

## Availability of heparin based products in Australia – FAQs for Health Professionals

**Q. Why have these guidelines been developed?**

**A.** The guidelines advise clinicians of alternatives to treatment with enoxaparin (Clexane), based on best available medical evidence, in the event of a developing shortage of heparin based products. The guidelines aim to prioritize use of heparin based products based on clinical need and to promote informed prescribing to ensure that there is no increase in preventable morbidity and mortality.

**Q. Are all heparin-based products likely to be in short supply? How long will the shortages last?**

**A.** It's not clear at this stage. The issue of heparin contamination is a worldwide problem and while only a small amount of Clexane (enoxaparin) has been recalled in Australia, there are some uncertainties regarding supply of Clexane and of other heparin based products in the next few months.

The presence of a contaminant has been traced to the raw materials used to produce the “approved pharmaceutical ingredient” (API) which is the starting point for the manufacture of heparin based products. There are concerns that manufacturers may experience delays in sourcing uncontaminated API for future production. This, coupled with the recent recall of Clexane in Australia and recalls of contaminated Clexane and contaminated unfractionated heparin products overseas, has the potential to lead to a global shortage of heparin based products. This is why these consensus [Guidelines](#) (link to Guidelines document TBA) have been developed, to guide clinicians in the most appropriate use of these products.

While the TGA is endeavouring to procure alternative supplies of heparin based products, a shortage of these products in Australia is a possible scenario for which we need to plan now. With the careful use of available supplies, the effects of any possible shortages can be minimized until normal supply levels can once again be restored.

**Q. Is only Clexane contaminated?**

**A.** In Australia the contaminant was identified in 5 batches of Clexane ([Clexane recall notice](#)) that were recalled in April, and in 4 batches of heparinised saline solution that were recalled in March ([Heparinised saline recall notice](#)). All other heparin based products in the Australian market – all other batches of Clexane, dalteparin (Fragmin), danaparoid (Orgaran), heparinised saline solutions and unfractionated heparins have been tested and are free of the contaminant.

**Q. Who has developed the guidelines?**

The guidelines have been developed by an expert group convened by the Department of Health and Ageing working through the Australian Health Protection Committee (AHPC), the Clinical Colleges, the AMA, the State and Territory Chief Health Officers and Australian clinical experts.

**Q. What evidence has been used in compiling the guidelines?**

The guidelines synthesize the available evidence on treatment and prophylaxis of venous thrombosis across the range of clinical settings. This evidence has been compiled from Australian and International consensus statements, peer reviewed literature and the Cochrane database.

**Q. What do these guidelines contain?**

Contained within the guidelines is a discussion of the reasons leading to their development, the clinical categories of conditions and priorities for usage of heparin based products and the stages of response to any shortages. This is supported by specific detail of the available treatments in Australia, evidence for the use of the various treatment options for anticoagulation and VTE prophylaxis, and a schema for prioritizing the use of various anticoagulants in different clinical conditions.

**Q. Why have we moved to Stage 1 of the guidelines?**

**A.** Currently there are sufficient stocks of heparin based products for appropriate clinically indicated treatment and the government is seeking to procure on-going supplies of uncontaminated Clexane. However given the ongoing supply problems of heparin based products worldwide, and the potential for a shortage of the product in Australia in the future, it was considered prudent to remind clinicians to use heparin based products in a thoughtful manner at this time. Judicious use of heparin based products should allow Australia to remain in Stage 1 for as long as possible.

**Q: I have a patient currently being treated with Clexane for a DVT. Should I change his/her treatment?**

**A.** No. Patients can remain on Clexane while supplies remain available. In the event that it becomes difficult to procure Clexane you may wish to consider the alternative low molecular weight heparin, Fragmin or unfractionated heparin administered subcutaneously, or an oral anticoagulant such as warfarin. See the [Guidelines](#) (link) for more information.

**Q. What do I need to do in my practice today, in coming weeks and coming months?**

In your practice today you may have patients who are currently on Clexane. These patients should continue to be treated according to the best available evidence, as outlined in the guidelines. In the event that shortages develop you will need to review the ongoing treatment of your patients and may need to consider alternatives to their current anticoagulant therapy. The Guidelines have been developed to assist you in this.

**Q How will I know if/when there is a change in the supply situation and stage of the guidelines?**

The expert consensus group established to develop these Guidelines will continue to monitor the supply situation regularly, and will determine, according to the state of supply, when and if Australia should move to a subsequent stage. Should this be necessary, health professionals will be advised.