NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

20 November 2013

Update for the 2013/14 Invitation to Tender

The 2013/14 Invitation to Tender (2013/14 ITT) was issued on 7 November 2013 and is available on PHARMAC's website at http://www.pharmac.health.nz/news#tender.

This letter outlines some clarifications and changes to the 2013/14 ITT document, which will be updated on our website and in the eTender system where relevant.

1. Sildenafil Clarification

Sildenafil 25 mg, 50 mg and 100 mg and tablets is currently listed in Section B of the Pharmaceutical Schedule with the following restriction:

> SA1293 Special Authority for Subsidy
> Initial application — (Raynaud's Phenomenon* - for Pulmonary Arterial Hypertension see note below)) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
> All of the following:
> 1 Patient has Raynaud's Phenomenon*; and
> 2 Patient has severe digital ischaemia (defined
> 3 Patient is following lifestyle management (avoidance of cold exposure, sufficient protection, smoking cessation support, avoidance of sympathomimetic drugs) ; and
> 4 Patient is being treated with calcium channel blockers and nitrates (or these are contraindicated/not tolerated).
>
> Notes: Sildenafil is also funded for patients with Pulmonary Arterial Hypertension who are approved by the Pulmonary Arterial Hypertension Panel (an application must be made using form SA1293-PAH).
> Application details may be obtained from:
> The Coordinator, PAH Panel
> PHARMAC, PO Box 10 254, Wellington
> Phone: (04) 916 7512 Facsimile: (04) 974 4858 Email: PAH@pharmac.govt.nz
>
> Indications marked with * are Unapproved Indications.

Sildenafil 25 mg, 50 mg and 100 mg tablets is also listed on the Hospital Medicines List (HML) subject to the following restrictions:

> **Restricted**
> Any of the following:
> 1 For use in patients with approval by the Pulmonary Arterial Hypertension Panel; or
> 2 For use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or
> 3 For use in weaning patients from inhaled nitric oxide; or
> 4 For perioperative use in cardiac surgery patients; or
> 5 For use in intensive care as an alternative to nitric oxide; or
> 6 In-hospital stabilisation in emergency situations; or
> 7 All of the following:
> 7.1. Patient has Raynaud's phenomenon; and
> 7.2 Patient has severe digital ischaemia (defined as severe pain requiring hospital admission or with a high likelihood of digital ulceration; digital ulcers; or gangrene); and

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7.3 Patient is following lifestyle management (proper body insulation, avoidance of cold exposure, smoking cessation support, avoidance of sympathomimetic drugs); and
7.4 Patient has persisting severe symptoms despite treatment with calcium channel blockers and nitrates (unless contraindicated or not tolerated).

With regards to the 2013/14 ITT, we are seeking bids for the supply of sildenafil where:

- the current funded access would remain unchanged, described as "sildenafil [current access]" in Schedule 2 of the 2013/14 ITT; or

- sildenafil would be open listed without restrictions (i.e. there would be no Special Authority or HML restrictions or requirement to make PAH Panel applications), described as "sildenafil [widened access]" in Schedule 2 of the 2013/14 ITT.

PHARMAC is interested in determining whether the pricing of sildenafil will reduce enough via the tender to warrant consideration of the removal of the current funding restrictions. If a tender for sildenafil is awarded it would be for one or the other level of access but not both; i.e. PHARMAC would not award a tender to one brand for current access as well as awarding a tender to another brand for open access.

The two levels of access tendered for sildenafil apply to both the community and hospital markets (the "C" and "H" indicating this in Schedule 2 were inadvertently omitted in the initial 2013/14 ITT document dated 7 November 2013).

2. Racemic mixtures

In general, where a product tendered comes as a racemic mixture of a pharmaceutical, a bid for a single enantiomer of the particular pharmaceutical would be considered non-conforming unless explicitly permitted. For example:

a bid for ketoprofen would be non-conforming if the supplier's product was dexketoprofen; and

a bid for citalopram would be non-conforming if the supplier's product was escitalopram.

Please contact **Chloe Dimock** at chloe.dimock@pharmac.govt.nz if you are unsure whether this would be relevant for any of your potential bids.

3. Amendment to risperidone comment

In the tender comment section it was originally noted that 'a rebate currently exists' for all presentations of risperidone. A rebate no longer exists for any of the risperidone presentations in the 2013/14 ITT.

4. Dermatologicals

PHARMAC would like to express a preference for dermatological products which do not contain sodium lauryl sulphate (SLS).

5. Amendment to data estimates provided during consultation on the draft 2013/14 ITT

In the letter notifying the release of the 2013/14 ITT, we provided annual usage data that was requested by suppliers during the draft 2013/14 ITT consultation period. The relevant table can be found at the end of the letter which is available on PHARMAC's website at http://www.pharmac.health.nz/ckeditor_assets/attachments/580/notification-2013-11-07-invitation-to-tender-2013-14.pdf

Two lines were inadvertently omitted from the table, which is updated below with the additions in bold. 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 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.

As previously advised, in order to be fair to all suppliers, we are unlikely to provide any further data requested by individual suppliers relating to tender items while the 2013/14 ITT remains open.

DHB hospital usage (1 July 2012 to 30 June 2013)

Chemical name and line item	DHB hospital usage
Imipenem with cilastatin inj 500 mg with cilastatin 500 mg	6,700 injections
Iron polymaltose inj 50 mg per ml, 2 ml	100,000 injections
Lidocaine [lignocaine] hydrochloride oral [viscous] soln 2%	380,000 ml
Losartan with hydrochlorothiazide tab 50 mg with hydrochlorothiazide 12.5 mg	4,100 tablets
Octreotide (somatostatin analogue) inj 100 mcg per ml, 1 ml	8,500 injections
Octreotide (somatostatin analogue) inj 50 mcg per ml, 1 ml	3,800 injections
Octreotide (somatostatin analogue) inj 500 mcg per ml, 1 ml	3,000 injections
Paracetamol inj 10 mg per ml, 100 ml	180,000 injections
Paracetamol Inj 10 mg per ml, 50 ml	49,000 injections
Pethidine hydrochloride inj 50 mg per ml, 1 ml	21,000 injections
Pethidine hydrochloride inj 50 mg per ml, 2 ml	13,000 injections
Streptomycin sulphate inj 400mg per ml, 2.5 ml ampoule	**35 injections**
Thiopental [Thiopentone] sodium inj 500 mg	**1,100 injections**
Vancomycin hydrochloride inj 500 mg	85,000 injections

Usage data for "PCT only" injectable products (1 July 2012 to 30 June 2013)

6. More information

If you have any queries regarding the tender or require any assistance with the eTender system please contact Chloe Dimock at chloe.dimock@pharmac.govt.nz.