NATIONAL BLOOD AUTHORITY
AUSTRALIA

SUPPLY OF IMPORTED PLASMA & RECOMBINANT PRODUCTS: FUTURE ARRANGEMENTS

STAKEHOLDER CONSULTATION

For public consultation from
15 July to 16 August 2013

Contents

Glossary

Term	Definition
Blood Service	Australian Red Cross Blood Service
Plasma or Plasma Derived	Manufactured from human plasma
Recombinant	Genetically engineered product

Introduction

The role of the National Blood Authority

The National Blood Authority (NBA) is responsible for contractual arrangements to ensure that Australia's blood and blood product supply is secure, safe, adequate and affordable.

To find out further information about the NBA visit the NBA website http://www.nba.gov.au

Informed purchasing

The NBA has been charged by all Australian governments with purchasing blood and blood products on their behalf for all patients. The maintenance of blood supply is an essential health service, and we aim to be a leading government agency in exercising this responsibility, and improve supply.

The NBA is the national manager of a number of contracts with suppliers of blood and blood products, including imported plasma and recombinant products (IPRP). Australian governments currently provide a total of over $1 billion annually to the NBA for these contracts. Under the national supply arrangements patients receive blood products free of charge, including products for treating haemophilia and other bleeding disorders. The NBA purchases products which meet the regulatory requirements for product safety, quality and efficacy of the Therapeutic Goods Act 1989.

Current arrangements for imported plasma and recombinant products

Under the national blood arrangements administered by the National Blood Authority (NBA), Australia imports a range of plasma derived and recombinant products, including those listed in Table 1:

Table 1 Products within scope of this RFI

Recombinant products:	Plasma derived products:
Factor VIII (rFVIII) Factor IX (rFIX) Factor VIIa (rFVIIa)	Activated prothrombin complex concentrate Anti-Rh(D) Immunoglobulin Protein C Factor XI Factor XIII

The products in Table 1 have been treated as a group by the NBA for tendering and supply management purposes, under the general title of 'Imported Plasma and Recombinant Products' (IPRP). (The NBA also contracts for the supply of imported intravenous immunoglobulin (IVIg) but that is not part of the IPRP arrangements).

The NBA last tendered for IPRP products in 2010 and currently manages contracts with Bayer (Kogenate FS), Baxter (FEIBA, Ceprotin, factor VII), CSL Behring (Rhophylac, Fibrogammin, factor XI) and Pfizer (Xyntha, BeneFix). The previous tender resulted in savings of approximately $30m per year (against planned expenditure) and improved service standards. 2011-12 was a transition year in which approximately 75% of rFVIII patients were required to switch product brands as a result of NBA tendering outcomes.

Information on the trends and volumes issued of these products can be found in Part 3 of the Annual Report (2011-12) on the NBA website at www.blood.gov.au/pubs/1112report/.

Future arrangements for supply of imported plasma and recombinant products

The initial term of the current IPRP contracts expires on 30 June 2014. To continue the supply of these products after that date, the NBA may decide to exercise contract extension options under the current contracts for one or two one year periods, or to go to tender, or to undertake a combination of these actions.

A range of factors may be relevant to inform this decision, including clinical and other stakeholder requirements, market conditions and developments, and value for money considerations. For example, the NBA is aware of a number of potentially relevant product development activities being undertaken by a number of companies, including possible direct competitors for current IPRP products, as well as some market intelligence indicators suggesting there may be potential to achieve improved value for money outcomes from a tender process.

The NBA is conducting consultations with suppliers and stakeholders via a Request for Information (RFI) and stakeholder consultation paper to inform forward decision making.

The NBA is interested in seeking feedback from all stakeholders, including patients, clinicians, nurses, scientists and suppliers to achieve the best possible outcome from the tender process.

Purpose of consultation paper

This consultation Paper seeks feedback from users of imported plasma and recombinant products on the products identified in Table 1. A key outcome of this consultation Paper is to identify the needs of product users in relation to these products to inform the decision to extend the current suite of contracts or conduct a Request for Tender.

Information on the trends and volumes issued of these products can be found in Part 3 of the Annual Report (2011-12) on the NBA website www.blood.gov.au/pubs/1112report/.

A Request for Information (RFI) has been disseminated to current and potential suppliers of imported plasma and recombinant products seeking information on products available to the NBA post June 2014. A copy of this RFI can be found on the NBA website.

Closing date

The NBA is seeking responses to the consultation items in Attachment A to this document **by Friday 16 August 2013.**

Providing your response

Please provide your response by answering the questions in Attachment A.

The NBA may consider publishing a summary of responses on a de-identified basis.

Forward your response to the NBA (Attention Consultation Coordinator) by mail or email:

By mail: National Blood Authority
Locked Bag 8430
Canberra ACT 2601

By email: supply.management.plasma@blood.gov.au

Enquires about issues raised in this RFI may be directed to supply.management.plasma@blood.gov.au

Attachment A – Issues for consultation

Instructions for responses

Please provide your response by providing answers to the questions below in the format provided. Please provide additional information by attachments if appropriate.

The questions below are asked in relation to the following range of products:

Recombinant products:	Plasma derived products:
Factor VIII (rFVIII) Factor IX (rFIX) Factor VIIa (rFVIIa)	Activated prothrombin complex concentrate Anti-Rh(D) Immunoglobulin Protein C Factor XI Factor XIII

The consultation paper targets a broad range of stakeholders and not all questions may be applicable to you or your organisation. If you are not able to respond to a particular question, please indicate this as not applicable.

There is space at the end of the table to include any additional comments in relation to the current or potential future arrangements for imported plasma and recombinant products, which are not covered by questions below.

Consultation Response

1. YOUR ROLE
Please advise your role e.g. are you a patient, carer, nurse, doctor, scientist, administrative officer or other (please indicate). **If you work for or represent an organisation such as a hospital, Haemophilia Treatment Centre, patient group or clinical college or association, please identify which organisation.**
2. PRODUCT DEMAND
Are you aware of any recent or potential future changes in relation to the pattern of clinical use of the products that may materially affect demand over the next five years? If so, please provide details.

3. PRODUCT RANGE AND CHOICE

a) For some products more than one product brand may be available in the market. Weighing the relative benefits and disadvantages of product brand choice, how important is it to you?

- **Important**
- **Not important**
- **Would prefer minimal product brand choice**

Please provide some comment on what the key benefit or disadvantages influence your view.

If product brand choice is important to you, do the product options currently available provide sufficient choice for clinicians and patients? If not, please explain why not.

b) Does the current combination of vial sizes efficiently deliver the required dose? If not, please explain why not.

4. CHANGE IN PRODUCT BRANDS

If the NBA were to issue a request for tender for supply of products from 1 July 2014, possible outcomes for some products include:

- **the replacement and transition of a current brand of a product with another brand**
- **a decrease in the number of available brands**
- **an increase in the number of available brands**

a) Noting that any new brands of products would be required to meet the safety and efficacy standards set out by the Therapeutic Goods Administration, please explain in detail any clinical and practical benefits or disadvantages associated with a change in brands.

b) What were the implications for you of the transition of a number of patients receiving ongoing rFVIII treatment as a result of the IPRP tender outcomes in 2010? Did you encounter any substantial difficulties?

How satisfied were you with the planning and communications concerning that transition period? Do you have any suggestions for how any product brand transition could be managed better in future?

5. ORDERING AND DELIVERY OF PRODUCTS

a) From where do you order your products e.g. do you order direct from the commercial supplier, through the Blood Service or through another arrangement?

b) Are you satisfied with ordering and delivery arrangements? If not please provide details. Are there any improvements you would like to see made?

6. PRODUCT SUPPLY

Suppliers may provide support such as training and education programs (both initially and ongoing), demonstration kits, information materials, dosing guides and on-call advice.

a) What services currently provided by suppliers (particularly for patients, treatment centres and clinicians) do you find useful, and why?

b) Are there any support services that are currently provided that are not useful to you, and why?
c) What product support services that are not currently provided would be useful, particularly with the introduction of a new product?
d) What is the quality and useability of the administration kits currently provided by suppliers?
e) Is there a facility for you to provide feedback to current suppliers e.g. positive comments, complaints, follow up training, education, product support services? How adequate is this facility?
7. OTHER FEEDBACK OR INFORMATION
Do you have any further suggestions or advice that could assist the NBA in improving the supply of these imported plasma and recombinant products, including feedback on or possible improvements to the NBA tender or consultation process?