Hospital Pharmaceuticals Review

PTAC, Hospital Pharmaceuticals Subcommittee, Gastrointestinal Subcommittee and Diabetes Subcommittee minutes for web publishing

Alimentary Tract and Metabolism therapeutic group

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This document contains minutes relevant to the consultation document of 25 September 2012 relating to products in the Alimentary Tract and Metabolism therapeutic group.

Note that this document is not a complete record of the relevant PTAC and Subcommittee meetings; only the relevant portions of the minutes relating PTAC and its Subcommittees advice on the review of Hospital Pharmaceuticals are included.

Contents

Hospital Pharmaceuticals Subcommittee – 2 August 2011

1 Antacids and Antiflatulents

1.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antacids and Antiflatulents heading.

1.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Aluminium hydroxide with magnesium hydroxide and simeticone
  - Oral liq 200 mg with magnesium hydroxide 200 mg and simeticone 20 mg per 5 ml
  - Tab 200 mg with magnesium hydroxide 200 mg and simeticone 20 mg
- Calcium carbonate
  - Tab 420 mg
- Simeticone
  - Oral drops 100 mg per ml
- Sodium alginate with magnesium alginate
  - Powder for oral soln 225 mg with magnesium alginate 87.5 mg
- Sodium alginate with sodium bicarbonate and calcium carbonate
  - Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml
  - Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg
- Sodium citrate
  - Oral liq 8.8% (300 mmol/L)
- Aluminium hydroxide
  - Tab 600 mg

1.3 The Subcommittee noted that aluminium hydroxide oral liq 400 mg with magnesium hydroxide 400 mg and simeticone 30 mg per 5 ml are not in use in DHB hospitals and are not subsidised in the Pharmaceutical Schedule. The Subcommittee recommended that it not be included in a national PML.

1.4 The Subcommittee recommended that, as simeticone capsules are not subsidised in the Pharmaceutical Schedule, and as they do not have a unique use within hospitals, that they not be included in a national PML.

1.5 The Subcommittee noted that sodium alginate 250 mg with sodium bicarbonate 133.5 mg and calcium carbonate 80 mg tablets are not in wide use in DHB hospitals and are not subsidised in the Pharmaceutical Schedule. The Subcommittee recommended that this not be included in a national PML.

1.6 The Subcommittee noted that sevelamer hydrochloride tablets are not currently in use in DHB hospitals, and recommended that this not be included in a national PML.

2 Antidiarrhoeals and Intestinal Anti-Inflammatory Agents

2.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antidiarrhoeals and Intestinal Anti-Inflammatory Agents heading.

2.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Diphenoxylate hydrochloride with atropine sulphate
  - Tab 2.5 mg with atropine sulphate 25 µg
- Loperamide hydrochloride
  - Cap 2 mg
  - Tab 2 mg
- Budesonide
  - Cap 3 mg
- Glyceryl trinitrate
  - Ointment 0.2%
- Hydrocortisone acetate
  - Rectal foam 10%
- Mesalazine
  - Tab 400 mg
  - Tab EC 500 mg
  - Tab long-acting 500 mg
  - Suppos 500 mg
  - Suppos 1 g
  - Enema 1 g per 100 ml
- Olsalazine
  - Cap 250 mg
  - Tab 500 mg
- Sodium cromoglicate
  - Cap 100 mg
- Adalimumab
  - Inj 40 mg per 0.8 ml (pen/syringe)
- Infliximab
  - Inj 100 mg

2.3 The Subcommittee recommended that the listing of budesonide capsules in a national PML be subject to restrictions on its use that are in line with the Special Authority restriction for it in the Pharmaceutical Schedule.

2.4 The Subcommittee noted that PTAC had previously recommended against the listing of glyceryl trinitrate ointment in the Pharmaceutical Schedule. The Subcommittee noted that PTAC had considered that it was of little additional benefit for pain relief, but members noted that it is more commonly used for wound healing, and is often used in the surgical setting. The Subcommittee recommended that PHARMAC determine if new evidence was available for glyceryl trinitrate ointment and to provide any such information to PTAC.

