

29 April 2005

To All Pharmaceutical Suppliers, Medical Groups and Interested Parties

By facsimile (3 pages)

CONSULTATION ON PROVISIONAL AGREEMENT FOR NATIONAL SUPPLY OF RECOMBINANT FACTOR VIII

PHARMAC has reached provisional agreements subject to consultation and PHARMAC Board approval for the national supply of Recombinant Factor VIII to DHBs. Those brands proposed to be listed on Section H of the Pharmaceutical Schedule are:

- Kogenate FS supplied by Bayer New Zealand Limited; and
- ReFacto supplied by Wyeth (NZ) Ltd; and
- Recombinate supplied by Baxter Healthcare Ltd.

Further details of each provisional agreement follow. Only those brands of Recombinant Factor VIII listed on the Pharmaceutical Schedule would be available for purchase.

Kogenate FS – proposed preferred supply brand

- Kogenate FS would be supplied by Bayer in 250 IU, 500 IU and 1,000 IU presentations.
- Kogenate FS would be the preferred supplier of Recombinant Factor VIII under the preferred supply criteria proposed below.
- All patients currently receiving alternate brands of Recombinant Factor VIII could remain on their current brand of Recombinant Factor VIII if it remained clinically appropriate to do so.

Proposed preferred supply criteria:

- (a) Subject to paragraphs (b) and (c) below:
- (i) patients receiving Kogenate FS prior to 1 July 2005;
 - (ii) patients commencing treatment with Recombinant Factor VIII after receiving plasma derived Factor VIII;
 - (iii) new patients commencing treatment with Recombinant Factor VIII;
 - (iv) patients undergoing tolerisation with Recombinant Factor VIII; or
 - (v) patients not regularly receiving Recombinant Factor VIII but requiring prophylaxis for surgical procedures or in emergency situations;

are required to use Kogenate FS from 1 July 2005.

- (b) Patients receiving, prior to 1 July 2005, an alternate brand of Recombinant Factor VIII may continue to receive that brand if they continue to tolerate it.

- (c) Patients whose clinician, for clinical reasons, recommends that the patient receive an alternate brand of Recombinant Factor VIII listed in the Pharmaceutical Schedule may receive that brand.

Kogenate FS would be listed and supplied at the prices set out below:

Brand	Presentation; pack size	Proposed list price
Kogenate FS	250 IU vial with diluent; 1	\$200.00
Kogenate FS	500 IU vial with diluent; 1	\$400.00
Kogenate FS	1,000 IU vial with diluent; 1	\$800.00

Note: A discount on invoice may apply to the above prices.

The proposal includes an annual exchange rate adjustment provision allowing a risk-sharing arrangement between DHB Hospitals and the supplier. Any resulting changes in price following the exchange rate calculation would be reflected in either a change to the list price or a confidential discount on invoice between DHB Hospitals and the supplier.

The period of preferred supply would be from 1 July 2005 until 30 June 2008. During the preferred supply period, DHB Hospitals could only purchase an alternative brand of Recombinant Factor VIII for patients who had commenced treatment on that brand of Recombinant Factor VIII prior to 1 July 2005 and for those patients who have tried Kogenate FS and who for clinical reasons have changed to an alternate brand of Recombinant Factor VIII.

ReFacto

ReFacto would be supplied by Wyeth in 250 IU, 500 IU and 1,000 IU forms; a 2,000 IU presentation would be listed on the Pharmaceutical Schedule once all necessary consents have been obtained under the Medicines Act 1981.

Under the preferred supply criteria outlined above for Kogenate FS, only patients who had begun treatment on ReFacto prior to 1 July 2005 would be able to be treated with ReFacto, and those patients where for clinical reasons, Kogenate FS was deemed unsuitable on an individual patient basis.

ReFacto would be listed and supplied at the prices set out below:

Brand	Presentation; pack size	Proposed price
ReFacto	250 IU vial with diluent; 1	\$215.00
ReFacto	500 IU vial with diluent; 1	\$430.00
ReFacto	1,000 IU vial with diluent; 1	\$860.00
ReFacto	2,000 IU vial with diluent; 1	\$1,720.00

Note: ReFacto 2,000 IU vial with diluent would be listed on the Pharmaceutical Schedule once all necessary consents were obtained under the Medicines Act 1981.

The above prices are determined at a \$0.86/IU rate. If national purchases of ReFacto exceed 5,000,000 IU for the period of 1 July to 30 June for any given year, the rate per IU would be reduced to \$0.80 resulting in the following prices for the remainder of that year:

Brand	Presentation; pack size	Proposed price
ReFacto	250 IU vial with diluent; 1	\$200.00
ReFacto	500 IU vial with diluent; 1	\$400.00
ReFacto	1,000 IU vial with diluent; 1	\$800.00
ReFacto	2,000 IU vial with diluent; 1	\$1,600.00

At the end of the period, the price would revert back to \$0.86 per IU until the same target level was achieved in the following period. The price/volume discount would run until the 12 month period ending 30 June 2008.

Recombinate

Recombinate would be supplied by Baxter in 250 IU, 500 IU and 1,000 IU forms.

Under the preferred supply criteria outlined above for Kogenate FS, only patients who had begun treatment on Recombinate prior to 1 July 2005 would be able to be treated with Recombinate (unless, for clinical reasons, Kogenate FS was deemed unsuitable on an individual patient basis).

Recombinant would be listed and supplied at the prices set out below:

Brand	Presentation; pack size	Proposed price
Recombinant	250 IU vial with diluent; 1	\$245.00
Recombinant	500 IU vial with diluent; 1	\$490.00
Recombinant	1,000 IU vial with diluent; 1	\$980.00

No additional price discounts or foreign exchange rate adjustments are proposed for Recombinate.

Additional points of note

Only those brands of Recombinant Factor VIII listed on the Pharmaceutical Schedule would be available for purchase. These proposals do not affect the supply or availability of plasma derived (AHF or Biostate) Factor VIII.

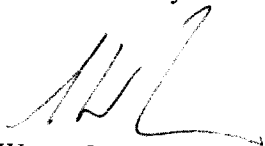
PHARMAC is considering implementing a Special Authority (SA) for Recombinant Factor VIII. All patients would be required to have a SA number that would be brand specific, recording which brand of Recombinant Factor VIII is being received. SA applications would receive automatic approval and would be valid without further approval unless notified otherwise. Patients changing brand of Recombinant Factor VIII would be required to apply for a new SA number.

For those DHBs who do not purchase Recombinant Factor VIII through DHB Hospital pharmacies will not be required to do so; current supply chain mechanisms would continue.

Deadline for consultation

If you wish to make comments for the PHARMAC Board to consider when making its decision on whether to accept these proposals, please forward them to Matthew Perkins (Email: matthew.perkins@pharmac.govt.nz; Ph: +64 4 9167 507) at PHARMAC by **4:00pm, 13 May 2005**.

Yours sincerely



Wayne McNee
Chief Executive