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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 mgCalquence®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 | ADALIMUMABInjection 20 mg in 0.4 mL pre‑filled syringe Injection 40 mg in 0.8 mL pre‑filled syringeInjection 40 mg in 0.8 mL pre‑filled penAbrilada®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 METHIONINESachets containing oral powder 25 g, 30HCU express 15Vitaflo 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 PHENYLALANINESachets containing oral powder 34 g, 30PKU express 20Vitaflo 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 PHENYLALANINESachets containing oral powder 25 g, 30PKU express 15Vitaflo 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 TYROSINESachets containing oral powder 25 g, 30TYR express 15Vitaflo 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, 30MSUD express 15Vitaflo 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 | BARICITINIBTablet 2 mgTablet 4 mgOlumiant®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 | BORTEZOMIBPowder for injection 2.5 mgBortezomib JunoJuno 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 | BORTEZOMIBPowder for injection 1 mgPowder for injection 2.5 mgPowder for injection 3 mgPowder for injection 3.5 mgDBL BortezomibPfizer 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 + FORMOTEROLPressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms (as bromide) and formoterol fumarate dihydrate 5 micrograms per dose, 120 dosesBreztri AerosphereAstrazeneca 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 | DAPAGLIFLOZINTablet 10 mgForxiga®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 | DAPAGLIFLOZINTablet 10 mgForxiga®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 | DARATUMUMABSolution for subcutaneous injection 1,800 mg in 15 mL vialDarzalex®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 | ELOTUZUMABPowder for I.V. infusion 300 mgPowder for I.V. infusion 400 mgEmpliciti®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 | ESKETAMINENasal spray solution 28 mgSpravato®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 | ETANERCEPTInjection 50 mg in 1 mL single use dose-dispenser cartridge, 4Enbrel®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 ALFAInjection 300 I.U. in 0.5 mL multi-dose cartridgeInjection 450 I.U. in 0.75 mL multi-dose cartridgeInjection 900 I.U. in 1.5 mL multi-dose cartridgeOvaleap®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 CARBOHYDRATEOral liquid 250 mL, 30KetoVie® Peptide 4:1Cortex Health Pty Ltd | Ketogenic diet | To present additional data to progress the November 2020 recommended listing for KetoVie Peptide 4:1. |
| Change to listing | HYDROCORTISONECapsule 0.5 mgCapsule 1 mgCapsule 2 mgCapsule 5 mgAlkindi®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 | HYPROMELLOSEEye drops 3 mg per mL, 10 mLRevive 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 listingWITHDRAWN | INCLISIRANInjection 284 mg in 1.5 mL pre-filled syringeLeqvio®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 | LANADELUMABSolution 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 | LORLATINIBTablet 25 mgTablet 100 mgLorviqua®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 + IVACAFTORTablet containing lumacaftor 100 mg with ivacaftor 125 mgOrkambi®Vertex Pharmaceuticals (Australia) Pty. Ltd. | Cystic fibrosis | To provide additional data as specified in the Deed of Supply. |
| Change to listing | METHOXSALENSolution for blood fraction 20 microgram per mL, 10 mLUvadex®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 | NIRAPARIBCapsule 100 mgZejula®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 | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mLInjection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®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 | OPICAPONECapsule 50 mgOngentys®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 | PALBOCICLIBTablet 75 mgTablet 100 mgTablet 125 mgIbrance®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 mLSolution concentrate for I.V. infusion 1,100 mg in 11 mLUltomiris®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 | SECUKINUMABInjection 150 mg in 1 mL pre-filled penCosentyx®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 | SELINEXORTablet 20 mgXpovio®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 | SELINEXORTablet 20 mgXpovio®Antengene (Aus) Pty. Ltd. | Triple classrefractory/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 | SELINEXORTablet 20 mgXpovio®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 | SILTUXIMABPowder for injection 100 mgPowder for injection 400 mgSylvant®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 | TRABECTEDINPowder for I.V. infusion 0.25 mgPowder for I.V. infusion 1 mgYondelis®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 solventDiphereline®Ipsen Pty Ltd | Central precocious puberty (CPP) | To request a General Schedule, Restricted Benefit listing for the treatment of CPP. |
| Change to listing | UPADACITINIBTablet 15 mgTablet 30 mgRinvoq®Abbvie Pty Ltd | Severe atopic dermatitis | To request a General Schedule, Authority Required (telephone) listing for the treatment of severe atopic dermatitis. |
| New listing | ZANUBRUTINIBCapsule 80 mgBrukinsa®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 | ZANUBRUTINIBCapsule 80 mgBrukinsa®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) | GUANFACINEIntuniv®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) | EVOLOCUMABRepatha®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) | SOMATROPINMultiple 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 | BUDESONIDECapsule 3 mgEntocort®Chiesi Australia Pty Ltd | Mild to Moderate Crohn Disease | – |
| Review of positive PBAC recommendations not accepted by applicants | ENOXAPARINInjection 120 mg in 0.8 mL pre-filled syringeInjection 150 mg in 1 mL pre-filled syringeClexane Forte®; Enoxaparin Winthrop®; Clexane Forte Safety-Lock®Sanofi-Aventis Australia Pty Ltd | Unrestricted benefit | – |
| Review of positive PBAC recommendations not accepted by applicants | RAMUCIRUMAB100 mg in 10 mL vial500 mg in 50 mL vialCyramza®Eli Lilly Australia Pty Ltd | Advanced gastric or gastro-oesophageal junction adenocarcinoma | – |
| Review of positive PBAC recommendations not accepted by applicants | SECUKINUMAB150 mg /mL powder for injection150 mg/mL pre-filled syringe Cosentyx®Novartis Pharmaceuticals Australia Pty Ltd | Severe chronic plaque psoriasis | – |
| Review of positive PBAC recommendations not accepted by applicants | SEVELAMERPowder for oral liquid, 2.4gRenvela®Sanofi-Aventis Australia Pty Ltd | Chronic kidney disease | – |
| Review of positive PBAC recommendations not accepted by applicants | TENOFOVIR ALAFENAMIDE Tablet 25 mgVemlidy®Gilead Sciences | Chronic hepatitis B | – |
| Review of positive PBAC recommendations not accepted by applicants | TRIGLYCERIDES MEDIUM CHAIN FORMULAOral liquid 500mL, 12Nutrini Peptisorb®Nutricia Australia Pty Ltd | Change to pack size/quantities  | – |
| New listing | DAROLUTAMIDETablet 300 mgNubeqa®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 CEDAZURIDINETablet containing decitabine 35 mg + cedazuridine 100 mgInqovi®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 | MELATONINTablet 1 mgTablet 5 mgSlenyto®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 | RIPRETINIBTablet 50 mgQinlock®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 | VENETOCLAXTablet 50 mgTablet 100 mgVenclexta®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 | ENZALUTAMIDECapsule 40 mgXtandi®Astellas Pharma Australia Pty LtdABIRATERONETablet 250 mgTablet 500 mgZytiga®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*.