younger. |
| Change to listing | HYPROMELLOSE  Eye drops 3 mg per mL, 10 mL  Revive Tears®  Petrus Pharmaceuticals Pty Ltd | Severe dry eye syndrome, including Sjogren's syndrome | To request a Restricted benefit listing of a new brand under the same conditions as the currently listed hypromellose eye drops; and to seek advice on therapeutic bioequivalence. |
| New listing  WITHDRAWN | INCLISIRAN  Injection 284 mg in 1.5 mL pre-filled syringe  Leqvio®  Novartis Pharmaceuticals Australia Pty Ltd | Hypercholesterolaemia | To request a General Schedule, Authority Required (online/telephone) listing for the treatment of heterozygous familial hypercholesterolaemia, and non-familial hypercholesterolaemia with atherosclerotic cardiovascular disease. |
| New listing | LANADELUMAB  Solution for subcutaneous injection 300 mg in 2 mL  Takhzyro®  Takeda Pharmaceuticals Australia Pty Ltd | Hereditary angioedema | Resubmission to request an Authority Required (telephone/online) listing for the prevention of recurrent attacks of hereditary angioedema (C1-esterase inhibitor deficiency or dysfunction) in patients aged 12 years and older. |
| Change to listing | LORLATINIB  Tablet 25 mg  Tablet 100 mg  Lorviqua®  Pfizer Australia Pty Ltd | Locally advanced (stage IIIB) or metastatic (stage IV) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) | To request a General Schedule, Authority Required (online/telephone) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive NSCLC in patients who have not received prior treatment with an ALK inhibitor. |
| – | LUMACAFTOR + IVACAFTOR  Tablet containing lumacaftor 100 mg with ivacaftor 125 mg  Orkambi®  Vertex Pharmaceuticals (Australia) Pty. Ltd. | Cystic fibrosis | To provide additional data as specified in the Deed of Supply. |
| Change to listing | METHOXSALEN  Solution for blood fraction 20 microgram  per mL, 10 mL  Uvadex®  Terumo Bct Australia Pty Ltd | Steroid dependent or steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD) | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of patients with steroid dependent or steroid intolerant or steroid refractory cGVHD, as part of treatment with integrated, closed system, extracorporeal photopheresis. |
| New listing | NIRAPARIB  Capsule 100 mg  Zejula®  Glaxosmithkline Australia Pty Ltd | High grade epithelial ovarian, fallopian tube, or primary peritoneal cancer | To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of newly diagnosed, advanced, high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer (HGEOC) that is responsive (complete/partial) to platinum-based chemotherapy. |
| Change to listing | NIVOLUMAB  Injection concentrate for I.V. infusion 40 mg in 4 mL  Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  Bristol-Myers Squibb Australia Pty Ltd | Second-line squamous cell oesophageal carcinoma (2L OSCC) | To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for 2L OSCC that have failed treatment with a fluoropyrimidine and platinum containing treatment regimen. |
| Change to listing | NUSINERSEN  Solution for injection 12.6 mg in 5 mL  Spinraza®  Biogen Australia Pty Ltd | Spinal muscular atrophy (SMA) | Resubmission to extend the current Section 100 (Highly Specialised Drugs Program), Authority Required (written) listing to include adults with SMA. |
| New listing | OPICAPONE  Capsule 50 mg  Ongentys®  Maxx Pharma Pty Ltd | Parkinson Disease (PD) | To request a General Schedule, Restricted benefit listing for the treatment of PD, as adjunctive therapy to levodopa-decarboxylase inhibitor combinations in patients motor function fluctuations due to end-of-dose effects. |
| Change to listing | PALBOCICLIB  Tablet 75 mg  Tablet 100 mg  Tablet 125 mg  Ibrance®  Pfizer Australia Pty Ltd | Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer | To request an Authority Required listing of palbociclib tablets under the same conditions as the already listed capsules. |
| New listing | RAVULIZUMAB  Solution concentrate for I.V. infusion 300 mg in 3 mL  Solution concentrate for I.V. infusion 1,100 mg in 11 mL  Ultomiris®  Alexion Pharmaceuticals Australasia Pty Ltd | Paroxysmal nocturnal haemoglobinuria (PNH) | Resubmission to request a Section 100 (Highly Specialised Drugs Program), Authority Required (written) listing for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH). |
