CONSULTATION

PHARMAC
Pharmaceutical Management Agency

9 March 2015

Proposal for various pharmaceuticals

PHARMAC is seeking feedback on a proposal for various pharmaceuticals (including new listings, amendments to funding restrictions and a delisting) from 1 May 2015. The proposed changes are summarised below. Details of the proposed changes and background information can be found on the following pages.

The following product would be listed in Section B of the Pharmaceutical Schedule from 1 May 2015:

- Glycopyrronium bromide inj 200 mcg per ml, 1 ml ampoule

The following products would be listed in Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List; HML) from 1 May 2015:

- Mannitol powder for inhalation.
- Altepase inj 2 mg vial.
- Cardioplegia solution (e.g. *Custodiol-HTK*).
- Multivitamin and mineral supplement for patients with burns.

The restrictions relating to the following products would be amended in Section B and/or Part II of Section H of the Pharmaceutical Schedule (as applicable) as follows from 1 May 2015:

- Menthol: the compounding rules would be amended.
- Dornase alfa: the Special Authority criteria would be amended to widen access to patients under the age of six and remove the FEV_1 requirement from the eligibility criteria for long term use of dornase alfa.
- Erlotinib and gefitinib: access would be widened to allow patients experiencing intolerance within the first six weeks of starting either treatment to switch between these treatments.
- Trastuzumab: access would be widened to include neoadjuvant treatment.
- Infliximab: the restrictions for Ulcerative Colitis would be amended to include paediatric measures of severity.
- Zoledronic acid (Aclasta): access would be widened to include inherited bone fragility disorders.

The restrictions relating to the following products would be amended in Section D and Part II of Section H of the Pharmaceutical Schedule (as applicable) as follows from 1 May 2015:

- Fat Modified Products: the modular feed criterion would be amended.
- Food Modules/Nutrient Modules: for products listed under these subgroups with the criterion "modular formula" would be amended.
- Amino acid formula and extensively hydrolysed formula: the criteria would be amended to include definition of a reasonable trial.
- Paediatric Products: access to the products listed under the Paediatric Products subheading in the Special Foods therapeutic group would be widened to include patients who have or are expected to eat little or nothing for 3 days.

The following product would be delisted from the HML from 1 May 2015:

- Diclofenac sodium eye drops 0.1%, single dose

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Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Feedback sought

PHARMAC welcomes feedback on this proposal. **Please specify in your response which product(s) your feedback relates to.** To provide feedback, please submit it in writing by **5 pm** on **Monday, 23 March 2015** to:

Danae Staples-Moon
Funding Coordinator
PHARMAC

Email: consult@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

The proposal is to list, delist, or amend restrictions applying to various pharmaceuticals in the Pharmaceutical Schedule. All proposed changes would occur on 1 May 2015. Existing restrictions for these pharmaceuticals can be found on PHARMAC's website at the links below – for practical reasons these may not be reproduced in their entirety for all pharmaceuticals in this consultation document.

www.pharmac.govt.nz/PharmaceuticalSchedule/Schedule?osq
www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/section-h/

New Listings in Section B of the Pharmaceutical Schedule

- Glycopyrronium bromide injection 200 mcg per ml, 1 ml ampoule (Max Health) would be listed in the Antispasmodics and Other Agents Altering Gut Motility subgroup of the Alimentary Tract and Metabolism therapeutic group in Section B of the Pharmaceutical Schedule at a price and subsidy of $28.56 per 10 ampoules.

New Listings in Part II of Section H of the Pharmaceutical Schedule (the HML)

The following products would be listed on the HML:

Under Diagnostic Agents (Various)

- Mannitol powder for inhalation. (*e.g. Aridol*)

Under Antifibrinolytic Agents (Blood and Blood Forming Organs)

- Altepase inj 2 mg vial.

Under Cardioplegia Solutions (Various)

- Electrolytes Inj 15 mmol/l sodium chloride, 9 mmol/l potassium chloride, 1 mmol/l potassium hydrogen 2-ketoglutarate, 4 mmol/l magnesium chloride, 18 mmol/l histidine hydrochloride, 180 mmol/l histidine, 2 mmol/l tryptophan, 30 mmol/l mannitol, 0.015 mmol/l calcium chloride, 1000 ml bag (*e.g. Custodiol-HTK*).

