PHARMAC
Pharmaceutical Management Agency

6 July 2015

PHARMAC decision on the funding of haemophilia treatments

PHARMAC has decided to change the funding of haemophilia treatments, a proposal that was the subject of a consultation letter dated 26 May 2015 (www.pharmac.health.nz/news/consultation-2015-05-26-haemophilia).
In summary the effect of the decision means that:

- Xyntha (Pfizer) will be awarded Preferred Brand Status for recombinant factor VIII (rFVIII). It will be the nationally preferred or first treatment choice of rFVIII.
- Kogenate FS (Bayer) will be awarded Second Brand Status for rFVIII. It will be the second treatment choice of rFVIII for patients.
- Advate (Baxalta) will be awarded Rare Clinical Circumstances Brand Status and will only be funded for patients where treatment with Xyntha and Kogenate FS are clinically inappropriate.
- A Haemophilia Treatments Panel will be established to receive and assess applications for funded access to Kogenate FS and Advate. No application to the Haemophilia Treatments Panel will be required for patients prescribed Xyntha.
- The changes will be phased-in over a six-month period from 1 September 2015 to 29 February 2016 and the arrangements referred to above will apply for three years, from 1 March 2016 to 28 February 2019.
- BeneFIX, Pfizer's brand of recombinant factor IX (rFIX) will continue to be funded and there will be no changes to its current funded access arrangements. A new alternative brand of rFIX, Rixubis (Baxalta) may be listed in the future following Medsafe registration.
- There will be no changes to the current funded access arrangements for recombinant factor VIIa (rFVIIa) and factor eight inhibitor bypassing fraction (FEIBA).
- The distribution channels for all haemophilia treatments will remain the same and patients will continue to receive their medicine from the same source.

Additional Information

PHARMAC would like to highlight the following:

- Patients will need to be closely monitored if they are being switched to Xyntha. The number of blood tests and frequency of blood tests should be tailored to patient needs. Clinicians have advised that this could involve around four blood tests (one prior to switch and additional tests at one, three and six months).

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- Access to funding for the second brand and rare clinical circumstances brand will be by application to the Haemophilia Treatments Panel. Application details will be available on PHARMAC's website www.pharmac.health.nz/haemophilia-treatments from 1 August 2015, and applications will be considered from 1 September 2015.

- PHARMAC has received clinical advice that a brand switch may not be appropriate for some patients including for example but not limited to those who:

    - previously had high titre inhibitor levels
    - are undergoing active or have undergone immune tolerance therapy
    - have a known product allergy
    - have recently commenced therapy (Previously Untreated Patients or PUPs)
    - occupy the same residential setting with other siblings where one sibling is unable to be switched due to clinical reasons, as it would be safer to have only one brand kept in the household.

  Clinicians can make applications to the Haemophilia Treatments Panel for consideration of Kogenate FS and Advate funding for patients in unforeseen clinical situations.

- PHARMAC and Pfizer will work with clinicians to ensure that they have the information, resources and support they need to implement change with patients who are switching brands, including demonstration material for the administration of Xyntha.

- PHARMAC will work closely with haemophilia treatment centres and the Haemophilia Foundation of New Zealand to help ensure that patients receive the support they need as they undergo this change.

- PHARMAC acknowledges concerns raised around security of supply in this market, given that one brand may have a substantial share of the market as a result of this decision. PHARMAC will work with all relevant suppliers to ensure security of supply of these products during and after the implementation of the Preferred Brand status.

- Other than the establishment of the Haemophilia Treatments Panel to administer funded access to rFVIII, this decision will not result in any other changes to the role of the National Haemophilia Management Group (NHMG). The decision to move the funding of rFVIII, rFIX, rFVIIa and FEIBA to the Combined Pharmaceutical Budget was made in 2013, as it was in line with PHARMAC's role of managing the funding of medicines in New Zealand.

