CONSULTATION

PHARMAC
Pharmaceutical Management Agency

January 2014

Request for information on the potential listing of a range of medicines

PHARMAC is interested in receiving information from suppliers and other interested parties relating to the supply of a range of medicines that are not currently registered with Medsafe in New Zealand.

Background

PHARMAC occasionally receives applications for listing, or clinical advice indicating that there is a need for a particular medicine, but is subsequently unable to find a supplier to allow progression of negotiations with a view to a listing in the Pharmaceutical Schedule.

These medicines can be unregistered and/or low-volume pharmaceuticals. This Request for Information (RFI) is to ascertain whether there is any interest from suppliers to seek listings of these pharmaceuticals on the Pharmaceutical Schedule. For the avoidance of doubt, this is a RFI only; it is not a proposal to list the medicines identified in this RFI. It is hoped that the information obtained via this RFI will enable PHARMAC to determine whether such proposals should be developed.

Request for information

PHARMAC is interested in information from suppliers and other interested parties, including proposed pricing, related to the potential listing and supply of the pharmaceuticals shown in the table below.

The table also shows where the pharmaceutical would likely be listed – i.e. either in both of Section H (the Hospital Medicine List (HML)) and Section B (community pharmaceuticals) of the Pharmaceutical Schedule or in Section H (the HML) only – if a proposal to list was progressed.

Pharmaceutical*	HML	Section B
3,4 Diaminopyridine 10mg tablets	yes	yes
Alpha tocopheryl acetate 156 iu/ml oral liquid	yes	yes
Aprotinin injection 10,000 kIU per ml (equivalent to 200 mg/ml), 50 ml vial	**HML only**	no
Arginine powder	yes	yes
Arginine injection 600 mg/ml, 25 ml vial	yes	yes
Atropine 0.5% eye drops	yes	yes
Betaine powder	yes	yes
Calcium acetate 667 mg capsules	yes	yes
Cevimeline 30 mg capsule	yes	yes
Cyclizine oral liquid	yes	yes

Pharmaceutical*	HML	Section B
Defibrotide 80mg/ml , 2.5ml ampoule	yes	yes
Indomethacin 25 mg capsule	yes	yes
Indomethacin 50 mg capsule	yes	yes
Indomethacin 75 mg long-acting capsule	yes	yes
Indomethacin 100 mg suppository	yes	yes
Levocarnitine 500 mg capsule	yes	yes
Levocarnitine 500 mg per 15 ml oral solution	yes	yes
Levocarnitine 200mg per ml, 5ml injection	**HML only**	no
Levofloxacin 500 mg tablet	yes	yes
Mitotane 500 mg tablet	yes	yes
Naproxen 250 mg/5ml oral liquid	yes	yes
Pivmecillinam 200 mg tablet	yes	yes
Pimozide 2 mg tablet	yes	yes
Pimozide 4 mg tablet	yes	yes
Pipobroman 25 mg tablet	yes	yes
Piroxicam 10 mg dispersible tablet	yes	yes
Piroxicam 20 mg dispersible tablet	yes	yes
Pyridoxal-5-phosphate 50mg tablet	yes	yes
Sodium benzoate 500 mg capsule	yes	yes
Sodium benzoate powder	yes	yes
Sodium benzoate oral solution 100 mg/ml	yes	yes
Sodium benzoate 20% 20ml injection	**HML only**	no
Sodium phenylbutyrate oral liquid 250 mg/ml	yes	yes
Sodium phenylbutyrate tablet 500 mg	yes	yes
Trientine dihydrochloride capsules 300 mg	yes	yes
Urokinase injection 10,000 IU,	**HML only**	no
Urokinase injection 50,000 IU,	**HML only**	no
Urokinase injection 100,000 IU,	**HML only**	no
Urokinase injection 250,000 IU,	**HML only**	no
Urokinase injection 500,000 IU	**HML only**	no

*pharmaceuticals may be listed subject to Special Authority restrictions

Suppliers and other interested parties should provide information about the registration of the particular pharmaceutical, for example:

- Is it registered for use in New Zealand?
- If it is not registered for use in New Zealand, is there a clear pathway for registration?
- If it is not registered in New Zealand, where is it registered internationally?

- If it is not registered in New Zealand, does the supplier have access to the international registration dossier?

PHARMAC's preference is to list registered pharmaceuticals or those where there is an intention to register and a clear pathway to registration has been demonstrated. In rare exceptions, PHARMAC may consider listing an unregistered pharmaceutical.

PHARMAC's listing of any unregistered pharmaceuticals is not an endorsement of the medicine's quality, safety or efficacy, nor does it impact upon a medical practitioner's obligations to comply with relevant legislation and regulations (including the Health and Disability Commissioner's Code of Consumer Rights).

PHARMAC notes that the supply of unregistered pharmaceuticals under section 29 of the Medicines Act 1981 places additional administrative workload on the supply chain, which has a cost associated with it. PHARMAC is considering ways in which to address this issue.

Information related to Market Size

We have limited information relating to the potential subsidised market size for the pharmaceuticals included in this RFI. For many items there is no history of a supplier in New Zealand. Also, for some pharmaceuticals, the historical data (that is, data related to when the pharmaceutical was last listed or when there was a supplier available) is not recent enough to be useful.

