



Australian Government
Department of Health and Ageing

Dear Colleagues

**Consensus Guidelines for Australian Clinicians for the
use of anti-coagulants during heparin-based product shortages**

Following the identification of a contaminant in international stocks of heparin, and the recall from the Australian market of quantities of the low molecular weight heparin product enoxaparin (Clexane®), the Therapeutic Goods Administration (TGA) and the Department of Health and Ageing have been working to develop contingency plans to mitigate the risk of potential future shortages of heparin-based products in Australia.

The Department, working with the Australian Health Protection Committee (AHPC), the Committee of Presidents of Medical Colleges (CPMC) and the Australian Medical Association (AMA), has developed a set of *Consensus Guidelines for Australian Clinicians for the use of anti-coagulants during heparin-based product shortages*. These Guidelines are intended to extend the availability of heparin based products by prioritising their use according to clinical need, ensure there are no increases in preventable morbidity and mortality, and facilitate national consistency in the utilisation of these products.

The Guidelines set out a staged approach, with the different stages determined by the remaining availability of the various heparin-based products. Each stage provides guidance for clinicians on the use of alternatives to Clexane and identifies those patients in whom the use of anticoagulants, and particularly Clexane, should be continued as a priority.

As at 16 May 2008 the AHPC has determined that we are currently in Stage 1, in which:

Greater than 6 weeks of uncontaminated Australian stocks of Clexane remain; alternative heparin-based products such as dalteparin (Fragmin®), unfractionated heparin (UFH) and fondaparinux (Arixtra®) are available, and are uncontaminated.

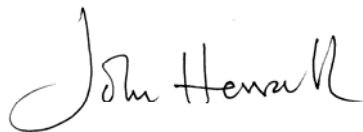
In Stage 1 clinicians should:

- **Avoid all usage of heparin based products which is not evidence-based, so long as a patient's clinical condition is not compromised;**
- **Use available enoxaparin (Clexane) and the alternative low molecular weight heparin dalteparin, where clinically indicated and according to the evidence;**
- **For lower risk patients, consider using preventive strategies such as early mobilisation, graduated compression stockings and mechanical calf stimulation, wherever possible, as long as a patient's clinical condition is not compromised;**
- **Consider substitution of low molecular weight heparin with alternatives such as unfractionated heparin and/or warfarin, and/or other suitable anticoagulant therapies such as fondaparinux where the evidence suggests no additional patient risk and as long as a patient's clinical condition is not compromised.**

These guidelines have been endorsed by the Australian Medical Association, the Committee of Presidents of Medical Colleges, and by all State and Territory Chief Health Officers.

The TGA is continuing to explore all options to augment supply of the heparin products for the Australian market. Your cooperation in implementing these guidelines, together with the judicious use of available supplies, is required if Australia is to ensure that any impact on clinical services can be minimised until normal heparin supply levels can once again be restored.

Yours sincerely



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Chief Medical Officer



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