- The funding of plasma-derived products and haemophilia services will continue to be managed by the NHMG. It is not within PHARMAC's remit to fund haemophilia services from the Combined Pharmaceutical Budget. Whilst the decision in 2013 means the NHMG cannot reinvest savings from this decision into haemophilia services; it does mean that additional funding requests to DHBs are not required when a patient requires large amounts of rFVIII for surgery or to manage an acute bleed.

Resources for implementation of decision

The following resources will be available on our website at www.pharmac.health.nz/haemophilia-treatments and will be disseminated to clinicians and haemophilia treatments centres in August 2015:

- application forms for consideration of Kogenate FS and Advate funding for submission to the Haemophilia Treatments Panel;
- clinician information sheet;
- patient information sheet;
- link to a demonstration video for Xyntha administration; and
- link to information about Xyntha.

Consideration of feedback

We appreciate all of the consultation feedback that we received and acknowledge the time people took to respond. All consultation responses received by 19 June 2015 were considered in their entirety in making a decision on the proposed changes. Further detail on the consultation responses received and PHARMAC's comments on the main issues raised can be found on pages 10-13.

Details of the decision

Recombinant factor VIII

Preferred Brand

- Xyntha (Pfizer) will be awarded Preferred Brand Status for rFVIII in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2016 until 28 February 2019.
- Xyntha will be listed at the following prices and subsidies in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2015 as follows (prices expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Price and subsidy from 1 September 2015
Moroctocog alfa [recombinant factor VIII]	Inj 250 iu prefilled syringe	Xyntha	1	$225.00	$210.00
Moroctocog alfa [recombinant factor VIII]	Inj 500 iu prefilled syringe	Xyntha	1	$450.00	$420.00

Moroctocog alfa [recombinant factor VIII]	Inj 1000 iu prefilled syringe	Xyntha	1	$900.00	$840.00
Moroctocog alfa [recombinant factor VIII]	Inj 2000 iu prefilled syringe	Xyntha	1	$1,800.00	$1,680.00
Moroctocog alfa [recombinant factor VIII]	Inj 3000 iu prefilled syringe	Xyntha	1	$2,700.00	$2,520.00

- A confidential rebate will apply to Xyntha, reducing its net cost to the Combined Pharmaceutical Budget and DHBs.

- The restriction criteria for Xyntha in Section B and Part II of Section H of the Pharmaceutical Schedule will be as follows from 1 March 2016:

  Section B

  Preferred Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

  Section H

  Preferred Brand of recombinant factor VIII from 1 March 2016 until 28 February 2019. When used in the treatment of haemophilia, funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

- As the Preferred Brand, Xyntha will be the first rFVIII treatment choice for patients with haemophilia A. Requirements for funded access to Xyntha would be unchanged. For the avoidance of doubt, no applications to the Haemophilia Treatments Panel will be required.

Second Brand

- Kogenate FS (Bayer) will be awarded Second Brand Status for rFVIII in the community and hospitals from 1 March 2016 until 28 February 2019.

- Kogenate FS will be listed at the following prices and subsidies in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2015 as follows (prices expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Price and subsidy from 1 September 2015
Octocog alfa [recombinant factor VIII]	Inj 250 iu vial	Kogenate FS	1	$250.00	$237.50
Octocog alfa [recombinant factor VIII]	Inj 500 iu vial	Kogenate FS	1	$500.00	$475.00
Octocog alfa [recombinant factor VIII]	Inj 1,000 iu vial	Kogenate FS	1	$1,000.00	$950.00

Octocog alfa [recombinant factor VIII]	Inj 2,000 iu vial	Kogenate FS	1	$2,000.00	$1,900.00
Octocog alfa [recombinant factor VIII]	Inj 3,000 iu vial	Kogenate FS	1	$3,000.00	$2,850.00

- A confidential rebate will apply to Kogenate FS, reducing its net cost to the Combined Pharmaceutical Budget and to DHBs. There will also be a separate rebate arrangement for Kogenate FS when it is used for tolerisation.

- The restriction criteria for Kogenate FS in Section B and Part II of Section H of the Pharmaceutical Schedule will be as follows from 1 March 2016:

  Section B

  Second Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel.