2.5 The Subcommittee noted that it has previously recommended that sulphasalazine (tab 500 mg and tab EC 500 mg) be included in a national PML.

2.6 The Subcommittee recommended that the listing of adalimumab for Crohn's disease in a national PML be subject to restrictions on its use that are in line with the Special Authority restriction for it in the Pharmaceutical Schedule.

2.7 Members noted that adalimumab was now approved for use in fistulising Crohn's disease and that PHARMAC staff were expecting a funding application for this use.

2.8 The Subcommittee noted that use of adalimumab in DHB hospitals for Crohn's disease is often outside the Special Authority restrictions, primarily to provide a short-term doubling of the dose.

2.9 The Subcommittee recommended that the view of gastroenterologists be sought on the access criteria and dosing regimens for TNF inhibitors for Crohn's disease and ulcerative colitis for a national PML. Members noted that the Otago guidelines for these would likely be a good basis to start from.

3 Antihaemorrhoidals

3.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antihaemorrhoidals heading.

3.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Cinchocaine hydrochloride with hydrocortisone
  - Oint 5 mg with hydrocortisone 5 mg per g
  - Suppos 5 mg with hydrocortisone 5 mg per g
- Fluocortolone caproate with fluocortolone pivalate and cinchocaine
  - Oint 950 µg with fluocortolone pivalate 920 µg and cinchocaine hydrochloride 5 mg per g
  - Suppos 630 µg with fluocortolone pivalate 610 µg and cinchocaine hydrochloride 1 mg
- Oily phenol
  - Inj 5%, 5 ml

3.3 The Subcommittee noted that there was some use of hamamelis extract in DHB hospitals, but recommended that this not be included in a national PML.

3.4 The Subcommittee noted that zinc oxide ointment and suppositories had been delisted from the Pharmaceutical Schedule, and considered that it was not necessary for these to be listed in a national PML.

4 Antiobesity Drugs

4.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antiobesity Drugs heading.

4.2 The Subcommittee noted that orlistat and phentermine are not widely used in DHB hospitals and are not subsidised in the Pharmaceutical Schedule. The Subcommittee recommended that they not be included in a national PML.

5 Antispasmodics and Other Agents Altering Gut Motility

5.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antispasmodics and Other Agents Altering Gut Motility heading.

5.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Cisapride
  - Oral liq 1 mg per ml
  - Tab 10 mg
- Hyoscine butylbromide (scopolamine)
  - Inj 20 mg, 1 ml
  - Tab 10 mg
- Mebeverine
  - Tab 135 mg

5.3 The Subcommittee noted that peppermint oil 0.2 ml capsules are considered to be a useful treatment for Irritable Bowel Syndrome but considered that this should only be included in a national PML if they are also funded in the Pharmaceutical Schedule.

5.4 The Subcommittee noted that peppermint oil oral liquid was not widely used in DHB hospitals, and considered that it did not need to be included in a national PML.

5.5 The Subcommittee noted that there is some use of propantheline bromide tablets in DHB hospitals, but recommended that this not be included in a national PML.

6 Antiulcerants

6.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Antiulcerants heading.

6.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Misoprostol
  - Tab 200 µg
- Cimetidine
  - Tab 200 mg
  - Tab 400 mg
- Famotidine
  - Tab 20 mg
  - Tab 40 mg

- Ranitidine
  - Inj 25 mg per ml, 2 ml
  - Oral liq 150 mg per 10 ml
  - Tab 150 mg
  - Tab 300 mg
- Lansoprazole
  - Cap 15 mg
  - Cap 30 mg
- Omeprazole
  - Cap 10 mg
  - Cap 20 mg
  - Cap 40 mg
  - Powder for oral soln
  - Inj 40 mg
  - Inf 40 mg
- Pantoprazole
  - Inj 40 mg
  - Tab 20 mg
  - Tab 40 mg
- Sucralfate
  - Tab 1 g

6.3 The Subcommittee considered that, although bismuth 120 mg tablet is not widely used in DHB hospitals, it is a last-line treatment option for H. Pylori infection, and recommended that it be included in a national PML.

