

MARCH 2017 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
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| <p>ABIRATERONE ACETATE</p> <p>Tablet 250 mg</p> <p>Zytiga®</p> <p>Medical Oncology Group of Australia</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Metastatic castration-resistant prostate cancer</p> | <p>To request to amend the current clinical criteria to allow abiraterone acetate to be administered with a corticosteroid such as prednisolone (instead of administration with prednisolone).</p> | <p>The PBAC recommended the proposed amendment to the current Authority Required PBS listing for abiraterone acetate for the treatment of metastatic castration resistant prostate cancer to allow use with a corticosteroid rather than just prednisone or prednisolone. The choice of corticosteroids used in combination with abiraterone acetate would be a clinical decision.</p> <p>The manufacturer/supplier of abiraterone acetate is Janssen-Cilag Pty Ltd</p> |
| <p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES</p> <p>Oral powder 400 g</p> <p>Neocate Junior®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>The dietary management of conditions involving gastrointestinal tract impairment</p> | <p>To request an Authority Required listing of a drug for the treatment of cows' milk protein enteropathy, severe cows' milk protein enteropathy with failure to thrive, combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae, proven combined immunoglobulin E mediated allergy to cows' milk protein and soy protein, eosinophilic eosophagitis, cows' milk anaphylaxis. and severe intestinal malabsorption including short bowel syndrome.</p> | <p>The PBAC recommended the listing of Neocate Junior®, as an Authority Required listing for the treatment of: cows' milk protein enteropathy; severe cows' milk protein enteropathy with failure to thrive; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E mediated allergy to cows' milk protein and soy protein; eosinophilic oesophagitis; cows' milk anaphylaxis and; severe intestinal malabsorption including short bowel syndrome; on a cost-minimisation basis to Alfamino Junior®.</p> |

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| <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Oral liquid 130 mL, 30 Oral liquid 174 mL, 30</p> <p>PKU Air®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Phenylketonuria</p> | <p>To request changes to the Restricted Benefit listing of PKU Air.</p> | <p>The PBAC recommended the continued listing of PKU Air® for the dietary management of phenylketonuria, with a change in nutritional profile.</p> |
| <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Oral liquid 87 mL, 30 Oral liquid 130 mL, 30 Oral liquid 174 mL, 30</p> <p>PKU Cooler®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Phenylketonuria</p> | <p>To request changes to the Restricted Benefit listing of PKU Cooler.</p> | <p>The PBAC recommended the continued listing of PKU Cooler® for the dietary management of phenylketonuria, with a change in nutritional profile.</p> |

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| <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE</p> <p>Sachets containing oral powder 34 g, 30</p> <p>TYR Express20®</p> <p>Vitaflo Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Tyrosinaemia</p> | <p>To request a Restricted Benefit listing of a new sachet size containing 20 g protein equivalent for the dietary management of tyrosinaemia.</p> | <p>The PBAC recommended the listing of TYR Express20® as a Restricted Benefit for the dietary management of tyrosinaemia on a cost-minimisation basis against the comparator TYR Express15® at an equivalent price per gram of protein equivalent.</p> |
| <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID</p> <p>Sachets containing oral powder 12.5 g, 30</p> <p>PKU Anamix First Spoon®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Phenylketonuria</p> | <p>To request a Restricted Benefit listing for phenylketonuria.</p> | <p>The PBAC recommended the listing of PKU Anamix First Spoon® as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis to PKU Gel® at an equivalent cost per gram of protein equivalent.</p> |

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| <p>BOTULINUM TOXIN TYPE A</p> <p>Lyophilised powder for injection 100 units</p> <p>Botox®</p> <p>Allergan Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Urinary incontinence due to idiopathic overactive bladder</p> | <p>To request a change to listing to include prescribing by gynaecologists.</p> | <p>The PBAC recommended the amendment to the current Section 100 Botulinum Toxin Program listing of botulinum toxin type A for the treatment of patients with urinary incontinence due to idiopathic overactive bladder to add gynaecologists to the specialists able to provide this treatment through the PBS.</p> |
| <p>BREXIPRAZOLE</p> <p>Tablet 1 mg Tablet 2 mg Tablet 3 mg Tablet 4 mg</p> <p>Rexulti®</p> <p>Lundbeck Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p> | <p>Schizophrenia</p> | <p>To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.</p> | <p>The PBAC recommended the Authority Required (STREAMLINED) listing of brexpiprazole for the treatment of schizophrenia on a cost-minimisation basis with lurasidone.</p> <p>The PBAC accepted cost-minimisation on the basis of equi-effective doses of brexpiprazole 3.58 mg per day and lurasidone 78.9 mg per day.</p> <p>The PBAC accepted brexpiprazole gives a similar benefit to patients and is likely as safe as lurasidone in the acute and maintenance settings of the disease.</p> |

