CONSULTATION

PHARMAC
Pharmaceutical Management Agency

26 May 2015

Haemophilia treatments funding proposal

PHARMAC is seeking feedback on a proposal involving the funding of haemophilia treatments. The treatments include recombinant factor VIII (rFVIII), recombinant factor IX (rFIX), recombinant factor VIIa (rFVIIa) and factor VIII inhibitor bypassing fraction. We have reached provisional agreements for the listing and supply of these treatments.

We are seeking feedback on our proposal. The closing date for submissions has been extended to **4pm Friday, 19 June 2015**. Details of how to provide feedback are provided on the final page of this document.

The purpose of this consultation is to understand whether there are any practical or clinical issues we need to be aware of, and to seek views and any information that we may not be aware of, prior to making a decision.

This consultation document contains the following sections:

1. What PHARMAC is proposing to do;
2. Background to proposal;
3. Details of the proposal; and
4. How to provide feedback.

Specific questions are set out below; however, we encourage you to provide comment to us on any aspects of this proposal.

1. What is PHARMAC proposing to do?

Our proposal is to continue funding of four haemophilia treatments, and to make changes to the funding rules. The four treatments are rFVIII, rFIX, rFVIIa and factor VIII inhibitor bypassing fraction.

The changes proposed for rFVIII would result in funding for a Preferred Brand, a Second Brand and a Rare Clinical Circumstances Brand. An expert panel would be established (the Haemophilia Treatments Panel) which would consider applications for funded access to the Second Brand or Rare Clinical Circumstances Brand of rFVIII for specific patients, taking into account a patient's specific clinical circumstances and the suitability of the relevant brand sought.

If implemented, the changes to rFVIII funding would mean that some patients would need to change the brand of rFVIII they currently use.

Changes would occur from 1 September 2015, and would be phased-in over a six-month period, giving patients time to make any adjustments necessary to move to the Preferred Brand or clinicians time to make funding applications for the appropriate funded Second Brand or Rare Clinical Circumstances Brand of rFVIII.

This proposal would involve only minor changes to the listing of the other haemophilia treatments – rFIX, rFVIIa and factor VIII inhibitor bypassing fraction.

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Recombinant Factor VIII

Preferred Brand Status, Second and Rare Clinical Circumstances Brand Statuses

- Moroctocog alfa (Xyntha, Pfizer) would be awarded Preferred Brand Status and would be the nationally preferred or first treatment choice of rFVIII. An application to the Haemophilia Treatments Panel would not be required for patients prescribed Xyntha.

- Octocog alfa (Kogenate FS, Bayer) would be awarded Second Brand Status and would be the second treatment choice of rFVIII for patients. Funded access would be by application to the Haemophilia Treatments Panel.

- Octocog alfa (Advate, Baxalta) would be awarded Rare Clinical Circumstances Brand Status and would only be funded for patients where treatment with Xyntha and Kogenate FS are clinically inappropriate. Funded access would be by application to the Haemophilia Treatments Panel.

- A **Haemophilia Treatments Panel** would be established, and managed by PHARMAC. The Haemophilia Treatments Panel would be largely comprised of haematologists who treat haemophilia. Clinicians would need to make an application to the Haemophilia Treatments Panel for funded access to Kogenate FS or Advate if they considered a switch to Xyntha would compromise appropriate clinical care for their current patients.

- PHARMAC proposes that patients would, where possible, be treated with Xyntha in order to obtain the best value for money from the more favourable price for this product. Clinicians would be able to seek access to funded treatment with Kogenate FS as the second treatment choice in cases where it is considered that the use of Xyntha would be likely to compromise appropriate treatment and care. Funded access to Advate would only be provided in cases where the use of Xyntha and Kogenate FS would be considered likely to compromise treatment and care.

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

    - previously had high titre inhibitor levels;
    - are undergoing active or have undergone immune tolerance therapy;
    - have a known product allergy; and
    - have recently commenced therapy (Previously Untreated Patients or PUPs).

    PHARMAC would work closely with clinicians and the Haemophilia Treatments Panel to coordinate ongoing funding of Kogenate FS and Advate for these patient groups.

- All new patients commencing rFVIII treatment from 1 March 2016 would be commenced on Xyntha as the nationally preferred brand where possible.

- This proposed arrangement would apply for three years (1 March 2016 to 28 February 2019).

- PHARMAC is aware of the impending availability of new longer-acting rFVIII products. This proposal would not prevent the funding of these products. However, because they are new treatments, they would need to be assessed by PHARMAC through its normal funding processes before a funding decision is made.

Questions

What is your view on the appropriateness of having brand preferences for funded rFVIII treatments?

What is your view on PHARMAC establishing a Haemophilia Treatments Panel to assess applications for funded access to the brands which do not have Preferred Brand Status?