  Application details may be obtained from PHARMAC's website www.pharmac.govt.nz or:

  The Coordinator, Haemophilia Treatments Panel
  PHARMAC, PO Box 10254
  Wellington

  Phone: 0800 023 588 Option 2
  Facsimile: (04) 974 4881
  Email: haemophilia@pharmac.govt.nz

  Section H

  Second Brand of recombinant factor VIII from 1 March 2016 until 28 February 2019. When used in the treatment of haemophilia, access to funded treatment by application to the Haemophilia Treatments Panel.

  Application details may be obtained from PHARMAC's website www.pharmac.govt.nz or:

  The Coordinator, Haemophilia Treatments Panel
  PHARMAC, PO Box 10254
  Wellington

  Phone: 0800 023 588 Option 2
  Facsimile: (04) 974 4881
  Email: haemophilia@pharmac.govt.nz

- As the Second Brand, Kogenate FS will be the second rFVIII treatment choice for patients with haemophilia A, where treatment with Xyntha is not suitable. Clinicians will need to make applications to the Haemophilia Treatments Panel for funded access to Kogenate FS. Applications will be made on a form provided by PHARMAC. Clinicians will be required to provide relevant patient information for consideration by the Haemophilia Treatments Panel.

- There will be a six-month transition period, beginning 1 September 2015 for clinicians to make these applications for existing treated patients to avoid disruption to patient care. After 1 March 2016, only patients whose applications have been approved by the Haemophilia Treatments Panel will have funded access to Kogenate FS.

- Between 1 March 2016 and 28 February 2019, applications could be made to the Haemophilia Treatments Panel for funded access to Kogenate FS should a patient's clinical circumstances change, or for a new patient where treatment with Xyntha is not suitable.

Rare Clinical Circumstances Brand

- Between 1 March 2016 and 28 February 2019, funded access to other brands of rFVIII, including Advate (Baxalta) will only be available for patients in rare clinical circumstances where treatment with Xyntha and Kogenate FS is not clinically appropriate. Clinicians will need to make applications to the Haemophilia Treatments Panel for funded access to these brands.

- Advate will be awarded Rare Clinical Circumstances Brand status for rFVIII from 1 March 2016 until 28 February 2019.

- Advate will be listed at the following prices and subsidies in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2015 as follows (prices expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Price and subsidy from 1 September 2015
Octocog alfa [recombinant factor IX]	Inj 250 iu vial	Advate	1	$237.50	$287.50
Octocog alfa [recombinant factor IX]	Inj 500 iu vial	Advate	1	$475.00	$575.00
Octocog alfa [recombinant factor IX]	Inj 1,000 iu vial	Advate	1	$950.00	$1,150.00
Octocog alfa [recombinant factor IX]	Inj 1,500 iu vial	Advate	1	$1,425.00	$1,725.00
Octocog alfa [recombinant factor IX]	Inj 2,000 iu vial	Advate	1	$1,900.00	$2,300.00
Octocog alfa [recombinant factor IX]	Inj 3,000 iu vial	Advate	1	$2,850.00	$3,450.00

- The restriction criteria for Advate in Section B and Part II of Section H of the Pharmaceutical Schedule will be as follows from 1 March 2016:

  Section B

  Rare Clinical Circumstances Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel.

  Application details may be obtained from PHARMAC's website www.pharmac.govt.nz or:

  The Coordinator, Haemophilia Treatments Panel
  PHARMAC, PO Box 10254
  Wellington

  Phone: 0800 023 588 Option 2
  Facsimile: (04) 974 4881
  Email: haemophilia@pharmac.govt.nz

Section H

Rare Clinical Circumstances Brand of recombinant factor VIII from 1 March 2016 until 28 February 2019. When used in the treatment of haemophilia, access to funded treatment by application to the Haemophilia Treatments Panel.

Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz or:

The Coordinator, Haemophilia Treatments Panel
PHARMAC, PO Box 10254
Wellington

Phone: 0800 023 588 Option 2
Facsimile: (04) 974 4881
Email: haemophilia@pharmac.govt.nz

- There will be a 6-month transition period, beginning 1 September 2015, for clinicians to make applications for existing patients who require ongoing funded treatment with Advate. Applications will be made on a form provided by PHARMAC. Clinicians will be required to provide relevant patient information for consideration by the Haemophilia Treatments Panel. After 1 March 2016, only patients whose applications have been approved by the Haemophilia Treatments Panel will have funded access to Advate.

- Between 1 March 2016 and 28 February 2019, applications could be made to the Haemophilia Treatments Panel for funded access to Advate should a patient's clinical circumstances change or for a new patient where treatment with Xyntha and Kogenate FS is not suitable.

Recombinant factor IX

BeneFIX (Pfizer)

- BeneFIX will continue to be funded at its current prices and subsidies in Section B and Part II of Section H of the Pharmaceutical Schedule as a result of this decision.

- Access to BeneFIX will continue to be managed by the NHMG from 1 September 2015 with restriction criteria as follows:

  Section B

  For patients with haemophilia, whose funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

  Section H

  When used in the treatment of haemophilia, access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

- A confidential rebate will apply to BeneFIX, reducing its net cost to the Combined Pharmaceutical Budget and DHBs.

- BeneFIX will have protection from subsidy reduction and delisting until 31 August 2018.

- A 3000 iu vial presentation of BeneFIX may be listed in the future, subject to Medsafe registration.

Rixubis (Baxalta)

- A new brand of rFIX treatment, Rixubis, will be listed at a later date, subject to Medsafe registration.

- Rixubis will be listed with restriction criteria similar to those for BeneFIX in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Nonacog gamma	Inj 250 iu vial	Rixubis	1	$287.50
Nonacog gamma	Inj 500 iu vial	Rixubis	1	$575.00
Nonacog gamma	Inj 1,000 iu vial	Rixubis	1	$1,150.00
Nonacog gamma	Inj 2,000 iu vial	Rixubis	1	$2,300.00
Nonacog gamma	Inj 3,000 iu vial	Rixubis	1	$3,450.00

Recombinant factor VIIa

- Eptacog alfa (NovoSeven RT) will continue to be listed on the Pharmaceutical Schedule subject to the following restriction criteria:

  Section B

  For patients with haemophilia, whose funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

  Section H

  When used in the treatment of haemophilia, access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

- The prices and subsidies for NovoSeven RT in Section B and Part II of Section H of the Pharmaceutical Schedule will be amended from 1 July 2016 as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Price and subsidy from 1 July 2016
Eptacog alfa	Inj 1 mg syringe	NovoSeven RT	1	$1,163.75	$1,178.30
Eptacog alfa	Inj 2 mg syringe	NovoSeven RT	1	$2,327.50	$2,356.60
Eptacog alfa	Inj 5 mg syringe	NovoSeven RT	1	$5,818.75	$5,891.50
Eptacog alfa	Inj 8 mg syringe	NovoSeven RT	1	$9,310.00	$9,426.40

- NovoSeven RT will have protection from subsidy reduction and delisting until 30 June 2019.

Factor VIII inhibitor bypassing fraction

- Factor VIII inhibitor bypassing fraction (FEIBA) will continue to be listed on the Pharmaceutical Schedule subject to the following restriction criteria:

  Section B

  For patients with haemophilia, whose funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

  Section H

  When used in the treatment of haemophilia, access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

- The prices and subsidies for FEIBA in Section B and Part II of Section H of the Pharmaceutical Schedule will be amended from 1 September 2015 as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Price and subsidy from 1 September 2015
Factor eight inhibitors bypassing ~~agent~~ **fraction**	Inj 500 U	FEIBA	1	$1,640.00	$1,450.00
Factor eight inhibitors bypassing ~~agent~~ **fraction**	Inj 1,000 U	FEIBA	1	$3,280.00	$2,900.00

Feedback received

The main themes raised in response to consultation and PHARMAC's comments are outlined below:

Themes	PHARMAC comments
Commercial/supply issues	
Lack of transparency regarding magnitude of savings and details of RFP bids to allow others to weigh up this proposal over other possible funding scenarios for these haemophilia treatments.	The majority of the savings obtained in this proposal are via confidential rebates, so PHARMAC is unable to provide further detail on the magnitude of savings involved. Although PHARMAC prefers transparent pricing, the ability for suppliers to provide confidential rebates does enable PHARMAC to obtain better net pricing for products. Due to the commercial sensitivity of the RFP process, it is difficult to involve all stakeholders in the RFP evaluation process. PHARMAC however sought the expert advice of haemophilia treaters on the Haematology Subcommittee of PTAC as part of this process. Relevant medical and commercial information were disclosed to them to enable them to provide a recommendation to PHARMAC.
PHARMAC should be able to negotiate these prices without a need to switch a large number of patients. New patients could be started on the preferred brand and existing patients be given an option to switch.	PHARMAC notes that lowest prices are offered by suppliers when there is greater certainty of market share. This is observed through PHARMAC's competitive procurement processes, including this RFP for haemophilia treatments where the greater the market share, the lower the prices that were offered. Given that there are only a small number of new haemophilia patients beginning treatment each year, it would not be possible to achieve the market share required to obtain the most cost-effective prices without a brand switch. We note that brand switches involving large patient numbers have occurred in Australia and the UK to obtain the pricing of treatments there.
The proposal essentially restricts routine rFVIII use to one brand. This leaves the New Zealand haemophilia population vulnerable to the impact of severe unplanned shortages of the Preferred Brand for example in the event of a product recall due to quality issues. A 50:50 market split would be safer. It would be very difficult to source alternative product for such a large number of patients within such a short time. In 2001, there was a worldwide shortage with Kogenate FS due to quality issues requiring patients to be switched back to plasma-derived products.	For many life-saving essential medicines in New Zealand, only one brand is funded, often following a competitive process. Drawing from the experience of supply security for these other medicines, PHARMAC considers that having multiple brands of a product in a market does not improve security of supply. When there are limited or only one supplier, forecasting of stock requirements is more accurate which helps prevent out-of-stock situations. Further, in exchange for market exclusivity, the supply contracts we have in place for these haemophilia treatments require suppliers to agree to rigorous conditions to prevent and manage potential out-of-stocks. This includes significant stock-holding, frequent stock reporting to PHARMAC and a commitment to source a suitable alternative to prevent a potential out-of-stock occurring. PHARMAC notes that there are now significantly more alternative brands of rFVIII (PHARMAC is aware of 4 others besides Xyntha) available when compared to the shortage that occurred in 2001. There is currently uncertainty in what proportion of patients would seek funding to remain on Kogenate FS or Advate after 1 March 2016. PHARMAC will monitor the brand switch and work with clinicians and relevant suppliers to ensure the risk of an out-of-stock situation with Xyntha, Kogenate FS and Advate is mitigated as much as possible.
Clinical issues	
There was feedback supporting the establishment of the Haemophilia Treatments Panel and also against it. If the Panel was established, its role should be limited to the administration of funding for the rFVIII products only as a result of the RFP. It should not take over the role of the Haemophilia Treaters Group (HTG). Some felt that there is no need to establish another Panel to	The role of the Panel will be limited to administering access to two specific brands of rFVIII, Kogenate FS and Advate, based on criteria approved by PHARMAC. To preserve the integrity and objectivity of the Panel, its determinations will be made by consensus and Panel members will not participate in assessing applications involving patients in their care or from their treatment centres. The Chair of the Panel will be a senior clinician from another specialty which will help facilitate discussions. Although the HTG could potentially coordinate such a change, due to the 6 month transition period PHARMAC considers that a representative smaller group of clinicians will be more agile and easier to administer. Because funding for patients will need to be considered on a case-by-case basis, funding decisions made by a Panel will enhance national