| Change to listing | SECUKINUMAB  Injection 150 mg in 1 mL pre-filled pen  Cosentyx®  Novartis Pharmaceuticals Australia Pty Ltd | Ankylosing spondylitis | To request an increase in the maximum quantity to 2 and a reduction in the number of repeats from 5 to 2. |
| New listing | SELINEXOR  Tablet 20 mg  Xpovio®  Antengene (Aus) Pty. Ltd. | Relapsed and/or refractory multiple myeloma | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with bortezomib and dexamethasone, for the treatment of relapsed and/or refractory multiple myeloma. |
| New listing | SELINEXOR  Tablet 20 mg  Xpovio®  Antengene (Aus) Pty. Ltd. | Triple class  refractory/penta-refractory multiple myeloma (TCR/PR MM) | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with dexamethasone, for the treatment of TCR/PR MM in patients who have received at least four prior therapies. |
| New listing | SELINEXOR  Tablet 20 mg  Xpovio®  Antengene (Aus) Pty. Ltd. | Relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL) | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of relapsed and/or refractory DLBCL in patients who have received at least two lines of systemic therapy. |
| New listing | SILTUXIMAB  Powder for injection 100 mg  Powder for injection 400 mg  Sylvant®  Eusa Pharma (UK) Ltd | Idiopathic multicentric Castleman’s disease (iMCD) | To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing for the treatment of iMCD. |
| New listing | TRABECTEDIN  Powder for I.V. infusion 0.25 mg  Powder for I.V. infusion 1 mg  Yondelis®  Specialised Therapeutics Pharma Pty Ltd | Advanced (unresectable and/or metastatic) leiomyosarcoma | To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic leiomyosarcoma following a prior anthracycline-containing regimen. |
| Change to listing | TRIPTORELIN  Powder for I.M. injection (prolonged release) 22.5 mg (as embonate), with solvent  Diphereline®  Ipsen Pty Ltd | Central precocious puberty (CPP) | To request a General Schedule, Restricted Benefit listing for the treatment of CPP. |
| Change to listing | UPADACITINIB  Tablet 15 mg  Tablet 30 mg  Rinvoq®  Abbvie Pty Ltd | Severe atopic dermatitis | To request a General Schedule, Authority Required (telephone) listing for the treatment of severe atopic dermatitis. |
| New listing | ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  BeiGene Aus Pty Ltd | Waldenstrom macroglobulinemia | To request a General Schedule, Authority Required (telephone) listing for the treatment of adult patients with Waldenstrom macroglobulinemia. |
| New listing | ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  BeiGene Aus Pty Ltd | Relapsed and/or refractory mantle cell lymphoma | To request a General Schedule, Authority Required (telephone) listing for the treatment of relapsed and/or refractory mantle cell lymphoma. |
| Sub-committee report  (DUSC Analysis) | GUANFACINE  Intuniv®  Takeda Pharmaceuticals Australia Pty Ltd | Treatment of attention deficit hyperactivity disorder (ADHD) | To compare the predicted and actual utilisation of guanfacine for the treatment of ADHD since PBS listing. |
| Sub-committee report  (DUSC Analysis) | EVOLOCUMAB  Repatha®  Amgen Australia Pty Limited | Treatment of heterozygous familial hypercholesterolaemia (FH) | To compare the predicted and actual utilisation of evolocumab for the treatment of heterozygous FH since PBS listing. |
| Sub-committee report  (DUSC Analysis) | SOMATROPIN  Multiple brands and sponsors | Treatment of short stature and slow growth | To assess the utilisation of PBS listed somatropin for the treatment of short stature and slow growth. |
| Review of  positive PBAC recommendations not accepted by applicants | BUDESONIDE  Capsule 3 mg  Entocort®  Chiesi Australia Pty Ltd | Mild to Moderate Crohn Disease | – |
| Review of  positive PBAC recommendations not accepted by applicants | ENOXAPARIN  Injection 120 mg in 0.8 mL pre-filled syringe  Injection 150 mg in 1 mL pre-filled syringe  Clexane Forte®; Enoxaparin Winthrop®; Clexane Forte Safety-Lock®  Sanofi-Aventis Australia Pty Ltd | Unrestricted benefit | – |
