CONSULTATION

PHARMAC
Pharmaceutical Management Agency

10 October 2014

Hospital Medicines List: Clarithromycin injection and tobramycin powder

PHARMAC is seeking feedback on:

- a request to PHARMAC to list tobramycin (1.2 g lyophilised powder) for adding to orthopaedic bone cement; and
- a proposal to widen the restrictions on the use of parenteral clarithromycin to allow usage as a first-line macrolide for severe pneumonia.

If progressed, each of these would result in changes to Part II of Section H of the Pharmaceutical Schedule.

Further information can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback. To provide feedback, please submit it in writing by **Friday, 24 October 2014** to:

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

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

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Tobramycin

Background

Before implementation of the Hospital Medicines List (HML) on 1 July 2013, PHARMAC consulted and sought clinical feedback on the suitability of listing various medicines on the HML. The Hospital Pharmaceuticals Subcommittee reviewed information on products proposed for listing under the antibacterial heading of the HML, however this review did not include antibiotic powders for addition to orthopaedic bone cement in theatres.

Since implementing the HML, some orthopaedic surgeons have asked PHARMAC to list tobramycin powder in the HML to enable it to be used for adding to polymethylmethacrylate bone cement. The specific aminoglycoside and presentation requested is tobramycin injection 1.2 g (lyophilised powder) (hereinafter referred to as "tobramycin powder"). The reason given for such usage is to achieve the high doses of aminoglycoside required to maintain elution rates and concentrations sufficient for certain orthopaedic interventions. Antibiotic-impregnated bone cements are available, but have lower doses of antibiotic compared to what can be attained with hand-mixed antibiotic-laden bone cement.

PHARMAC has taken advice from a member of the Anti-Infective Subcommittee whose view was that the addition of certain antibiotics to bone cement in theatres is "standard of care" for certain orthopaedic interventions.

Tobramycin powder is registered in some countries, but not in New Zealand. In countries where it is registered, it does not have a registered indication for adding to bone cements. In New Zealand, tobramycin powder could be supplied to a medical practitioner and administered to patients in accordance with sections 29 and 25 of the Medicines Act 1981.

PHARMAC has not entered into a provisional agreement for the supply and listing of tobramycin powder, so any potential listing of this chemical in the HML would not guarantee DHB Hospitals price or availability.

Details of the consultation

PHARMAC is seeking feedback in response to the following questions:

1. Is the use of tobramycin powder, by hand mixing with orthopaedic bone cement in theatre, a "standard of care" in certain orthopaedic interventions in New Zealand?

2. Was tobramycin powder hand mixed with orthopaedic bone cement used at your DHB hospital before 1 July 2013? If so, what dose was typically included?

3. If tobramycin powder was to be listed in the HML, should there be a restriction on its use? If so, what should the restriction be?

Clarithromycin IV

Details of the proposal

The proposal is that, from 1 January 2015, the restriction applying to clarithromycin infusion (inj 500 mg vial) in Part II of Section H of the Pharmaceutical Schedule would be amended as follows (deletion in strikethrough):

> Infusion
> 1. Atypical mycobacterial infection; or
> 2. Mycobacterium tuberculosis infection where there is drug resistance or intolerance to standard pharmaceutical agents; or
> 3. Community-acquired pneumonia ~~(clarithromycin is not to be used as the first line macrolide)~~.

Background

PHARMAC received a request from Canterbury DHB seeking that the HML restriction on clarithromycin injection be widened to allow it to be provided as a first-line macrolide for community-acquired pneumonia.

The Anti-Infective Subcommittee considered the request and the restriction at its March 2014 meeting and the relevant minute is as follows:

> The Subcommittee considered that there would be no clinical issues with amending the restriction. The Subcommittee **recommended** widening access to parenteral clarithromycin to allow usage as a first-line macrolide for severe pneumonia, if cost neutral to erythromycin IV including administration costs.