Under Multivitamin Preparations (Alimentary tract and Metabolism)

- Multivitamin and mineral supplement Cap (e.g. *Clinicians Multivitamin and Mineral Boost*), for patients with burns subject to the following restrictions:

  Restricted
  Limited to 3 months treatment
  Both:
  1. Patient was admitted to hospital with burns; and
  2. Any of the following:
     2.1 Burn size is greater than 15% of total body surface area (BSA) for all types of burns; or
     2.2 Burn size is greater than 10% of BSA for mid-dermal or deep dermal burns; or
     2.3 Nutritional status prior to admission or dietary intake is poor.

  Note: Multivitamin and mineral supplement capsule composition includes vitamin A 250 IU, thiamine 2.5 mg, riboflavin 2.5 mg, nicotinamide 12.5 mg, vitamin B5 10 mg, pyridoxine 5 mg, vitamin B12 6.2 mcg, vitamin C 125 mg, cholecalciferol 2.5 mcg, vitamin E 25 mg, betaine 12.5 mg, biotin 12.5 mcg, boron 250 mcg, calcium 25 mg, choline 6.2 mg, chromium 25 mcg, co-enzyme Q10 1.2 mg, copper 125 mcg, folic acid 37.5 mg, inositol 6.2 mg, iodine 25 mcg, iron 250 mcg, L-Glutamine 6.2 mg, magnesium 12.5 mg, molybdenum 12.5 mg, manganese 0.5 mg, potassium 5 mg, selenium 18.7 mcg, zinc 1.9 mg

Amendments to restrictions in Section B and/or Part II of Section H of the Pharmaceutical Schedule (the HML)

In relation to menthol

- The compounding rules applying to menthol crystals 25 g (PSM, Midwest) and 100 g (Midwest) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough):

  Only in combination
  1) Only in combination with **a dermatological base or proprietary Topical Corticosteroid–Plain, refer dermatological base, page 209** ~~aqueous cream, 10 % urea cream, wool fat with mineral oil lotion, 1% hydrocortisone with wool fat and mineral oil lotion, and glycerol, paraffin and cetyl alcohol lotion;~~
  2) With or without other dermatological galenicals

In relation to dornase alfa

- The Special Authority criteria for dornase alfa, nebuliser solution 2.5 mg per 2.5 ml ampoule (Pulmozyme) in Section B of the Pharmaceutical Schedule would be amended to widen access to patients under the age of six and remove the FEV_1 requirement from the eligibility criteria for long term use of dornase alfa. Patients would continue to be required to have formal assessments and regular lung function tests, which would be forwarded to the panel on an annual basis. Eligibility would continue to be assessed by application to the Cystic Fibrosis Advisory Panel.

In relation to erlotinib

- The Special Authority for erlotinib tab 100 mg and 150 mg (Tarceva) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough):

  Special Authority for Subsidy
  Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
  Either:
  1 All of the following:
    1.1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
    1.2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
    1.3 ~~Either~~ **Any of the following:**
      1.3.1 Patient is treatment naïve; or
      1.3.2 Both:
        1.3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and
        1.3.2.2 Patient has not received prior treatment with gefitinib; ~~and~~ **or**
      1.3.3 Both:
        1.3.3.1 The patient has discontinued gefitinib within 6 weeks of starting treatment due to intolerance; and
        1.3.3.2 The cancer did not progress while on gefitinib; and
    1.4 Erlotinib is to be given for a maximum of 3 months, or
  2 The patient received funded erlotinib prior to 31 December 2013 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

  Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

- The restrictions for erlotinib on the HML would be amended in the same way.

In relation to gefitinib

- The Special Authority for gefitinib tab 250 mg (Iressa) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough):

  Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
  ~~Either~~
  ~~1~~ ~~All of the following:~~
    ~~1.~~1 Patient has ~~treatment naïve~~ locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
    2 Either
      2.1 Patient is treatment naïve; or
      2.2 Both:
        2.2.1 The patient has discontinued erlotinib within 6 weeks of starting treatment due to intolerance; and
        2.2.2 The cancer did not progress whilst on erlotinib; and
    3~~2~~ There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
    4~~3~~ Gefitinib is to be given for a maximum of 3 months.~~, or~~

~~2 The patient received funded gefitinib prior to 1 August 2012 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.~~

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

- The restrictions for gefitinib on the HML would be amended in the same way.