| Review of  positive PBAC recommendations not accepted by applicants | RAMUCIRUMAB  100 mg in 10 mL vial  500 mg in 50 mL vial  Cyramza®  Eli Lilly Australia Pty Ltd | Advanced gastric or  gastro-oesophageal junction adenocarcinoma | – |
| Review of  positive PBAC recommendations not accepted by applicants | SECUKINUMAB  150 mg /mL powder for injection  150 mg/mL pre-filled syringe  Cosentyx®  Novartis Pharmaceuticals Australia Pty Ltd | Severe chronic plaque psoriasis | – |
| Review of  positive PBAC recommendations not accepted by applicants | SEVELAMER  Powder for oral liquid, 2.4g  Renvela®  Sanofi-Aventis Australia Pty Ltd | Chronic kidney disease | – |
| Review of  positive PBAC recommendations not accepted by applicants | TENOFOVIR ALAFENAMIDE  Tablet 25 mg  Vemlidy®  Gilead Sciences | Chronic hepatitis B | – |
| Review of  positive PBAC recommendations not accepted by applicants | TRIGLYCERIDES MEDIUM CHAIN FORMULA  Oral liquid 500mL, 12  Nutrini Peptisorb®  Nutricia Australia Pty Ltd | Change to pack size/quantities | – |
| New listing | DAROLUTAMIDE  Tablet 300 mg  Nubeqa®  Bayer Australia Limited | Castration resistant carcinoma of the prostate | Resubmission to request an Authority Required (Telephone) listing for the treatment of castration resistant carcinoma of the prostate. |
| New listing | DECITABINE WITH CEDAZURIDINE  Tablet containing decitabine 35 mg + cedazuridine 100 mg  Inqovi®  Otsuka Australia Pharmaceutical Pty. Ltd | High risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML) | Resubmission to request an Authority Required (non-immediate/delayed) - In Writing only/Electronic listing for the treatment of high-risk myelodysplastic syndrome and chronic myelomonocytic leukaemia. |
| New listing | MELATONIN  Tablet 1 mg  Tablet 5 mg  Slenyto®  Aspen Pharmacare Australia Pty Ltd | Insomnia | Resubmission to request an Authority Required (Telephone) listing for the treatment of insomnia in patients between the ages of 2 to 18 with Smith-Magenis syndrome. |
| New listing | RIPRETINIB  Tablet 50 mg  Qinlock®  Specialised Therapeutics PM Pty Ltd | Gastrointestinal stromal tumour | Resubmission to request an Authority Required (Written) listing for the treatment of metastatic or unresectable malignant gastrointestinal stromal tumour. |
| Change to listing | VENETOCLAX  Tablet 50 mg  Tablet 100 mg  Venclexta®  AbbVie Pty Ltd | Acute myeloid leukaemia | Resubmission to request a General Schedule - Authority Required (telephone/online) listing for the treatment of patients with newly diagnosed acute myeloid leukaemia, who are ineligible for standard intensive remission induction chemotherapy. |
| Change to listing | ENZALUTAMIDE  Capsule 40 mg  Xtandi®  Astellas Pharma Australia Pty Ltd  ABIRATERONE  Tablet 250 mg  Tablet 500 mg  Zytiga®  Janssen-Cilag Pty Ltd | Castration resistant carcinoma of the prostate | Request by the PBAC to consider changing the PBS indication for these items from metastatic castration resistant carcinoma of the prostate to castration resistant carcinoma of the prostate. |

**Version 4**

Amendment

1. INCLISIRAN agenda item has been withdrawn.

Items added or amended previously (Version 2, 3)

* Added – ENZALUTAMIDE and ABIRATERONE.
* Added – Five (5) Early Re-entry resubmissions received (pages 17–18).
* Added – Seven (7) items scheduled for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants (pages 15–17).
* Amended – NIVOLUMAB (Advanced or metastatic non-HER2 positive gastro-oesophageal junction cancer or oesophageal adenocarcinoma) agenda item was withdrawn.
* Amended – dapagliflozin (Heart failure), nusinersen and ravulizumab: *resubmission* added to ‘purpose of submission’.
* Amended – ETANERCEPT: deleted *Non-radiographic Axial Spondyloarthritis*, replaced with *Psoriatic arthritis*.
* Amended – SELINEXOR: (for all three agenda items) deleted *20mg*, replaced with *200mg*.
* Amended – RAVULIZUMAB: deleted *Solution for I.V. infusion 300 mg in 3 mL*, replaced with *Solution concentrate for I.V. infusion 300 mg in 3 mL and   
  Solution concentrate for I.V. infusion 1,100 mg in 11 mL*.