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| <p>CHORIONIC GONADOTROPIN</p> <p>Injection set containing 3 vials powder for injection 1,500 units and 3 vials diluent 1 mL Injection set containing 1 vial powder for injection 5,000 units and 1 vial diluent 1 mL</p> <p>Pregnyl®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Anovulatory infertility, infertility, combined deficiency of human growth hormone and gonadotrophins, hypogonadism or delayed puberty, and assisted reproductive technology</p> | <p>To request a Restricted Benefit and Section 100 (IVF Program) listing of a new form of chorionic gonadotrophin for the currently listed indication.</p> | <p>The PBAC recommended the listing of chorionic gonadotrophin vials containing powder for injection corresponding to 1500 IU and 5000 IU under the same conditions as the currently PBS-listed chorionic gonadotrophin ampoules.</p> |
| <p>CERTOLIZUMAB</p> <p>Injection 200 mg in 1 mL single dose auto-injector</p> <p>Cimzia®</p> <p>UCB Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Severe active rheumatoid arthritis, severe psoriatic arthritis, and active ankylosing spondylitis</p> | <p>To request an Authority Required listing of a new formulation for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis and active ankylosing spondylitis.</p> | <p>The PBAC recommended the Authority Required listing of Cimzia® single dose auto-injector (a pre-filled pen) with the same conditions as the pre-filled syringe form of certolizumab pegol on a cost-minimisation basis.</p> <p>The PBAC considered that Cimzia® pre-filled syringes and Cimzia® pre-filled pen should not be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) due to the different injection methods required.</p> |

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| <p>CRIZOTINIB</p> <p>Capsule 200 mg Capsule 250 mg</p> <p>Xalkori®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Non-small cell lung cancer</p> | <p>To inform the PBAC of the outcome of the Managed Entry Scheme (MES) for crizotinib and to request changes to the restriction to remove the need for oncologists to register patients for the MES and to remove the grandfather restriction.</p> | <p>Crizotinib was listed on the PBS on 1 July 2015 with a managed entry scheme (MES). With this submission to the PBAC, the PBAC considered that the requirements of the crizotinib Deed of Agreement had been fulfilled and therefore the MES could be concluded.</p> <p>Therefore, the PBAC recommended the current crizotinib listing be amended to remove the requirement for patients to be registered for the MES. Further, the PBAC noted that all patients who were eligible under the grandfathering treatment restriction would now have moved onto PBS-subsidised treatment, so recommended to remove the restriction pertaining to grandfathered patients.</p> <p>The recommendation does not change the way that patients can access crizotinib for non-small cell lung cancer.</p> |
| <p>DEGARELIX</p> <p>Powder for injection 80 mg (as acetate), injection set Powder for injection 120 mg (as acetate), injection set</p> <p>Firmagon®</p> <p>Ferring Pharmaceuticals Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate</p> | <p>To request that the Authority Required (STREAMLINED) listing be changed to a Restricted Benefit listing to be consistent with other listed gonadotropin-releasing hormone (GnRH) analogues.</p> | <p>The PBAC recommended amending the listing of degarelix from Authority Required (STREAMLINED) to a Restricted Benefit for the treatment of locally advanced (equivalent to stage C) or metastatic (equivalent to Stage D) carcinoma of the prostate to be consistent with the PBS-listed gonadotrophin releasing hormone agonists (goserelin, leuprorelin, and triptorelin) which are also used in this treatment setting.</p> |

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| <p>dTpa VACCINE</p> <p>Injection 0.5 mL</p> <p>Adacel®</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p> | <p>Prevention of pertussis</p> | <p>National Immunisation Program (NIP) listing for all women in every pregnancy, primarily to reduce the risk of pertussis in newborn infants up to 2 months of age.</p> | <p>The PBAC recommended a change to the circumstances under which dTpa vaccine, Adacel, is made available as a designated vaccine for the NIP to include vaccination of women during each pregnancy to reduce pertussis disease in infants (prior to being vaccinated) and in mothers on a cost-minimisation basis to dTpa, Boostrix. The PBAC considered that Adacel provides the same health benefit as Boostrix. One dose of Adacel is equi-effective as one dose of Boostrix.</p> |
| <p>FLUTICASONE FUROATE</p> <p>Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose</p> <p>Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose</p> <p>Arnuity Ellipta®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p> | <p>Asthma</p> | <p>Resubmission to request fluticasone furoate to be declared as a 'drug' for the purpose of section 85(2) of the National Health Act (Cth)(Act); and the listing instruments for each Breo Ellipta, Seretide and Flixotide be amended to reflected the full name of the active component of the respective inhaled corticosteroid of each product.</p> | <p>The PBAC considered that the evidence presented in the submission suggested that the furoate and propionate esters caused differences in the pharmacokinetic and pharmacodynamic properties of fluticasone and therefore could be considered different drugs for the purposes of section 85(2) of the <i>National Health Act 1953</i>.</p> <p>The PBAC recalled its previous advice that the equi-effective doses are fluticasone furoate 100 microgram once daily and fluticasone propionate 250 microgram twice daily; and fluticasone furoate 200 microgram once daily and fluticasone propionate 500 microgram twice daily.</p> <p>The recommendation does not change the way that patients can access fluticasone-containing medicines.</p> |