Themes	PHARMAC comments
manage the funding for Kogenate FS and Advate as this role could be carried out by the HTG. Some patients also questioned whether it would be possible to have a patient representative on the Panel.	consistency and enable greater objectivity in decision-making. Because the Panel will be determining funded access based on clinical criteria, it is appropriate that its membership is comprised of clinicians. A patient representative on the group would make it difficult to discuss individual patients' medical histories.
The proposed list of clinical situations, where a switch to Xyntha may not be clinically appropriate, is not exhaustive and consideration should be given to patients with other clinical situations which may make a switch to Xyntha difficult or clinically inappropriate.	We note that the list in the consultation letter is not exhaustive. PHARMAC will have discretion to consider funding Kogenate FS and Advate for patients in other clinical situations on an individual basis and it will take advice from the Haemophilia Treatments Panel in such cases.
There are some haemophilia patients with gene mutations which increase their risk of inhibitor development, even beyond 50 exposure days. This proposal could potentially put them at risk of inhibitor development.	Kogenate FS and Advate will be able to be accessed by patients who are unable to switch to Xyntha for clinical reasons. Applications for funding of Kogenate FS or Advate for these patients can be made to the Haemophilia Treatments Panel.
There has been recent published information suggesting that the risk of inhibitor development is increased with Kogenate FS use.	This issue was reviewed by the Medicines Adverse Reactions Committee (MARC) at Medsafe during its March 2015 meeting. MARC considered that there was insufficient evidence to support a difference in the risk of inhibitor development when patients are treated with different factor VIII products.
Has there been adequate consideration of the possibility of increased inhibitor risk with B-domain deleted molecules like Xyntha when compared to full length molecules like Advate?	PHARMAC's Haematology Subcommittee advised that there was no clinical reason not to award Preferred Brand Status to Xyntha when it evaluated the RFP bids. The Haemophilia Treaters Group also did not raise clinical concerns about Xyntha when it was consulted by PHARMAC at various times when developing the RFP. Xyntha is registered for use in New Zealand by Medsafe with similar indications to Advate and Kogenate FS.
It is unclear from the consultation letter if there will be adequate monitoring of inhibitor levels in patients during the brand switch and will the required treatment be provided for patients who do develop inhibitors as a result of this brand switch?	Patients would need to be closely monitored for inhibitors during the brand switch. The clinical advice we have received indicates that patients would have about four additional blood tests to monitor for inhibitors. Our clinical advice is that, based on experience overseas, the risk of developing inhibitors as a result of a brand switch is very low. However, if patients do develop inhibitors, they would be provided with the required treatment.
Can there be special consideration for funding of Advate or Kogenate FS for patients under the age of 18 to minimise the risk of this brand switch to them, and provide them with the best chance of a normal life in adulthood?	The Haemophilia Treatments Panel and PHARMAC will have discretion to consider funding of Kogenate FS and Advate for patients where it is demonstrated that a brand switch would jeopardise appropriate clinical care.
A six-month transition would be adequate to coordinate a brand switch for most patients. There would need to be consideration of additional support for patients who live further away from their treatment centres and need to travel to attend clinics for	PHARMAC will work closely with haemophilia treatment centres and the Haemophilia Foundation of New Zealand to help ensure that patients receive the support they need as they undergo this change.