In relation to trastuzumab

- The early breast cancer initial Special Authority criteria for trastuzumab inj 150 mg and 440 mg vial (Herceptin) and 1 mg for ECP (Baxter) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough):

  Initial application — (early breast cancer*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:
  All of the following:
  1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
  2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
  3 Any of the following:
  3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
  3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
  3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
  3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned, or
  3.5~~3.4~~Other treatment regimen, in association with adjuvant chemotherapy, is planned.

- The restrictions for trastuzumab on the HML would be amended in the same way.

In relation to infliximab for severe ulcerative colitis

- The restrictions for infliximab (inj 100 mg [Remicade]) for severe ulcerative colitis on the HML would be amended as follows (additions in bold):

  Initiation - severe ulcerative colitis
  Gastroenterologist
  All of the following:
  1. Patient has histologically confirmed ulcerative colitis; and
  2. Either;
  2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is ≥ 4**; or**
  2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is ≥ 65; and
  3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and
  4. Surgery (or further surgery) is considered to be clinically inappropriate; and
  5. Patient must be reassessed for continuation after 3 months of therapy.

  Continuation - severe ulcerative colitis
  Gastroenterologist
  All of the following:

1. Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
2. **Either:**
   - **2.1 Patient is 18 years or older and the** SCCAI score has reduced by ≥ 2 points from the SCCAI score when the patient was initiated on infliximab**; or**
   - **2.2 Patient is under 18 years and the PUCAI score has reduced to < 10 points;** and
3. Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

In relation to zoledronic acid (Aclasta)

- The restrictions for zoledronic acid (inj 0.05 mg per ml, 100 ml vial [Aclasta]) for osteogenesis imperfecta on the HML would be amended as follows (additions in bold, deletions in strikethrough):

  ~~Osteogenesis imperfecta~~ **Inherited bone fragility disorders**

  Patient has been diagnosed with **an inherited bone fragility disorder (e.g.** ~~clinical or genetic~~ osteogenesis imperfecta**).**

Amendments to restrictions in Section D and Part II of Section H of the Pharmaceutical Schedule (the HML)

In relation to Fat Modified Products

- The initial Special Authority criteria for Fat Modified Products (fat modified feed powder 400 g OP [Monogen]) in Section D of the Pharmaceutical Schedule would be amended as follows (additions in bold):

  Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
  :Any of the following:
  1 Patient has metabolic disorders of fat metabolism; or
  2 Patient has a chyle leak; or
  3 Modified as a modular feed**, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule,** for adults.

- The restrictions for Fat Modified Products on the HML would be amended in the same way.

In relation to Nutrient Modules

- The Special Authority criterion for use as a component in modular formula for products listed under the Carbohydrate subheading, Fat subheading and Protein subheading in the Food Module subgroup in the Special Foods therapeutic group (e.g. Polycal, Calogen, Liquigen, MCT Oil, Protifar, Resource Beneprotein, Promod) in Section D of the Pharmaceutical Schedule would be amended as follows (additions in bold):

  For use as a component in a modular formula **made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule.**

Note – the above refers only to the individual criterion, as it is placed in different sections within the relevant Special Authorities.

- The restrictions for products listed under the Carbohydrate subheading, Fat subheading and Protein subheading in the Food Module subgroup in the Special Foods therapeutic group on the HML would be amended in the same way.

In relation to amino acid formula

- The initial Special Authority criteria for amino acid formula (powder 48.5 g OP [Vivonex Pediatric], 400 g OP [Neocate LCP], powder (unflavoured) 400 g OP [Elecare, Elecare LCP, Neocate Advance, Neocate Gold], powder (vanilla) 400 g OP [Elecare, Neocate Advance]) in Section D of the Pharmaceutical Schedule would be amended as follows (additions in bold):

  Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
  Any of the following:
  1. Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
  2. History of anaphylaxis to cow's milk protein formula or dairy products; or
  3. Eosinophilic oesophagitis.

  Note: A reasonable trial is defined as a 2-4 week trial

- The restrictions for amino acid formula on the HML would be amended in the same way.