Are there any other points you wish to raise about the proposed funding arrangements for rFVIII?

Transition process and implementation

- There would be a six-month transition period from 1 September 2015 to 29 February 2016 to enable current patients to be safely transitioned to Xyntha, where possible, during their next routine clinic visit.

- This six-month transition period would also allow time for clinicians to make applications to the Haemophilia Treatments Panel for continued funding of Kogenate FS or Advate in situations where they consider a change to Xyntha would be clinically inappropriate for any of their patients.

- From 1 March 2016, only patients with access approved from the Haemophilia Treatments Panel would be eligible for funded treatment with Kogenate FS and Advate. For existing patients, applications to the Haemophilia Treatments Panel should be made prior to 1 March 2016 to avoid interruption to clinical care.

- A Haemophilia Treatments Panel application is not required for patients who remain on, or are switched to, Xyntha.

- PHARMAC would continue to work closely with the National Haemophilia Management Group, the Haemophilia Treaters Group and the Haemophilia Foundation to support clinicians and patients through this proposed change process.

Questions

What is your view on a six-month transition period to allow people to transition to a new brand of rFVIII?

What might be the main concerns for a person with haemophilia (or their family) if they need to change their brand of rFVIII?

What can doctors or nurses do to help a person with haemophilia (or their family) if a change in brand of rFVIII was required?

Would a video demonstration on how to use a different brand of rFVIII be helpful?

What other resources might help people with the proposed change?

Is there anything else we should consider with regard to the proposed rFVIII transition as part of this consultation?

Recombinant Factor IX

- Nonacog alfa (BeneFIX, Pfizer) would continue to be funded and there would be no substantive changes to its current funded access arrangements.

- A 3000 iu presentation of BeneFIX would be listed on the Pharmaceutical Schedule once it has been approved by Medsafe.

- An alternative brand of rFIX, nonacog gamma (Rixubis, Baxalta) could be listed in the future, subject to Medsafe registration. It would be listed subject to restriction criteria similar to those currently in place for BeneFIX.

- There would be no brand funding restrictions for rFIX so choice of brand for treatment would be based on clinician and patient preference.

Recombinant Factor VIIa

- Eptacog alfa (NovoSeven RT, Novo Nordisk) would continue to be funded on the Pharmaceutical Schedule and there would be no substantive changes to its current funded access arrangements.

- Eptacog alfa would continue to be able to be used in non-haemophilia indications in hospitals.

Factor Eight Inhibitor Bypassing Fraction

- Baxalta's brand of factor eight inhibitor bypassing fraction (FEIBA) would continue to be funded on the Pharmaceutical Schedule and there would be no substantive changes to its current funded access arrangements.

2. Background to proposal

Haemophilia

Haemophilia is a condition that affects the blood's clotting ability due to a deficiency in blood clotting factors. Haemophilia A is associated with factor VIII deficiency and haemophilia B is associated with factor IX deficiency. There is an estimated 400-600 people with haemophilia in New Zealand but not all patients require treatment with factor VIII or IX replacement, depending on the severity of their condition. Every year, approximately 200 patients require factor VIII replacement therapy and 40 patients require factor IX replacement.

A complication of haemophilia treatment is the development of an inhibitor, which usually occurs shortly after replacement therapy has been initiated. The inhibitors are antibodies directed against the specific deficient factor. Recombinant factor VIIa and factor eight inhibitor bypassing agent (FEIBA) are treatments used in the treatment and management of patients with inhibitors.

2015 competitive process

The National Haemophilia Management Group (NHMG) was established in 2006 and is responsible, on behalf of 20 DHBs, for management oversight of a national haemophilia service in New Zealand. The Haemophilia Treaters Group is made up of clinicians who are involved in the clinical management of patients with haemophilia in New Zealand, and it collaborates closely with the NHMG. Since 2007, PHARMAC has managed haemophilia treatments procurement activities for DHBs in close collaboration with the NHMG and Haemophilia Treaters Group.

In July 2013, Government decided that expenditure on most haemophilia treatments, including rFVIII, rFIX, rFVIIa and factor eight inhibitor bypassing fraction, should be part of the Combined Pharmaceutical Budget managed by PHARMAC on behalf of DHBs. In performing its statutory function of making decisions about which haemophilia treatments will be funded, PHARMAC works closely with the NHMG and the Haemophilia Treaters Group.

In February 2015, PHARMAC issued a request for proposals (RFP) for the funding of the haemophilia treatments (rFVIII, rFIX, rFVIIa and factor eight inhibitor bypassing fraction)(http://www.pharmac.health.nz/news/rfp-2015-02-02-haemophilia-products/). Bids received were evaluated from a financial and clinical perspective, taking into account considerations around security of supply and product usability. The products were also evaluated by haematologists and nurses who are specialists in the area of haemophilia.