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| <p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Relapsed or refractory chronic lymphocytic leukaemia (CLL).</p> <p>Relapsed or refractory small lymphocytic lymphoma (SLL).</p> | <p>Re-submission to request Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia and relapsed or refractory small lymphocytic lymphoma.</p> | <p>The PBAC recommended out-of-session the General Schedule Authority Required listing of ibrutinib, but on the basis that it be available only for use as monotherapy in patients who meet certain conditions for the treatment of:</p> <ul style="list-style-type: none"> • relapsed or refractory chronic lymphocytic leukaemia • relapsed or refractory small lymphocytic lymphoma. |
| <p>MESALAZINE</p> <p>Tablet (enteric coated) 800 mg</p> <p>Asacol®</p> <p>Baxter Healthcare Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p> | <p>Ulcerative colitis</p> | <p>To request an Authority Required (STREAMLINED) listing for treatment of ulcerative colitis.</p> | <p>The PBAC recommended the General Schedule Authority Required (STREAMLINED) listing of Asacol (800 mg mesalazine enteric coated tablet) for the treatment of ulcerative colitis on a cost-minimisation basis against the oral formulation of mesalazine on the PBS with the lowest per mg price.</p> |

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| <p>METHOTREXATE</p> <p>Injection 7.5 mg in 0.15 mL pre-filled syringe Injection 10 mg in 0.2 mL pre-filled syringe Injection 15 mg in 0.3 mL pre-filled syringe Injection 20 mg in 0.4 mL pre-filled syringe Injection 25 mg in 0.5 mL pre-filled syringe</p> <p>Trexject®</p> <p>Link Medical Products Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p> | <p>Rheumatoid arthritis and psoriasis</p> | <p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of rheumatoid arthritis and psoriasis for use in patients where the oral tablet form of methotrexate is unsuitable.</p> | <p>The PBAC recommended the General Schedule Authority Required (Streamlined) listing of methotrexate pre-filled syringe (with embedded needle) for subcutaneous administration for the treatment of rheumatoid arthritis or psoriasis when methotrexate oral tablets are unsuitable, on a cost-minimisation basis with methotrexate 50 mg vial, taking into account the offsets associated with reduced administration costs.</p> <p>The equi-effective doses are one methotrexate pre-filled syringe (7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg dose strengths) was equivalent to one methotrexate 50 mg vial for injection.</p> <p>The PBAC considered that there was a clinical need for this presentation of methotrexate.</p> |
| <p>NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p> | <p>Renal cell carcinoma (RCC)</p> | <p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for second-line treatment of clear cell variant renal cell carcinoma.</p> | <p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of nivolumab for the second-line treatment of some patients with metastatic renal cell carcinoma.</p> <p>The PBAC was satisfied that nivolumab provides, for some patients, a significant improvement in overall survival and no increase in toxicity over everolimus.</p> |

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| <p>NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Non-small cell lung cancer</p> | <p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic squamous NSCLC with progression on or after prior chemotherapy.</p> | <p>At the November 2016 meeting, the PBAC deferred making a recommendation regarding the listing of nivolumab. The PBAC requested that the Department hold discussions with the sponsor to address the Committee's concerns.</p> <p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of nivolumab for the treatment of locally advanced or metastatic, squamous or non-squamous, non-small cell lung cancer (NSCLC) in patients who meet certain conditions. The PBAC considered that the risk sharing arrangements proposed by the sponsor adequately addressed the remaining uncertainty regarding the incremental effectiveness of nivolumab in patients ≥ 75 years of age compared to standard chemotherapy and preferred this approach to establishing a managed entry scheme.</p> |
| <p>RITUXIMAB</p> <p>Solution for subcutaneous injection 1600 mg in 13.4 mL</p> <p>MabThera SC®</p> <p>Roche Products Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Chronic lymphocytic leukaemia (CLL)</p> | <p>To request a General Schedule and Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new presentation of rituximab for the treatment of CLL.</p> | <p>The PBAC recommended an Authority Required (STREAMLINED) General Schedule and Section 100 - Efficient Funding of Chemotherapy listing of rituximab subcutaneous injection 1,600 mg/13.4 mL for the treatment of chronic lymphocytic leukaemia.</p> <p>The PBAC was satisfied that rituximab subcutaneous (1,600 mg) gave the same health benefit and was as safe as an intravenous course of rituximab at a dose of 500 mg/m².</p> |

