

29 May 2009

## Proposal to list low molecular weight heparin in the Pharmaceutical Schedule

### *Proposal Summary*

PHARMAC is seeking feedback on a proposal to list one brand of low molecular weight heparin in Section B of the Pharmaceutical Schedule from 1 August 2009 under a sole supply agreement. In summary, it is proposed that:

- Clexane (enoxaparin) would be listed in Section B of the Pharmaceutical Schedule under Special Authority Criteria;
- Clexane would be the only low molecular weight heparin that would be listed in Section B of the Pharmaceutical Schedule; and,
- Clexane would be the only brand of enoxaparin listed in Section H of the Pharmaceutical Schedule.

This proposal would not change the current provisions for the use of low molecular weight heparin by hospitals, including the use of dalteparin and tinzaparin, and use of the Discretionary Community Supply (DCS) mechanism.

The proposal would enable relevant practitioners in the community to be able to use Clexane.

### **Feedback sought**

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **1 pm Monday, 15 June 2009** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

## Details of the proposal

### Access for Community Patients – Section B of the Pharmaceutical Schedule

From 1 August 2009, Clexane (enoxaparin) would be listed in Section B of the Pharmaceutical Schedule under the following Special Authority criteria:

#### **Special Authority for Subsidy**

**Initial application - (Pregnancy or Malignancy)** from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Either:

- 1 Low molecular weight heparin treatment is required during a patients pregnancy; or
- 2 For the treatment of venous thromboembolism where the patient has a malignancy.

**Initial application - (Venous thromboembolism other than in pregnancy or malignancy)** from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

- 1 For the initial management of venous thromboembolism prior to oral anti-coagulant treatment; or
- 2 For prophylaxis of venous thromboembolism in high risk surgery; or
- 3 For prophylaxis of venous thromboembolism in Acute Coronary Syndrome surgical intervention; or
- 4 To be used in association with cardioversion of atrial fibrillation.

Renewals would be available under the above criteria (we note that if a patient would not be able to have two initial applications even if they are under different criteria).

Clexane would be the only brand of low molecular weight heparin listed in Section B of the Pharmaceutical Schedule until 30 June 2012.

### Access for Hospital Patients – Section H of the Pharmaceutical Schedule

Clexane would be the Hospital Supply Status brand of enoxaparin in Section H of the Pharmaceutical Schedule until 30 June 2012, with a Discretionary Variance (DV) limit of 1%.

We note that the current provisions for the use of low molecular weight heparin in DHB hospitals would continue, including the use of:

- other LMWHs such as dalteparin or tinzaparin; and,
- the current Discretionary Community Supply (DCS) criteria for enoxaparin, dalteparin and tinzaparin.

## Proposed Clexane Pricing

Clexane would be listed in Sections B and H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, exclusive of GST):

<i>Chemical</i>	<i>Brand</i>	<i>Form</i>	<i>Strength</i>	<i>Pack Size</i>	<i>Price and Subsidy</i>
Enoxaparin sodium	Clexane	Injection	20 mg	10	\$39.20
Enoxaparin sodium	Clexane	Injection	40 mg	10	\$52.30
Enoxaparin sodium	Clexane	Injection	60 mg	10	\$78.85
Enoxaparin sodium	Clexane	Injection	80 mg	10	\$105.12
Enoxaparin sodium	Clexane	Injection	100 mg	10	\$135.20
Enoxaparin sodium	Clexane	Injection	120 mg	10	\$168.00
Enoxaparin sodium	Clexane	Injection	150 mg	10	\$192.00

## **Background to the Proposal**

Currently, there are no presentations of LMWH listed in Section B of the Pharmaceutical Schedule. However, LMWHs (enoxaparin, dalteparin and tinzaparin) are available via Discretionary Community Supply (DCS) for a range of conditions including venous thromboembolism, pregnancy, surgery, cardiovascular events and malignancy according to the following criteria:

### **Discretionary Community Supply (DCS) criteria**

For the treatment of venous thromboembolism (VTE) for a maximum of 14 days or until a stabilised therapeutic INR is established.

For a maximum treatment period from the time of diagnosis to 8 weeks post partum for a confirmed thromboembolic event during pregnancy.

For prophylaxis of thromboembolism for patients considered high risk after consultation with a specialist from diagnosis of pregnancy to 8 weeks post partum.

For a maximum treatment period from diagnosis of pregnancy to 8 weeks post partum for women normally maintained on long-term oral anticoagulation who are at very high risk of thromboembolism.

For the treatment for a maximum of 7 days pre and post operatively for patients on oral anticoagulants requiring surgical intervention in a public hospital or until an appropriate therapeutic INR level is reached.

For a maximum of 14 days treatment in high-risk patients post pelvic, colo-rectal and major orthopaedic surgery.

For a maximum of 7 days treatment for patients with an acute coronary syndrome (ACS) awaiting further hospital intervention.

For a maximum of 14 days treatment post cardioversion in non anticoagulated patients with atrial fibrillation or until appropriate therapeutic INR level is reached.

For treatment of malignancy – associated venous thromboembolism.

The above DCS criteria were formed in 2003 following meetings of the Cardiovascular Working Group and the LMWH Working Group.

Recent advice from the Cardiovascular Subcommittee and PTAC has indicated that:

- there are no significant safety concerns with General Practitioners prescribing LMWH;
- a listing in Section B would improve accessibility; and,
- given the current lack of experience with LMWH in General Practice, and the different dosing regimes, only one LMWH should be listed in Section B to reduce confusion and make education easier.

Following this advice from the Cardiovascular Subcommittee and PTAC, PHARMAC issued a Request for Proposals for the supply of one brand of LMWH in Section B of the Pharmaceutical Schedule. This proposal is the result of that process.