Experience in other countries

Before running the 2015 competitive process, PHARMAC sought advice from the NHMG, the Haemophilia Treaters Group and PHARMAC's Haematology Subcommittee of the Pharmacology and Therapeutic Advisory Committee (PTAC) on the appropriateness of introducing brand restrictions for funded rFVIII. Similar restrictions have successfully been introduced in other countries, including the United Kingdom and Australia, resulting in significantly lower treatment prices without compromising the quality and safety of treatment. In 2014, a national brand switch in Australia was implemented following a 6-month transition period.

The development of inhibitors is a potential risk during product switches. However, during national product switches in other countries switching was not observed to be associated with an enhanced inhibitor risk (Lillicrap D et al. Haemophilia 2014: 20 (4): 87-93). The

clinical advice PHARMAC has received indicates that there are potential patient groups which are at greater risk of developing inhibitors. In line with this advice, PHARMAC proposes to continue to fund specific brands of rFVIII for patients in these groups via application to the Haemophilia Treatments Panel.

Why the proposed change?

Haemophilia treatments are essential life-saving medicines for people with haemophilia. Currently, in New Zealand, approximately $25 million per year is spent on these treatments; of which $18 million is used to fund rFVIII. Usage is likely to increase in New Zealand, where patients are living longer and healthier lives.

There are a number of rFVIII brands now available worldwide and international experience supports the feasibility and safety of national brand switches. Competitive processes in other countries have succeeded in obtaining significant price reductions.

The proposed changes in New Zealand would enable us to make these treatments more cost-effective and enable us to obtain savings following a competitive process in this therapy area. These savings would contribute towards making the funding of all medicines in New Zealand more sustainable into the future.

We are aware of the impact of this proposed change on clinicians and patients. If the proposal is approved, PHARMAC would work with the NHMG, haemophilia treatment centres, the Haemophilia Foundation and pharmaceutical suppliers to ensure adequate support and resources are in place for clinicians, patients and their families during a change.

3. Details of the proposal

Recombinant factor VIII

Preferred Brand

- Xyntha (Pfizer) would be awarded Preferred Brand Status for rFVIII in the community and DHB hospitals from 1 March 2016 until 28 February 2019.

- From 1 September 2015, the list prices and subsidies for Xyntha would be reduced in Section B and Part II of Section H of the Pharmaceutical Schedule as follows (prices expressed ex-manufacturer, excluding GST):

Section B

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Moroctocog alfa	Inj 250 iu vial	Xyntha	1	$225.00	$210.00
Moroctocog alfa	Inj 500 iu vial	Xyntha	1	$450.00	$420.00
Moroctocog alfa	Inj 1000 iu vial	Xyntha	1	$900.00	$840.00
Moroctocog alfa	Inj 2000 iu vial	Xyntha	1	$1800.00	$1680.00
Moroctocog alfa	Inj 3000 iu vial	Xyntha	1	$2700.00	$2520.00

Section H

Chemical	Presentation	Brand	Pack size	Current price	Proposed price
Moroctocog alfa	Inj 250 iu vial	Xyntha	1	$225.00	$210.00
Moroctocog alfa	Inj 500 iu vial	Xyntha	1	$450.00	$420.00
Moroctocog alfa	Inj 1000 iu vial	Xyntha	1	$900.00	$840.00
Moroctocog alfa	Inj 2000 iu vial	Xyntha	1	$1800.00	$1680.00
Moroctocog alfa	Inj 3000 iu vial	Xyntha	1	$2700.00	$2520.00

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

- The restriction criteria for Xyntha in Section B and Part II of Section H of the Pharmaceutical Schedule would be amended from 1 March 2016 as follows (additions in bold, deletions in strikethrough):

  Section B

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

  Preferred Brand of recombinant factor VIII for patients with haemophilia. Access to 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, treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.~~

  Preferred Brand of recombinant factor VIII. 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 would 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 would be required.

