SuPPLY OF IMPORTED PLASMA & RECOMBINANT PRODUCTS: FUTURE ARRANGEMENTS

STAKEHOLDER CONSULTATION

For public consultation from
13 January 2016 to 17 March 2017

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# Glossary

| **Term** | **Definition** |
| --- | --- |
| 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 <https://www.blood.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*. The NBA undertakes national supply planning to ensure that the supply of products is available to meet clinical requirements in Australia.

Where new product types or new variants of existing products are developed, in some cases these require consideration through a health technology assessment process described in Schedule 4 of the National Blood Agreement (see <https://www.blood.gov.au/changes-national-product-list> ) so that a decision can be made by governments about whether these products should be brought within the supply and funding arrangements managed by the NBA. The NBA manages the process for such proposals to be made and evaluated, to support government decision making. (Please note that this consultation process is not directly a process for deciding that new variants or alternatives can be added to the arrangements managed by the NBA).

## Current arrangements for imported plasma and recombinant products

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

**Table 1: Imported Plasma and Recombinant Products**

| Recombinant products: | Plasma derived products: |
| --- | --- |
| Factor VIIa (rFVIIa)Factor VIII (rFVIII)Factor IX (rFIX) | Activated prothrombin complex concentrateAnti-Rh(D) ImmunoglobulinC1 esterase inhibitor concentrateProtein CFactor XI Factor XIIIFibrinogen Concentrate |

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).

## IPRP products covered by this consultation

The IPRP products in Table 2 will expire over the period 30 June 2017 to 30 June 2018 (unless the NBA exercises contractual options to extend) and are the products within the scope of this Stakeholder Consultation Paper. The NBA is interested in obtaining relevant information about these products. To assist with forward planning the NBA is also interested in obtaining information about any new variants of these products, or any new products which are alternative treatments which may replace these products.

**Table 2: Products covered by this consultation**

|  |
| --- |
| Recombinant products |
| Factor VIIa (rFVIIa) |
| Factor VIII (rFVIII) |
| Factor IX (rFIX) |

# Future arrangements for supply of IPRP

For the products covered by this consultation, where the current contracts expire during 30 June 2017 to 30 June 2018, the NBA may decide to:

* exercise available options to extend the contracts
* go to tender
* negotiate outside the tendering arrangement with suppliers (where permitted by procurement rules); or
* undertake a combination of these actions.

A range of factors may be relevant to inform future decision making, including:

* clinical and other stakeholder requirements
* market conditions and developments
* security of supply
* value for money considerations
* new product developments.

The NBA is aware of a number of potentially relevant product development activities being undertaken by companies, including possible direct competitors for current IPRP products or new variants or alternatives to these products. The NBA is also aware of market intelligence indicators suggesting there may be potential to achieve improved value for money outcomes.

The NBA is conducting consultations with suppliers and stakeholders through a request for information, and through this stakeholder consultation paper, to inform forward planning and decision making and to obtain the best overall value for money in any future procurement arrangements.

The NBA is interested in seeking feedback from all stakeholders, including clinicians, nurses, scientists, patients and patient representative groups, as well as from suppliers, for these purposes

# Purpose of consultation paper

This consultation paper seeks feedback from users of imported plasma and recombinant products on the products covered by the consultation. A key outcome of this consultation paper is to identify the needs of product users in relation to these products to inform decisions to extend the current suite of contracts or conduct a tender.

Information on the product trends and volumes issued can be found in Part 2 of the Annual Report (2014-15) on the NBA website at <https://www.blood.gov.au/sites/default/files/nba-annualreport-2014-15-as-at-20151013sm_1.pdf> .

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 from 1 July 2017. 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 17 March 2017.**

# 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 email: iprptender@blood.gov.au

Enquires about issues raised in this consultation may be directed to iprptender@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, including potential variants or alternatives to those products:

|  |
| --- |
| Recombinant products |
| Factor VIIa (rFVIIa) |
| Factor VIII (rFVIII) |
| Factor IX (rFIX) |

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 2017, 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 2014? 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. NEW PRODUCTS** |
| **To assist with forward planning this section asks about new variants of products covered by this consultation, or new products which may be alternatives products covered by this consultation. (Please note that this consultation process is not directly a process for deciding that new variants or alternatives can be added to the arrangements managed by the NBA).****Please explain the basis for your answers.****a) Are you aware of new types of or variants for, or alternatives for, products that are covered by this consultation? What are those new variants or products? What is the basis for your awareness of these products (eg trial participation, published information, conference information, etc)?** |
|  |
| **b) How might the new products be used? What might be the variations in how the products might be used?** |
|  |
| **c) What may be the potential advantages of the new products?** |
|  |
| **d) Are there potential disadvantages or limitations of the new products?** |
|  |
| **e) Please provide any additional information or views about the new products that may be useful for NBA forward planning.** |
|  |

|  |
| --- |
| **8. 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?** |
|  |