In relation to extensively hydrolysed formula

- The initial criteria for extensively hydrolysed formula (powder 450 g OP [Pepti Junior Gold Karicare Aptamil]) in Section D of the Pharmaceutical Schedule would be amended as follows (additions in bold):

  Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
  Any of the following:
  1. Both:
     - 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
     - 1.2 Either:
       - 1.2.1 Soy milk formula has been **reasonably** trialled without resolution of symptoms; or
       - 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
  2. Severe malabsorption; or
  3. Short bowel syndrome; or
  4. Intractable diarrhoea; or
  5. Biliary atresia; or
  6. Cholestatic liver diseases causing malabsorption; or
  7. Cystic fibrosis; or
  8. Proven fat malabsorption; or
  9. Severe intestinal motility disorders causing significant malabsorption; or
  10. Intestinal failure.

  Note: A reasonable trial is defined as a 2-4 week trial

- The restrictions for extensively hydrolysed formula on the HML would be amended in the same way.

In relation to Paediatric Products

- The restrictions for the products listed under the Paediatric Products subheading in the Special Foods therapeutic group (e.g. Pediasure, Nutrini, Fortini) on the HML would be amended as follows (additions in bold):

  Both:
  1. Child is aged one to ten years; and
  2. Any of the following:
     - 2.1 The child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
     - 2.2 Any condition causing malabsorption; or
     - 2.3 Faltering growth in an infant/child; or
     - 2.4 Increased nutritional requirements; or
     - 2.5 The child is being transitioned from TPN or tube feeding to oral feeding**; or**
     - **2.6 The child has eaten, or is expected to eat, little or nothing for 3 days.**

Delisting from Part II of Section H of the Pharmaceutical Schedule (the HML)

In relation to diclofenac sodium eye drops

- Diclofenac sodium eye drops 0.1%, single dose would be delisted from the HML.

Further Information

New listings

Glycopyrronium bromide

Glycopyrronium bromide injection 0.2 mg per ml, 1 ml ampoule is listed on the HML. PHARMAC has received requests to fund glycopyrronium bromide injection in Section B of the Pharmaceutical Schedule for use in controlling oral secretions in order to reduce noisy breathing in patients near death ('death rattle'). The Analgesic Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) has advised that there are two formulations of hyoscine injection that are funded and can be used for the management of noisy breathing in patients near death; hyoscine hydrobromide inj 400 mcg per ml, 1 ml and hyoscine N-butylbromide inj 20 mg per ml, 1 ml and that these have the same or similar therapeutic effect as glycopyrronium bromide for this indication. More information can be found on PHARMAC's Application Tracker at: http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=850

There have been ongoing supply issues with hyoscine hydrobromide injection and currently this is being supplied, sold and prescribed subject to the requirements of section 25 or 29 of the Medicines Act 1981, as applicable. Listing glycopyrronium bromide injection in Section B of the Pharmaceutical Schedule would provide an alternative treatment option for this indication.

For the avoidance of doubt management of noisy breathing in patients near death is an unapproved indication (i.e this indication does not have Medsafe approval), for any of these treatments.

Mannitol

Bronchial provocation (bronchoprovocation) testing using mannitol powder for inhalation as the inhalational challenge has good sensitivity and specificity for the diagnosis of asthma. It has been used extensively in respiratory laboratories within DHB hospitals to identify persons with bronchial

hyperresponsiveness and in patients with asthma to assess disease severity and response to treatment. Metacholine is also widely used for this purpose. At the time of the formation of the HML, metacholine was listed but mannitol was inadvertently overlooked.

Altepase

Alteplase is a thrombolytic therapy indicated in the treatment of myocardial infarction, pulmonary embolism and acute ischaemic stroke. The 10 mg and 50 mg vial presentations are already listed on the HML. PHARMAC has received requests from some DHB hospitals to list the 2 mg vial presentation as well, because in some clinical situations it would be more cost-effective.

Cardioplegia solution

Custodiol-HTK (electrolytes Inj 15 mmol/l sodium chloride, 9 mmol/l potassium chloride, 1 mmol/l potassium hydrogen 2-ketoglutarate, 4 mmol/l magnesium chloride, 18 mmol/l histidine hydrochloride, 180 mmol/l histidine, 2 mmol/l tryptophan, 30 mmol/l mannitol, 0.015 mmol/l calcium chloride, 1000 ml bag) is registered as a medical device in New Zealand. It is indicated overseas for the preservation of organ transplants (heart, kidney, liver, pancreas, lung) together with venous or arterial segments. PHARMAC has received requests from DHB hospitals for the listing of this solution on the HML for use in organ transplants as well as in more complex cardiac surgeries. These complex cardiac surgeries often involve a prolonged period of induced cardiac arrest and currently to maintain arrest, surgery is interrupted to infuse cold blood cardioplegia solution. The clinical feedback we have received indicates that Custodiol-HTK would be a better alternative as it can be administered as a once-off dose.