6.4 The Subcommittee noted that the combination pack of omeprazole, amoxycillin and clarithromycin has been discontinued, and considered that there was no need for this to be included in a national PML.

6.5 The Subcommittee noted that having oral liquid preparations of omeprazole is important, both for paediatric patients and for patients fed via nasogastric tubes. Members noted that this is currently achieved in different ways across DHBs – by manufacturing a liquid within the pharmacy (either from capsules or powder), outsourcing manufacture of a liquid from a powder, or by using dispersible tablets.

6.6 The Subcommittee recommended that PHARMAC seek the advice of pharmacists with expertise in extemporaneous compounding on what the preferred solution should be to ensure that hospital pharmacies have access to one or more appropriate sources of omeprazole oral liquid. Members noted that the volume of omeprazole liquid used in DHB hospitals is quite significant, so resource constraints are an important factor to take into account.

7 Bile and Liver Therapy

7.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to l-ornithine l-aspartate.

7.2 The Subcommittee noted that l-ornithine l-aspartate (5 g sachets) is widely used in DHB hospitals, and that it is included in the Discretionary Community Supply list. The Subcommittee recommended that it be included in a national PML, and considered that PHARMAC should consider it for listing in the Pharmaceutical Schedule for community use.

8 Diabetes

8.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Diabetes heading.

8.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Acarbose
  - Tab 50 mg
  - Tab 100 mg
- Glucagon hydrochloride
  - Inj 1 mg syringe kit
- Insulin isophane
  - Insulin human 100 u per ml, 10 ml
  - Insulin human 100 u per ml, 3 ml
- Insulin lispro with insulin lispro protamine
  - Inj insulin lispro 25% with insulin lispro protamine 75%, 100 u per ml, 3 ml
  - Inj insulin lispro 50% with insulin lispro protamine 50%, 100 u per ml, 3 ml
- Insulin neutral with insulin isophane
  - Inj insulin neutral 30% with insulin isophane 70%, 100 u per ml, 10 ml
  - Inj insulin neutral 30% with insulin isophane 70%, 100 u per ml, 3 ml
  - Inj insulin neutral 40% with insulin isophane 60%, 100 u per ml, 3 ml
  - Inj insulin neutral 50% with insulin isophane 50%, 100 u per ml, 3 ml
- Insulin glargine
  - Inj 100 u per ml, 10 ml
  - Inj 100 u per ml, 3 ml
  - Inj 100 u per ml, 3 ml disposable pen
- Insulin aspart
  - Inj 100 u per ml, 10 ml
  - Inj 100 u per ml, 3 ml
- Insulin glulisine
  - Inj 100 u per ml, 10 ml
  - Inj 100 u per ml, 3 ml
  - Inj 100 u per ml, 3 ml disposable pen
- Insulin lispro
  - Inj 100 u per ml, 10 ml
  - Inj 100 u per ml, 3 ml
- Insulin neutral
  - Inj human 100 u per ml, 10 ml
  - Inj human 100 u per ml, 3 ml
- Diazoxide
  - Cap 25 mg
  - Cap 100 mg
- Glibenclamide
  - Tab 5 mg
- Gliclazide
  - Tab 80 mg
- Glipizide
  - Tab 5 mg

- Metformin
  - Tab immediate-release 500 mg
  - Tab immediate-release 850 mg
- Pioglitazone
  - Tab 15 mg
  - Tab 30 mg
  - Tab 45 mg

8.3 The Subcommittee recommended that the listing of pioglitazone in a national PML be subject to restrictions on its use that are in line with the Special Authority restriction for it in the Pharmaceutical Schedule.