The table below gives usage information from the most recent financial year within the last 5 year period, where the pharmaceutical was listed for the full year, for those pharmaceuticals where information is available.

The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of the pharmaceuticals and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

The table includes data (where data was available) related to approved Named Patient Pharmaceutical Assessment (NPPA) applications, Community and/or DHB Hospital usage.

Pharmaceutical	NPPA	Community	Hospital
3,4 Diaminopyridine 10mg tablets	Nil	Nil	2,700 tablets (FYE 30 June 2013)
Alpha tocopheryl Acetate oral liquid 156 iu/ml	6,900 ml (FYE 30 June 2013)	Nil	5,700 ml (FYE 30 June 2013
Aprotinin injection 10,000 kIU per ml (equivalent to 200 mg/ml) 50 ml vial	Nil	Nil	379 vials (FYE 30 June 2013)
Arginine Powder	16,025 g (FYE 30 June 2013)	Nil	Nil
Arginine injection 600 mg per ml 25 ml vial	10 vials (FYE 30 June 2012)	Nil	Nil
Betaine powder	16,200 g (FYE 30 June 2013)	Nil	Nil

Pharmaceutical	NPPA	Community	Hospital
Indomethacin 25 mg capsule	490 capsules (FYE 30 June 2013)	320,000 capsules (FYE 30 June 2009)	4,300 capsules (FYE 30 June 2013)
Indomethacin 50 mg capsule	Nil	69,000 capsules (FYE 30 June 2009)	8,800 capsules (FYE 30 June 2008)
Indomethacin 75 mg long-acting capsule	Nil	730,000 capsules (FYE 30 June 2010)	2,400 capsules (FYE 30 June 2013)
Indomethacin 100 mg suppository	Nil	30,000 suppositories (FYE 30 June 2012)	3,900 suppositories (FYE 30 June 2012)
Levofloxacin 500 mg tablet	Nil	Nil	100 tablets (FYE 30 June 2012)
Levocarnitine (L-carnitine) 500 mg capsule	Nil	Nil	60 capsules (FYE 30 June 2010)
Levocarnitine (L-carnitine) oral solution (500 mg/15 ml)	15,000 ml (FYE 30 June 2013)	Nil	9,700 ml (FYE 30 June 2013)
Mitotane 500 mg tablet	6,800 tablets (FYE 30 June 2013)	Nil	19,000 tablets (FYE 30 June 2012)
Piprobroman 25 mg tablet	1,400 tablets (FYE 30 June 2013)	Nil	1,100 tablets (FYE 30 June 2013)
Piroxicam 10 mg dispersible tablet	Nil	56,000 tablets (FYE 30 June 2010)	4,400 tablets (FYE 30 June 2013)
Piroxicam 20 mg dispersible tablet	Nil	367,000 tablets (FYE 30 June 2010)	1,650 tablets (FYE 30 June 2011)
Pyridoxal-5-phosphate 50 mg tablet	1,750 tablets (FYE 30 June 2013)	Nil	50 tablets (FYE 30 June 2013)
Sodium benzoate 500 mg capsule	3,800 capsules (FYE 30 June 2013)	Nil	Nil
Sodium benzoate powder	6,550 g (FYE 30 June 2013)	Nil	Nil
Sodium benzoate 100 mg/ml solution	14,200 ml (FYE 30 June 2013)	Nil	5,400 ml (FYE 30 June 2012)
Sodium benzoate 20% injection	Nil	Nil	830 injections (FYE 30 June 2013)
Sodium phenylbutyrate 500 mg tablet	2,250 tablets (FYE 30 June 2013)	Nil	5,500 tablets (FYE 30 June 2011)
Trientine dihydrochloride 300 mg capsule	5,400 capsules (FYE 30 June 2013)	Nil	16,200 capsules (FYE 30 June 2010)
Urokinase 10,000 IU injection	15 injections (FYE 30 June 2012)	Nil	1,550 injections (FYE 30 June 2012)
Urokinase 100,000 IU injection	Nil	Nil	300 injections (FYE 30 June 2013)
Urokinase 500,000 IU injection	Nil	Nil	250 injections (FYE 30 June 2013)

* FYE = Financial Year Ending.

Feedback

To provide feedback, please provide your submissions in writing by **5:00 pm Friday, 7 March 2014** to:

Geralllt Jones	Email: **geralllt.jones@pharmac.govt.nz**
Formulary Researcher	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

We look forward to receiving your submission.

Information requested under the Official Information Act

Information 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 information, 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 information 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 withheld. PHARMAC will give due consideration to any such request

Process going forward

At this stage, PHARMAC expects to do the following:

1. Response to request for information due by 7 March 2014;
2. Evaluation of feedback in March/April 2014;
3. Further discussion with submitter(s), if necessary, in April 2014;

If, following consideration of feedback, PHARMAC decides to progress a potential listing:

4. Consulting on various proposals to list in May/June 2014;
5. PHARMAC Board or its delegate to consider various proposals, including consultation feedback, to list July 2014;
6. Implementation of listing proposals August – September 2014.

Please note that the above timeframes are approximate only and may be extended if the process takes longer than anticipated.