Second Brand

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

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

Section B

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Octocog alfa	Inj 250 iu vial	Kogenate FS	1	$250.00	$237.50
Octocog alfa	Inj 500 iu vial	Kogenate FS	1	$500.00	$475.00
Octocog alfa	Inj 1,000 iu vial	Kogenate FS	1	$1,000.00	$950.00
Octocog alfa	Inj 2,000 iu vial	Kogenate FS	1	$2,000.00	$1,900.00
Octocog alfa	Inj 3,000 iu vial	Kogenate FS	1	$3,000.00	$2,850.00

Section H

Chemical	Presentation	Brand	Pack size	Current price	Proposed price
Octocog alfa	Inj 250 iu vial	Kogenate FS	1	$250.00	$237.50
Octocog alfa	Inj 500 iu vial	Kogenate FS	1	$500.00	$475.00
Octocog alfa	Inj 1,000 iu vial	Kogenate FS	1	$1,000.00	$950.00
Octocog alfa	Inj 2,000 iu vial	Kogenate FS	1	$2,000.00	$1,900.00
Octocog alfa	Inj 3,000 iu vial	Kogenate FS	1	$3,000.00	$2,850.00

- A confidential rebate would apply to Kogenate FS, reducing its net cost to the Combined Pharmaceuticals Budget and to DHBs. There would 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 would be amended from 1 March 2016 as follows (additions in bold, deletions in strikethrough):

  Section B

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

  Second Brand of recombinant factor VIII for patients with haemophilia. Access to funded treatment by application to the Haemophilia Treatments Panel.

  Section H

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

  Second Brand of recombinant factor VIII. When used in the treatment of haemophilia, access to funded treatment by application to the Haemophilia Treatments Panel.

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

- There would be a 6-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 would have funded access to Kogenate FS.

- Between 1 March 2016 and 28 February 2019, applications could continue to 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) would only be available for patients in rare clinical circumstances where treatment with Xyntha and Kogenate is not clinically appropriate. Clinicians would need to make applications to the Haemophilia Treatments Panel for funded access to these brands.

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

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

Section B

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Octocog alfa	Inj 250 iu vial	Advate	1	$237.50	$287.50
Octocog alfa	Inj 500 iu vial	Advate	1	$475.00	$575.00
Octocog alfa	Inj 1,000 iu vial	Advate	1	$950.00	$1,150.00
Octocog alfa	Inj 1,500 iu vial	Advate	1	$1,425.00	$1,725.00
Octocog alfa	Inj 2,000 iu vial	Advate	1	$1,900.00	$2,300.00
Octocog alfa	Inj 3,000 iu vial	Advate	1	$2,850.00	$3,450.00

Section H

Chemical	Presentation	Brand	Pack size	Current price	Proposed price
Octocog alfa	Inj 250 iu vial	Advate	1	$237.50	$287.50
Octocog alfa	Inj 500 iu vial	Advate	1	$475.00	$575.00
Octocog alfa	Inj 1,000 iu vial	Advate	1	$950.00	$1,150.00
Octocog alfa	Inj 1,500 iu vial	Advate	1	$1,425.00	$1,725.00
Octocog alfa	Inj 2,000 iu vial	Advate	1	$1,900.00	$2,300.00
Octocog alfa	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 would be amended from 1 March 2016 as follows (additions in bold, deletions in strikethrough):

Section B

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

Rare Clinical Circumstances Brand of recombinant factor VIII for patients with haemophilia. Access to funded treatment by application to the Haemophilia Treatments Panel.

Section H

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

Rare Clinical Circumstances Brand of recombinant factor VIII. When used in the treatment of haemophilia, access to funded treatment by application to the Haemophilia Treatments Panel.

- There would 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 would be made on a form provided by PHARMAC. Clinicians would 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 would have funded access to Advate.

- Between 1 March 2016 and 28 February 2019, applications could continue to 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 would 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 proposal.

- Access to BeneFIX would continue to be managed by the NHMG with minor changes to its current restriction criteria on the Pharmaceutical Schedule from 1 September 2015 as follows (additions in bold):

  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 would apply to BeneFIX, reducing its net cost to the Combined Pharmaceuticals Budget and DHBs.

- BeneFIX would 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, would be listed at a later date, subject Medsafe registration.

- Rixubis would be listed with restriction criteria similar to that 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):

Section B

Chemical	Presentation	Brand	Pack size	Proposed 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

Section H

Chemical	Presentation	Brand	Pack size	Proposed price
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) would continue to be listed on the Pharmaceutical Schedule.

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

Section B

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
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

Section H

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price
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 would have protection from subsidy reduction and delisting until 30 June 2019.

- There would be minor changes to the restriction criteria for NovoSeven RT from 1 September 2015 as follows (additions in bold):

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.

Factor VIII inhibitor bypassing fraction

- Factor VIII inhibitor bypassing fraction (FEIBA, Baxalta) would continue to be funded and listed on the Pharmaceutical Schedule with the following changes from 1 September 2015 (deletions in strikethrough, additions in bold), including a reduction in the prices and subsidies for the product:

Section B

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

Section H

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

4. How to provide feedback

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm Friday, **19 June 2015** to:

Sue Anne Yee
Senior Therapeutic Group Manager/Team Leader
PHARMAC

Email: haemophilia@pharmac.govt.nz

Post: PO Box 10254, Wellington 6143

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request