8.4 The Subcommittee considered that there was a need for an oral liquid preparation of diazoxide, and recommended that PHARMAC seek the advice of pharmacists with expertise in extemporaneous compounding on whether this could be achieved by extemporaneous compounding, or whether a proprietary oral liquid preparation would be required.

8.5 The Subcommittee noted that there is no use of diazoxide 50 mg capsules in DHB hospitals, and considered that these did not need to be included in a national PML.

8.6 The Subcommittee recommended that, as insulin detemir was not subsidised in the Pharmaceutical Schedule, and as it does not have a unique use within hospitals, it not be included in a national PML.

8.7 The Subcommittee noted that chlorpropamide is not in use in DHB hospitals, and considered that it does not need to be included in a national PML.

8.8 The Subcommittee recommended that, as sitagliptin was not subsidised in the Pharmaceutical Schedule, and as it does not have a unique use within hospitals, it not be included in a national PML.

9 Digestives Including Enzymes

9.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Digestives Including Enzymes heading.

9.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Pancreatic enzyme
  - Cap EC 10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease
  - Cap EC 25,000 BP u lipase, 18,000 BP u amylase and 1,000 BP u protease
  - Cap EC 25,000 BP u lipase, 22,500 BP u amylase and 1,250 BP u protease
- Ursodeoxycholic acid
  - Cap 300 mg

9.3 The Subcommittee noted that other presentations of pancreatic acid capsules and tablets have been, or are being, discontinued, and considered that they did not need to be included in a national PML.

9.4 The Subcommittee considered pancreatic acid powder (25,000 u lipase, 30,000 u amylase and 1,400 u protease per g) was required for administration via nasogastric tubes, and recommended that this be included in a national PML.

9.5 The Subcommittee considered that there was a need for an oral liquid preparation of ursodeoxycholic acid, and recommended that PHARMAC seek the advice of pharmacists with expertise in extemporaneous compounding on whether this could be achieved by extemporaneous compounding, or whether a proprietary oral liquid preparation would be required.

9.6 The Subcommittee considered that there may be benefit from having an oral liquid formulation of ursodeoxycholic acid available in the community also.

10 Intestinal Anti-Infective Agents

10.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Intestinal Anti-Infective Agents heading.

10.2 The Subcommittee considered that, although tetracycline 250 mg tablet is not widely used in DHB hospitals, it is, in combination with bismuth, a last-line treatment option for H. Pylori infection and recommended that it be included in a national PML.

10.3 The Subcommittee noted that rifaximin (200 mg tablet) has been used in one DHB for the treatment of hepatic encephalopathy. The Subcommittee noted that there may be benefits in making this available on a national PML for patients for whom lactulose has failed, and requested that the Anti-Infective Subcommittee provide advice on this matter.

11 Laxatives

11.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Laxatives heading.

11.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Citric acid with magnesium oxide and sodium picosulfate
  - Powder for oral soln 12 g with magnesium oxide 3.5 g and sodium picosulfate 10 mg per sachet
- Macrogol 3350 with potassium chloride, sodium bicarbonate, sodium chloride and sodium sulphate
  - Powder for oral soln 59 g with potassium chloride 0.7425 g, sodium bicarbonate 1.685 g, sodium chloride 1.465 g and sodium sulphate 5.685 g per sachet
- Ispaghula (psyllium) husk
  - Powder for oral soln
  - Powder for oral soln, sugar-free
- Docusate sodium
  - Cap 50 mg
  - Cap 120 mg

- Docusate sodium with sennosides
  - Tab 50 mg with sennosides 8 mg
- Paraffin
  - Enema 133 ml
  - Oral liquid 1 mg per ml
- Poloxamer
  - Oral drops 10%
- Glycerol
  - Suppos 3.6 g
- Lactulose
  - Oral liq 10 g per 15 ml
- Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride
  - Powder for oral soln 6.563 g with potassium chloride 23.3 mg, sodium bicarbonate 89.3 mg and sodium chloride 175.4 mg
  - Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg
- Sodium citrate with sodium lauryl sulphoacetate
  - Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml
- Sodium phosphate with phosphoric acid
  - Enema 10% with phosphoric acid 6.58%
- Bisacodyl
  - Tab 5 mg
  - Suppos 5 mg
  - Suppos 10 mg
- Danthron with poloxamer
  - Oral liq 25 mg with poloxamer 200 mg per 5 ml
  - Oral liq 75 mg with poloxamer 1 g per 5 ml
- Sennosides
  - Tab 7.5 mg