Themes	PHARMAC comments
counselling through the brand switch. There should be allowance of a longer transition period for patients who need longer to adjust. This could be for clinical or psychosocial reasons.	
Other issues	
This proposal is against the long-held patient principle of product choice.	Sole brand medicine funding is commonplace in New Zealand. There are multiple examples in the Pharmaceutical Schedule were only one brand of a medicine is subsidised. In such circumstances patients could choose to use a different brand, although that brand would not be funded unless there was a clinical reason why the funded brand could not be used. This decision provides sufficient treatment choice to meet clinical need, as funding for Kogenate FS and Advate is available for patients whose treatment would be compromised if switched to Xyntha. In addition, the savings that will result from this decision will enable better health outcomes to be achieved for all New Zealanders by releasing funding that will be spent on other pharmaceuticals.
The savings obtained from this proposal should be used to fund additional haemophilia services (physiotherapy, specialist nurses, IVF pre-implantation diagnosis) and more or new haemophilia treatments (tolerisation of more patients or prophylaxis with bypassing agents for patients with inhibitors) instead of being channeled to the Combined Pharmaceutical Budget (CPB). Previously the NHMG was able to do this and it resulted in an efficient system which was world-leading. There is good evidence that adequate physiotherapy reduces requirement for treatment and reduces long-term complications from haemophilia. There is a risk that this proposal would diminish the role of the NHMG, resulting in it being inadequately funded and unable to provide comprehensive care to patients.	In 2013, in consultation with DHBs, PHARMAC decided that rFVIII, rFIX, rFVIIa and FEIBA would be funded from within the CPB, because it was in line with PHARMAC's role in managing the funding of medicines in New Zealand. It is not within PHARMAC's remit to fund haemophilia services from the CPB. The funding of plasma-derived products and haemophilia services continues to be managed by the NHMG. Whilst the inclusion of the recombinant products within the CPB means the NHMG cannot reinvest savings from this decision into haemophilia services; it does mean that additional funding requests to DHBs are not required when a patient requires large amounts of rFVIII for surgery or to manage an acute bleed. Whilst tolerisation can and is being funded from the CPB, prophylaxis with rFVIIa and FEIBA is a significant change from current clinical practice in New Zealand. PHARMAC has not formally assessed the risk and benefits of changing clinical practice in this way and would be willing to consider a funding application for this use. Other than the establishment of the Haemophilia Treatments Panel to administer funded access to rFVIII, there will be no changes to the role of the NHMG as a result of this decision.

This proposal would result in pharmaceutical suppliers withdrawing their product and their funding of haemophilia services from New Zealand. It also reduces the incentive for these suppliers to continue to fund research in this therapeutic area.	PHARMAC considers that it would be unlikely that suppliers would withdraw from the New Zealand market as a result of this decision, given the significant value of the market for haemophilia treatments (even following the savings achieved via this decision). Pfizer has advised that it will provide educational resources to support patients who are switched to Xyntha. PHARMAC will work alongside suppliers and other stakeholders (including the Haemophilia Foundation) to ensure patients and clinicians are well supported.
Some clinicians considered that PHARMAC did not consult early and widely enough on this proposal. Detailed discussions should have involved a wider group of clinicians, not just a select group of clinicians from the Haematology Subcommittee.	PHARMAC took steps to consult with the NHMG and HTG early on in the process, beginning in November 2014, and prior to PHARMAC issuing the RFP in February 2015. We continued to provide regular updates on our progress and thinking at the quarterly NHMG and HTG meetings, seeking and considering the views of these groups when developing the proposal. Due to the commercial sensitivity of certain aspects of the RFP, PHARMAC was only able to involve members of the Haematology Subcommittee in the evaluation of RFP bids received. Those members who were involved in the detail of the proposal are senior clinicians who treat haemophilia. They have been endorsed by their relevant professional body to provide clinical advice to PHARMAC on haematology issues, including haemophilia.
Some patients felt that the consultation period was too short for a change of this magnitude.	PHARMAC extended the consultation period for patients following this feedback.
Patients will understandably be nervous about such a change, especially given that some of them would have had previous negative experiences with the New Zealand health system where they contracted hepatitis C or HIV from contaminated blood products. There will also be a fear of developing inhibitors as a result of the brand switch which is a very significant side-effect and which has long-term consequences for a patient's health. Adequate resources need to be provided to support patients through this change including additional counselling time with clinicians, nurses, and social workers. Educational resources like patient leaflets, videos and product workshops would be helpful. There also needs to be consideration of additional funding for parties helping with this brand switch.	Noted. This feedback has been taken into consideration in PHARMAC's implementation planning. Resources include: • clinician information sheet • patient information sheet • a demonstration video for Xyntha administration, and • information about Xyntha. PHARMAC and Pfizer will work with clinicians to ensure that they have the information and resources they need to support patients who are changing brands. PHARMAC will work closely with haemophilia treatment centres and the Haemophilia Foundation of New Zealand to help ensure that patients receive the support they need as they undergo this change.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.