NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

5 November 2012

Decision on proposal for various Novartis products.

PHARMAC is pleased to announce the approval of an agreement with Novartis New Zealand Limited for **Neoral, Aclasta, Zometa and Risedronate Sandoz**. This was the subject of a consultation letter dated 27 September 2012.

In summary, the effect of the decision is that:

- From 1 January 2013 the price and subsidy of cyclosporin 25 mg, 50 mg and 100 mg capsules (Neoral) will be reduced;
- From 1 January 2013 the confidential rebate applying to zoledronic acid 5 mg in 100 ml (Aclasta) and 4 mg in 5 ml (Zometa) will be increased, reducing the net prices to the Funder;
- From 1 January 2014 an additional confidential rebates would apply to Neoral, Aclasta and Zometa which would further reduce the net prices to the Funder;
- Neoral, Aclasta and Zometa will have protection from subsidy reduction and delisting until 31 December 2015.
- Risedronate sodium (Risedronate Sandoz) will be listed, without restriction, in Section B and Part II of Section H of the Pharmaceutical Schedule at a price and subsidy of $4.00 per 4 x 35 mg tablets as soon as practicable, following Medsafe approval and stock becoming available in NZ (expected mid-2013); and
- Risedronate Sandoz would have protection from subsidy reduction and delisting until 30 June 2016.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 11 October 2012 were considered in their entirety in making a decision on the proposal. In general, most responders supported the proposal. Key issues raised and PHARMAC comments on these issues, grouped by pharmaceutical, are discussed in the table below:

Theme	PHARMAC Comment
All bisphosphonates should be funded via the same Special Authority criteria which includes either a DEXA scan, or FRAX or Garvan calculation without a T- score which do not require a DEXA scan.	Although we are listing risedronate without restriction we consider that there would be significant fiscal risk from widened access to other bisphosphonates at their current pricing. If suppliers of other bisphosphonates were to match the price of risedronate we could consider removing the relevant Special Authorities.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Theme	PHARMAC Comment
One responder considered that the savings from this proposal should be used to improve and/or widen access to support the clinical management of osteoporosis rather than 'transported' into other areas.	PHARMACs statutory objective is to secure the best health outcomes reasonably achievable from within the funding available; therefore, the savings PHARMAC generates from deals such as this one are directed to pharmaceutical treatments which would provide most health gain. These may, or may not, include osteoporosis treatments.
The funding of risedronate was welcomed, however, some had concerns about it being open listed and there being consequent inappropriate use of risedronate.	PHARMAC's use of access restrictions is principally to reduce financial risk to the Pharmaceutical Budget by targeting treatments to those patients that would benefit from them most. We consider that colleges, societies and registration authorities are primarily responsible for ensuring their members prescribe pharmaceuticals appropriately. We note that BPAC are planning an updated review of osteoporosis treatments in 2013, which would include discussion of appropriate risedronate prescribing.
One responder was concerned that the proposal would cause a substantial change in the funding environment leading to market changes which may, in the short to medium term, restrict rather than enhance the choice of agents available to patients, and reduce the support given to osteoporosis which they considered to be an underdiagnosed and undertreated disorder of high national health burden.	This proposal does not, in any way, restrict existing treatment choices, it provides wider funded treatment choices.
One responder requested that the Note applying to teriparatide (Forteo) be amended to include risedronate in the list of antiresorptive agents required to have been trialled.	We have not made this change. Teriparatide is significantly more expensive than the other osteoporosis treatments therefore we consider its use should be limited to last line treatment in patients with serious disease who have tried and failed at least alendronate, raloxifene, or zoledronic acid. If we were to change the Note as requested teriparatide may be used in patients with less serious disease prior to trialling other cheaper funded treatment options.
The cost to patients for GPs administering zoledronic acid is a barrier for patients. PHARMAC should address this.	Decisions regarding the funding of patient services are made by DHBs in accordance with the national Service Coverage Schedule.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.