11.3 The Subcommittee noted that macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride (Movicol) is subject to Special Authority restriction in the community, but considered that a restriction would not be required in a national PML because it is used in-hospital as a bowel-cleansing preparation.

11.4 The Subcommittee noted that macrogol 3350 with ascorbic acid, potassium chloride and sodium chloride (Glycoprep-C) sachets (70 g and 210 g) were not widely used in DHB hospitals, but considered that they should be included as alternative bowel-cleansing preparations.

11.5 The Subcommittee noted that lower dose glycerol suppositories (1.27 g and 2.55 g) were not widely used in DHB hospitals, but recommended that they be included in a national PML.

11.6 The Subcommittee noted that macrogol 3350 856.92 mg with potassium chloride 112.5 mg, sodium bicarbonate 25.32 mg, sodium chloride 22 mg and sodium sulphate 84.81 mg per g (Glycoprep) powder was not widely used in DHB hospitals and did not need to be included in a national PML.

11.7 The Subcommittee noted that there was little use of sterculia in DHB hospitals and that it was not subsidised in the Pharmaceutical Schedule, and considered that it did not need to be included in a national PML. Members noted that PHARMAC tenders

have historically been for 'bulk forming laxatives' which encompasses both sterculia and ispaghula (psyllium), and so one or the other will be funded in the community at any point in time.

11.8 The Subcommittee considered that, as sterculia with frangula is not fully subsidised in the Pharmaceutical Schedule and as it does not have a niche use in hospitals, it did not need to be included in a national PML.

11.9 The Subcommittee noted that docusate sodium enema was not commonly used in DHB hospitals, and that although it is subsidised in the Pharmaceutical Schedule, it is rarely used. The Subcommittee recommended that it not be included in a national PML.

11.10 The Subcommittee noted that sodium phosphate with phosphoric acid oral liquid was widely used in DHB hospitals, but recommended that, because of the risk of phosphate nephropathy and the availability of alternative laxatives, it should not be included in a national PML.

12 Metabolic Disorder Agents

12.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Metabolic Disorder Agents heading.

12.2 The Subcommittee noted that imiglucerase (inj 40 iu per ml, 200 iu vial and 400 iu vial) is fully subsidised in the Pharmaceutical Schedule and recommended it be included in a national preferred medicines list (PML).

12.3 The Subcommittee considered that the listing of imiglucerase in a national PML should be subject to a prescribing restriction that required prescribing of it to be done in conjunction with the Gaucher's Treatment Panel.

12.4 The Subcommittee considered that while the following pharmaceuticals are not widely used treatments in DHB hospitals, and are not subsidised in the Pharmaceutical Schedule, they are considered to be essential treatments for various metabolic disorders, and should be included in a national PML:

- Haem arginate
  - Inj 25 mg per ml, 10 ml ampoule
- L-carnitine
  - Cap 500 mg
  - Inj 200 mg per ml, 5 ml
  - Oral soln 500 mg per 15 ml
- Betaine
  - Powder
- Sodium benzoate
  - Cap 500 mg
  - Inj 20%
  - Powder
  - Soln 100 mg per ml
- Sodium phenylbutyrate
  - Inj 200 mg per ml, 10 ml
  - Oral liq 250 mg per ml
  - Tab 500 mg

- Trientine dihydrochoride
  - Cap 300 mg

12.5 Members noted that these metabolic products are very low volume items, and are unlikely to be stocked by all hospital pharmacies, but that stocks would need to be held within the country to ensure rapid access when required.