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| <p>TENOFOVIR ALAFENAMIDE</p> <p>Tablet 25 mg</p> <p>Vemlidy®</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p> | <p>Chronic hepatitis B</p> | <p>To request an Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis B infection.</p> | <p>The PBAC recommended the Authority Required (STREAMLINED) listing of tenofovir alafenamide 25 mg on a cost-minimisation basis to entecavir 0.5 mg and entecavir 1 mg for treatment of chronic hepatitis B in patients that have not been treated before for hepatitis B (treatment naïve) and patients who have failed previous therapy (treatment experienced), respectively. The equi-effective doses are tenofovir alafenamide 25 mg, entecavir 0.5 mg once daily for treatment naïve patients, and entecavir 1 mg once daily for treatment experienced patients.</p> |
| <p>1. TRIGLYCERIDES LONG CHAIN</p> <p>2. MEDIUM CHAIN TRIGLYCERIDES</p> <p>1. Oral liquid 250 mL, 18 (Carbzero)</p> <p>2. Oral liquid 250 mL, 18 (Betaquik)</p> <p>1. CarbZero®</p> <p>2. Betaquik®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing</p> <p>(Minor Submission)</p> | <p>1. Ketogenic diet</p> <p>2. Ketogenic diet; dietary management of conditions requiring a source of medium chain triglycerides</p> | <p>To request a change in nutritional profile and packaging for CarbZero® and Betaquik®.</p> | <p>The PBAC recommended the continued Restricted Benefit listing for Carbzero® and the Authority Required (Streamlined) listing for Betaquik® with changes in the product presentation from cartons to bottles, and changes in the electrolyte profile for both formulations.</p> |

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| <p>URSODEOXYCHOLIC ACID</p> <p>Tablet 500 mg</p> <p>Ursofalk®</p> <p>Orphan Australia Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Primary biliary cirrhosis</p> | <p>To request an Authority Required (STREAMLINED) listing of a new strength for the treatment of primary biliary cirrhosis</p> | <p>The PBAC recommended the Authority Required (STREAMLINED) listing of ursodeoxycholic acid 500 mg tablets on the PBS noting that the listing would reduce the pill burden for some patients.</p> |
| <p>USTEKINUMAB</p> <p>Injection concentrate for I.V. infusion 130 mg in 26 mL Injection 45 mg in 0.5 mL</p> <p>Stelara®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p> | <p>Crohn disease</p> | <p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the single intravenous induction dose and a Section 85 Authority Required listing for all subcutaneous doses thereafter for the treatment of severe Crohn disease and complex refractory fistulating Crohn disease.</p> | <p>The PBAC recommended that listing of ustekinumab for the treatment of severe Crohn's disease in adult patients on a cost-minimisation basis against infliximab. The PBAC did not recommend the listing of ustekinumab for the treatment of fistulising Crohn's disease.</p> <p>The PBAC considered the equi-effective doses for treatment of severe Crohn's disease in adult patients are:</p> <ul style="list-style-type: none"> • infliximab – 5 mg/kg administered at week 0, week 2, week 6 and then every 8 weeks thereafter; and • ustekinumab – administered as an IV tiered weight-based loading dose at week 0 and then subcutaneously 90 mg every 8 weeks. |
| <p>VORINOSTAT</p> <p>Capsule 100 mg</p> <p>Zolinza®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>New listing</p> <p>(Minor Submission)</p> | <p>Relapsed or refractory cutaneous T-cell lymphoma</p> | <p>Resubmission to request an Authority Required listing for the treatment of relapsed or chemotherapy refractory cutaneous T-cell Lymphoma.</p> | <p>At the November 2016 meeting, the PBAC deferred its decision on the submission lodged by Rare Cancers Australia to seek further clarification from the sponsor of vorinostat (Merck Sharp & Dohme (Australia) Pty Ltd) regarding the financial impact of a listing on the PBS, specifically, the patient numbers and an agreement for a Risk Sharing Arrangement.</p> <p>The PBAC recommended the General Schedule Authority Required listing of vorinostat for the treatment of cutaneous T-cell lymphoma. The PBAC recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of vorinostat would be acceptable at the price proposed in the resubmission.</p> |