Multivitamin and mineral supplement for patients with burns

At its May 2014 meeting, PTAC noted that while a number of vitamin and mineral preparations are already funded on the Pharmaceutical Schedule, none contain all the components that are suggested to be important in supporting burn healing. The Committee considered that a multivitamin and mineral supplement for patients with burns be listed on the HML subject to restrictions. The full minute of this discussion can be found at: http://www.pharmac.health.nz/assets/ptac-minutes-2014-05.pdf

Restriction changes

The proposed restriction changes are generally in line with recommendations from PTAC or one of the PTAC Subcommittees (subsequently ratified by PTAC). Advice from the most recent relevant PTAC or Subcommittee meeting is set out below. Links are provided where the minute is available on PHARMAC's website. Please contact Danae Staples-Moon if further information is required (contact details on page 1 of this document).

Menthol

- At its December 2013 meeting the Dermatological Subcommittee of PTAC recommended removal of the current restriction relating to which specific inert bases to which menthol may be added.

Erolitinib and gefitinib

- At its March 2014 meeting the Cancer Treatments Subcommittee of PTAC considered that both erlotinib and gefitinib were similar treatments; however, they may have different side

effect profiles in different patients. Members recommended that patients should be able to switch between these treatments if they experienced intolerance to either in the first 6 weeks of treatment.

Trastuzumab

- At its March 2014 meeting the Cancer Treatments Subcommittee of PTAC noted that in some centres trastuzumab was being used prior to surgery (neoadjuvant) for women with HER 2 positive early breast cancer. Members noted that whilst some trastuzumab was given prior to surgery the balance was given post-surgery and that total cumulative treatment did dose not exceeding 106 mg/kg (12 months' treatment).

Infliximab

- At its May 2014 meeting the Gastrointestinal Subcommittee of PTAC noted the HML restrictions for infliximab for ulcerative colitis (UC) use a score system (the Simple Clinical Colitis Activity Index, SCCAI ≥ 4) that is not appropriate for children with UC. Members considered the Paediatric Ulcerative Colitis Activity Index (PUCAI) score of 60 to 85 would be an appropriate measure of severe disease activity in children and recommended PHARMAC consider incorporating the PUCAI into the HML restrictions for UC. http://www.pharmac.health.nz/assets/ptac-gastrointestinal-subcommittee-minutes-2014-05-21.pdf

Zoledronic Acid (Aclasta)

- At its June 2014 meeting the Endocrinology Subcommittee of PTAC considered that there was a very small number of patients with other rare inherited bone fragility disorders such as osteoporosis pseudoglioma syndrome, McCune-Albright syndrome and some metabolic bone disorders (e.g. the mucolipidoses), who could benefit from zoledronic acid but who are potentially missing out on treatment because of the way the restriction is worded. The Subcommittee recommended that the HML restrictions for this indication be amended to include inherited bone fragility disorder.

Special Foods: Paediatric Products, Fat Modified Products, Food Modules/Nutrient Modules, Amino Acid Formula, Extensively Hydrolysed Formula

- At its December 2013 meeting the Special Foods Subcommittee of PTAC made recommendations regarding Paediatric Products, Fat Modified Products, Food Modules/Nutrient Modules, Amino Acid Formula, Extensively Hydrolysed Formula. Details of the recommendations can be found in the minute of this meeting http://www.pharmac.health.nz/assets/ptac-special-foods-subcommittee-minutes-2014-02.pdf

Delisting

Diclofenac sodium single-dose eye drops

- Diclofenac sodium eye drops 0.1%, single dose (0.3 ml), currently listed in the HML, has been discontinued world-wide due to low sales volumes and stock has been exhausted. The diclofenac sodium eye drops 0.1% multi-dose 5 ml preparation is still available and currently listed in Section B of the Pharmaceutical Schedule and the HML. At its October 2014 meeting the Ophthalmology Subcommittee of PTAC noted that PHARMAC had sought feedback from the hospitals using the single-dose preparation which indicated that neither a single-dose nor a preservative-free NSAID preparation was required and they would change over to using the multi-dose bottle. The Subcommittee did not identify any ongoing need for a single-dose unit NSAID preparation.