NATIONAL BLOOD AUTHORITY
AUSTRALIA

Patient Information Sheet

Interim Availability of Extended Half-Life Clotting Factor Products

You have received this information sheet because you (or your child or dependant) have been identified as potentially suitable for participation in arrangements that have been set up to provide temporary access to EHL products for some patients with high priority needs.

Background

The Medical Services Advisory Committee (MSAC) is currently evaluating whether extended half-life clotting factor products should be available under publicly funded supply arrangements managed by the National Blood Authority (NBA). Information about this evaluation can be found at http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1511-public .

About the interim arrangements

While this evaluation is underway some interim arrangements have been set up between the NBA and two suppliers, Bioverativ and Shire. The interim arrangements are in place on a temporary basis only and any longer term availability of EHL products under NBA arrangements will depend on decisions that may be made after the MSAC evaluation is finished.

Only a limited number of patients are can be covered under these interim arrangements:

- the Bioverativ product Eloctate (recombinant Factor VIII) will be available for around 40 patients
- the Biovertiv product Alprolix (recombinant Factor IX) will be available for around 60 patients, and
- the Shire product Adynovate (recombinant Factor VIII) will be available for around 100 patients.

(These numbers include continuing patients who were on the suppliers' extended access programs).

Patients with high priority needs will be nominated for participation in the limited interim arrangements by the Directors of the Haemophilia Treatment Centres providing the care for those patients. Decisions about the final prioritisation of patients to receive EHL products under the limited interim arrangements will be coordinated by the Australian Haemophilia Centre Directors' Organisation (AHCDO) through its Clinical Advisory Group sub-committee.

Regular clinical review will be maintained for patients using EHL products under the limited interim arrangements to monitor that clinical benefit is being demonstrated. Information on the use of EHL products under the limited interim arrangements will be collected in the Australian Bleeding Disorders Registry and will be available to assist with future of national supply planning and management.

Are the EHL clotting factor products safe?

The EHL products which are available under the interim arrangements are registered in Australia by the Therapeutic Goods Administration (TGA). This means that TGA has undertaken a comprehensive assessment of the safety and efficacy of the products before registration.

What happens next?

If you have any questions about the EHL products or any aspects of the limited interim arrangements you should raise these with your doctor or other staff at your HTC. If you agree with your HTC doctor that you would like to be (or would like your child or dependant to be) nominated for participation in the limited interim arrangements for EHL products, please complete the acknowledgement form on the reverse side of this page to indicate that you understand the details of these arrangements. A copy of this form will be retained in your HTC's records.

Patient Acknowledgement

Interim Availability of Extended Half-Life Clotting Factor Products

To be completed by a patient (or patient's parent/guardian) following discussion with their Haemophilia Treatment Centre clinician or other relevant staff.

I have read the Patient Information Sheet about the limited interim availability of Extended Half-Life (EHL) clotting factor products (over the page) and/or have had this explained to me. I have had a chance to ask questions and discuss this with a Haemophilia Treatment Centre (HTC) clinician or other relevant staff.

I am aware of and acknowledge the following important information about the availability of EHL products under the limited interim arrangements:

1. The limited interim arrangements for EHLs are temporary only, and ongoing access to the EHL products has not yet been fully assessed or decided by Australian Governments, and cannot be guaranteed after the cessation of the arrangements.
2. Only a limited number of patients will have access under the limited interim arrangements. Access will be prioritised to patients with high priority needs and will depend on demonstrated clinical benefit.
3. The EHL products are to be used in accordance with the instructions given by the treating HTC clinician or other relevant staff, and regular clinical review will be required to monitor that clinical benefit is being demonstrated.
4. Information on use of the EHL products, bleeding episodes, and other relevant data is to be recorded promptly in the Australian Bleeding Disorder Registry (ABDR) either through use of MyABDR or through ABDR data entry at an HTC.

Patient name:	
ABDR number:	
HTC:	
Treating clinician:	
Name(s) of parent/guardian (if relevant):	
Patient/parent/guardian signature(s) Signature:	Date:
Signature:	Date: