NATIONAL BLOOD AUTHORITY
AUSTRALIA

Frequently Asked Questions

What the outcome of the NBA tender for recombinant Factor VIII and IX means for patients

The National Blood Authority (NBA), on behalf of Australian governments, has successfully concluded the tender process for the supply of recombinant Factor VIII (rVIII) and IX (rFIX) products, to replace the contracts for these products which expire on 30 June 2014.

These products are critical for the treatment of Australian patients with bleeding disorders, such as haemophilia. Australia imports these products as they are not made in Australia.

The outcome of the tender gives Australian patients funded access to products equivalent to that available in other parts of the world at a very competitive price and has been highly successful at ensuring a secure supply of essential products for haemophilia patients. The effect on the implementation of these arrangements is expected to provide savings in the order of $50 million per year for product costs, while continuing to ensure a safe and secure supply of these important medicines in Australia.

As a result of the tender process, there will be a change in brand for rFVIII and for the first time there is a new market entrant for rFIX ensuring supply security and clinical choice.

The details of the new supply arrangements for these products compared to the previous arrangement are within the table below.

Imported Product	**New Arrangements** ***Trade Name (Supplier)***	**Previous Arrangements** ***Trade Name (Supplier)***
rFVIII	***National preferred rFVIII product*** ADVATE (Baxter)	
	Xyntha (Pfizer)	Xyntha (Pfizer)
	Kogenate FS* (Bayer) *Not available after a transition period*	Kogenate FS (Bayer)
rFIX	BeneFIX (Pfizer)	BeneFIX (Pfizer)
	RIXUBIS** (Baxter)	

* For patients on active immune tolerance therapy using Kogenate FS as at the time of the tender announcement, exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.

**At the time of implementation of the new arrangements from 1 July 2014, the registered indications for RIXUBIS will include routine prophylaxis, treatment and prevention of bleeding episodes, and perioperative management in adults (18 years and older) in haemophilia B, but will not include registered indications for paediatric patients

What does the tender outcome mean for me as a person with Haemophilia A?

- From 1 July 2014 the rFVIII products provided under the national supply arrangements to treat Haemophilia A will be the Baxter product ADVATE and the Pfizer product Xyntha.
- Kogenate FS will be phased out over the six month period 1 July 2014 to 31 December 2014.
- Transitioning patients will be switched from Kogenate FS to the national preferred product, ADVATE over the 6 month transition period (1 July 2014 to 31 December 2014).
- For patients on active immune tolerance therapy using Kogenate FS exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.
- If home delivery is available in your home state or territory, this will continue and will be arranged by your Haemophilia Treatment Centre (HTC) or treating clinician with the relevant supplier.
- If you are not treated through a HTC but use these products frequently, you will need to contact your treating clinician to seek their advice on the transition arrangement.

When will I have to change my rFVIII product?

- If you currently use Kogenate FS, your HTC or treating clinician will contact you to discuss the product options available to you and develop a plan to transition.
- The expectation is that patients will be transitioned to ADVATE as the national preferred product unless it is likely that this will compromise patient treatment and care.
- Your transition to ADVATE should occur at the earliest convenient opportunity for you and your treating clinician and HTC.
- The transition is expected to take no more than six months for most patients.
- For patients on active immune tolerance therapy using Kogenate FS exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.

What is the National Preferred Product Arrangement for rFVIII?

- The NBA has designated a national preferred product for rFVIII (ADVATE). This means that patients will be asked to consider transitioning at the next suitable patient review opportunity to the Baxter product ADVATE, unless transitioning of a patient will be likely to compromise patient treatment and care.
- The national preferred product arrangement will maximise material savings by ensuring the best value for money rFVIII product receives greater market share while maintaining a viable second supplier for the purposes of clinical choice and supply security.
- Patients are encouraged to discuss the preferred national product arrangement and product transition with their specialist and HTC.

I am concerned about possible health risks if I change products. Where can I get more information?

- Expert clinical opinion indicates that there is no demonstrated increase in health risks from changing products.
- The new tender provides supply of two alternative safe and high quality rFVIII products.
- You should discuss any concerns you have regarding changing products with your treating clinician.
- It is important to note that designation of ADVATE as the national preferred rFVIII product does not relate to any difference in safety and quality between the rFVIII products or the product support services available from either rFVIII supplier under the national arrangements.

What happens if I do not want to change from Kogenate FS?

- Supply of funded Kogenate FS under the national arrangements will not be available after the transition period.
- For patients on active immune tolerance therapy using Kogenate FS exceptional arrangements will be available for continuation of this product for a longer period where this is clinically necessary.
- Otherwise, for continuation of supply of Kogenate FS in any other situation, patients or their treating clinician would need to make arrangements directly with the supplier (Bayer) for direct supply and payment.
- In public hospital settings it would be up to the treating clinicians to make a make a submission to their hospital drug committee if they wish to seek approval for local funding of continued use of Kogenate FS.

What does the tender outcome mean for me as a person with Haemophilia B?

- From 1 July 2014 the recombinant Factor IX products provided under the NBA's supply arrangements to treat Haemophilia B will be the Pfizer product BeneFIX and the Baxter product RIXUBIS.
- Your treating clinician can provide you with information on both of the available products, BeneFIX and RIXUBIS and assist you to select which product is right for you.
- If home delivery is available in your home state or territory, this will continue and will be arranged by your HTC or treating clinician with the relevant supplier.

Will I still get my rFVIII and rFIX product delivered to my home?

- Yes, your home delivery arrangements (or alternative delivery to a workplace, if appropriate) will still be available.
- Suppliers will be required to offer and support home delivery arrangements.
- If you want to start home delivery, talk to your HTC about the process that will apply and whether this will work for you.
- Suppliers should not initiate any contact with you directly. Arrangements for your home delivery or product ancillary requirements will be initiated with the suppliers by the HTC.

What if I am not happy with the supply arrangements?

- Understanding your experience with the new product and the arrangements implemented by the suppliers is important to us.
- You are encouraged to provide your feedback to HTC staff who will in turn pass your feedback on to suppliers and the NBA.

How do I get more information?

- You should talk to your Australian treating clinician, HTC or Haemophilia Foundation Australia (HFA).
- Information and some useful links can also be found on the NBA website www.blood.gov.au including information for health professionals.