12.6 The Subcommittee noted that zinc acetate is used in the treatment of Wilson's disease, but deferred consideration of this until it considered all other oral zinc preparations.

13 Mouth and Throat

13.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Mouth and Throat heading.

13.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Benzydamine hydrochloride
  - Soln 0.15%
  - Spray 0.15%
- Benzydamine hydrochloride with cetylpyridinium chloride
  - Lozenge 3 mg with cetylpyridinium chloride 1.33 mg
- Chlorhexidine gluconate
  - Mouthwash 0.2%
- Choline salicylate with cetalkonium chloride
  - Adhesive gel 8.7% with cetalkonium chloride 0.01%
- Sodium carboxymethylcellulose
  - With pectin and gelatine paste
  - With pectin and gelatine powder
- Triamcinolone acetonide
  - 0.1% in dental paste USP
- Dichlorobenzyl alcohol with amylmetacaresol
  - Lozenge 1.2 mg with amylmetacresol 0.6 mg
- Hydrogen peroxide
  - Soln 10 vol
- Saliva substitute
  - Spray
- Thymol glycerine
  - Compound, BPC

13.3 The Subcommittee considered that further advice was required before making a recommendation on cetylpyridinium chloride lozenges and mouthwash, and requested the view of dentists and otolaryngologists on the need for these in a national PML.

13.4 The Subcommittee considered that further advice was required before making a recommendation on cetylpyridinium chloride with benzocaine mouthwash, and

requested the view of dentists and otolaryngologists on the need for this in a national PML.

13.5 The Subcommittee noted that enoxolone with povidone and sodium hyaluronate gel was used in one DHB, and was not subsidised in the Pharmaceutical Schedule. Members noted that an alternative treatment was choline salicylate with cetalkonium chloride, which was widely used and was partially subsidised in the community. The Subcommittee recommended that enoloxone with povidone and sodium hyaluronate gel not be included in a national PML.

13.6 The Subcommittee noted that three proprietary saliva substitute products were currently in use in DHB hospitals, and that saliva substitute spray (Oralube) was the most widely used of these. The Subcommittee noted that the other two products - carmellose sodium oral spray and hypromellose sodium oral gel – were significantly less used, and considered that these did not need to be included in a national PML if Oralube was available.

13.7 The Subcommittee noted that dichlorobenzyl alcohol with amylmetacresol and lignocaine lozenges were in use in one DHB, and were not subsidised in the Pharmaceutical Schedule. The Subcommittee recommended that this not be included in a national PML.

Gastrointestinal Subcommittee – 13 April 2012

14 Hospital Pharmaceuticals

14.1 The Subcommittee noted the developments and future initiatives planned in regards to PHARMAC becoming responsible for the funding of hospital pharmaceuticals.

14.2 The Subcommittee reviewed a series of recommendations by the Hospital Pharmaceuticals Subcommittee in regards to which pharmaceuticals relevant to respiratory medicine should be included on a national preferred medicines list (PML). The Subcommittee noted that PHARMAC had invited feedback from relevant colleges and professional societies, and noted the responses that were received.

Antidiarrhoeals and Intestinal Anti-Inflammatory Agents

14.3 The Subcommittee noted that the same funding criteria should apply to infliximab as currently has been proposed for adalimumab for severe Crohn's disease and for fistulising disease with the following additions:

- Infliximab criteria should include treatment for patients with acute, severe fulminant ulcerative colitis,
- Infliximab criteria should permit treatment for children
- Infliximab criteria should include patients with severe extra-intestinal manifestations of Crohn's disease

Antihaemorrhoidals

14.4 The Subcommittee noted that a barrier preparation such as zinc oxide should be available as an adjunct to peri-anal disease therapy.

Antispasmodics and Other Agents Affecting Gut Motility

14.5 The Subcommittee noted that cisapride has been recommended for addition to the PML however it is not available in the community. The Subcommittee recommended that cisapride be listed on the Community Pharmaceutical Schedule with the following Special Authority Criteria:

> **Initial Application** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
> Both:
> 1. Patient has a severe gastrointestinal motility disorder; and
> 2. An ECG has been performed and the patient is suitable for treatment

Antiulcerants

14.6 The Subcommittee noted that bismuth 120 mg tablet has been recommended for inclusion on the PML, and recommended that this be funded in the community.

Bile and Liver Therapy

14.7 The Subcommittee noted that treatment of hepatic encephalopathy can continue for several years, and such considered that treatments for this should be funded in the community, rather than from DHB hospitals. The Subcommittee recommended that rifaximin be included on the PML and in the community for the treatment of hepatic encephalopathy. Members noted that there is less evidence to support the efficacy of L-ornithine L-aspartate (LOLA), and increasing evidence to support rifaximin use in this population. The Subcommittee recommended that a supplier be sought and for a funding application to be submitted to PHARMAC.

Laxatives

14.8 The Subcommittee noted that while Picoprep is primarily used as a preparatory agent for colonoscopy, it can also be used for faecal disimpaction. Members noted that having Picoprep available in the community for this purpose would be beneficial.

14.9 The Subcommittee noted that the Hospital Pharmaceuticals Subcommittee had recommended that macrogol 3350 not be subject to prescribing restrictions in DHB hospitals. Members considered that it would also be appropriate to have the community Special Authority criteria apply in hospitals, provided that an additional provision for short-term use as a bowel cleanser was provided.

14.10 The Subcommittee recommended that two bulk forming laxatives be available for both hospital and community use, therefore in addition to psyllium it recommends that sterculia be listed.

14.11 The Subcommittee recommended that a liquid sennoside preparation be sought for funding.

Intestinal Anti-Infective Agents

14.12 The Subcommittee noted that tetracycline 250 mg tablet has been recommended for inclusion on the PML, and recommended that this be funded in the community.

14.13 The Subcommittee noted that the criteria currently applying to vancomycin injections should be clarified to allow funding for oral use to treat Clostridium dificile

Other Products

14.14 The Subcommittee considered that succinylated gelatin 4% (Gelofusine) should be included on the PML for use in endoscopy.

Diabetes Subcommittee – 20 April 2012

15 Hospital Pharmaceuticals

15.1 The Subcommittee noted the developments and future initiatives planned in regards to PHARMAC becoming responsible for the funding of hospital pharmaceuticals.

15.2 The Subcommittee reviewed a series of recommendations by the Hospital Pharmaceuticals Subcommittee in regards to which pharmaceuticals relevant to diabetes should be included on a national preferred medicines list (PML).

15.3 The Subcommittee noted that diazoxide is not currently listed on the community Schedule and that there is no registered product available in New Zealand. The Subcommittee recommended that diazoxide be subsidised in the community for patients with confirmed hypoglycaemia caused by hyperinsulinism.

15.4 The Subcommittee considered that a high strength glucose tablet should be available in hospitals as fewer tablets would be required to treat hypoglycaemia. Members noted that a dose of at least 15 g would usually be given.

16 Review of Alimentary Tract and Metabolism Recommendations

16.1 The Subcommittee reviewed its previous recommendations in relation to products in the Alimentary Tract and Metabolism group, feedback from other organisations, and recommendations from the Gastrointestinal Subcommittee and the Diabetes Subcommittee.

Antidiarrhoeals and Intestinal Anti-Inflammatory Agents

16.2 The Subcommittee noted the Gastrointestinal Subcommittee's recommendations in relation to prescribing restrictions for infliximab. Members noted that the proposed criteria are substantially wider than those that are currently in place for adalimumab, and that several of the additional criteria are off-label uses, and that PTAC has not previously reviewed the use of TNF inhibitors for these uses.

Antihaemorrhoidals

16.3 The Subcommittee noted that the Gastrointestinal Subcommittee had recommended that either zinc oxide with peru balsum, or an alternative barrier cream, be included in a national PML. The Subcommittee agreed with this recommendation.

Antispasmodics and Other Agents Affecting Gut Motility

16.4 The Subcommittee noted that it had previously recommended that cisapride be included in a national PML, and that the Gastrointestinal Subcommittee had recommended that this be subsidised in the community. The Subcommittee noted that this is a long-term treatment, and recommended that cisapride only be included in a national PML if it is subsidised in the community.

Antiulcerants

16.5 The Subcommittee noted that the Gastrointestinal Subcommittee had recommended prescribing restrictions for dispersible omeprazole or esomeprazole. Members noted that a 10 mg dose limit would not be practical as very young children are often prescribed higher doses than this.

16.6 The Subcommittee recommended that the prescribing criteria proposed by the Gastrointestinal Subcommittee for dispersible omeprazole or esomeprazole be amended as follows (changes in bold and strikethrough):

> Either:
>
> 1 Both:
>
> 1.1 The patient is a child ~~who requires a 10 mg dose or less,~~ for whom sprinkling the contents of omeprazole capsules on soft food has not been tolerated or is not appropriate; and
>
> 1.2 Patient has trialled an adequate course of sodium alginate powders and**/or** an H_2 antagonist and ~~both products~~ have been unsuccessful or not tolerated; or
>
> 2 Patient has a naso-gastric tube inserted.

Diabetes

16.7 The Subcommittee noted the Diabetes Subcommittee's recommendation to include a higher dose oral glucose preparation in a national PML.

Laxatives

16.8 The Subcommittee noted the Gastrointestinal Subcommittee's recommendation in relation to prescribing restrictions for macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride (Movicol), and for a paediatric preparation of macrogol 3350. The Subcommittee noted that any such prescribing restrictions should specify faecal disimpaction, as well as bowel cleansing.

16.9 The Subcommittee noted that there was interest in an oral liquid sennoside. The Subcommittee considered that this should be a community-led funding decision.

16.10 The Subcommittee noted the Gastrointestinal Subcommittee's recommendation in relation to bulk forming laxatives. The Subcommittee considered that this should be a community-led funding decision.

Metabolic Disorder Agents

16.11 The Subcommittee noted feedback suggesting that arginine preparations are required in a national PML. Members noted that although several forms are currently used at Auckland DHB, some of these have already been recommended for inclusion as part of the review of diagnostic agents. The Subcommittee recommended that arginine powder and arginine infusion (600 mg per ml, 25 ml) also be included in a national PML.

Mouth and Throat

16.12 The Subcommittee noted that it has deferred making a recommendation in relation to cetylpyridinium chloride lozenges and mouthwash, and on cetylpyridinium chloride with benzocaine mouthwash, pending external feedback on the need for these agents in a national PML, but that no such feedback was received. The Subcommittee recommended excluding these from a national PML, and that their exclusion should be highlighted in consultation.

Pharmacology and Therapeutics Advisory Committee – 2 and 3 August 2012

17 Alimentary Tract and Metabolism

17.1 The Committee considered a list of pharmaceuticals under consideration for use in DHB hospitals under the Alimentary Tract and Metabolism heading, including advice from the Hospital Pharmaceuticals Subcommittee, the Diabetes Subcommittee and the Gastrointestinal Subcommittee. Except where indicated, the Committee agreed with the recommendations by the subcommittees.

17.2 The Committee noted the recommendations from the Gastrointestinal Subcommittee in relation to infliximab. Members noted that the issue of extra-intestinal manifestations of Crohn's disease related to a variety of different conditions, such as uveitis and pyoderma gangrenosum, which can be caused by diseases other than Crohn's disease.

17.3 The Committee noted that it had already recommended that uveitis be included in the restrictions for infliximab, and considered that it would need to review applications for other indications before making any recommendations.

17.4 The Committee recommended that ursodeoxycholic acid be subject to prescribing restrictions that are in line with the Special Authority restrictions for it in the community.