SuPPLY OF IMPORTED PLASMA & RECOMBINANT PRODUCTS: FUTURE ARRANGEMENTS

REQUEST FOR INFORMATION (RFI)

Responses due 5:00pm (AEST) on
17 March 2017

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# Introduction

Under the national blood arrangements administered by the National Blood Authority (NBA), Australia imports a range of plasma derived and recombinant products, to supplement domestic supply and obtain products that are not manufactured in Australia.

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).

**Table 1: Imported Plasma and Recombinant Products (IPRP)**

|  |  |  |
| --- | --- | --- |
| Product Type | Brand  | Supplier |
| Activated Prothrombin Complex Concentrate | FEIBA | Baxalta Australia |
| Anti-Rh(D) Immunoglobulin | Rhophylac | CSL Behring |
| Protein C | CEPROTIN | Baxalta Australia |
| Fibrinogen Concentrate | Riastap | CSL Behring |
| Recombinant Factor VIIa | NovoSeven RT | Novo Nordisk |
| Recombinant Factor VIII | ADVATE | Baxalta Australia |
| Xyntha | Pfizer Australia |
| Recombinant Factor IX | RIXUBIS | Baxalta Australia |
| BeneFIX | Pfizer Australia |
| Factor XI | BPL Product  | CSL Behring |
| Factor XIII | Fibrogammin | CSL Behring |
| C1 esterase inhibitor concentrate | Berinert | CSL Behring |

Current agreements for products in Table 2 will expire over the period 30 June 2017 to 30 June 2018 (unless the NBA exercises contract options to extend) and are the products within the scope of this Request for Information (RFI).

**Table 2: Products within the scope of this RFI**

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

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>

# Future arrangements for supply of IPRP

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

* exercise available options
* go to tender
* negotiate outside the tendering arrangement with suppliers; 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 product developments
* security of supply
* value for money considerations.

The NBA is aware of a number of 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 via a RFI and a stakeholder consultation paper to inform forward 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 current or potential suppliers, to achieve the best possible outcome from any tender process and for these other purposes.

# Purpose of the RFI

This RFI seeks information from suppliers of imported plasma and recombinant products on the products identified in Table 3 below. The NBA is interested in obtaining relevant information about these products. A key outcome of this RFI is to identify and obtain information about current and possible future products to inform the future supply arrangements. To assist with forward planning the NBA is also interested in obtaining information about any new types or variants of these products, or any new products which are alternative treatments which may replace these products.

**Table 3: Products within the scope of this RFI**

| Imported Plasma and Recombinant Products: |
| --- |
| Recombinant Factor VIIaRecombinant Factor VIII Recombinant Factor IX  |

The purpose of this RFI is to:

1. provide the opportunity for current and potential suppliers of plasma and recombinant products to give the NBA their view on potential supply arrangements;
2. obtain information on those imported plasma and recombinant products that suppliers may be able to provide; and
3. enquire about suppliers’ plans to register relevant new products, both within Australia and globally.

The feedback and information obtained through this RFI and the consultation paper will enhance the NBA’s knowledge of the market, and help to inform the NBA’s decisions on future procurement decisions for supply of IPRP products beyond 1 July 2017.

Note that responding to this request is not a mandatory or voluntary pre-qualification stage for participation in any potential competitive tender process.

# Closing Date

The NBA is seeking responses to this RFI **by 5:00pm (AEST) on Friday 17 March 2017.**

# Providing your response

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

There are no conditions for participation in this RFI.

The NBA may consider publishing a summary of responses on a de-identified basis. Where requested, the NBA will keep information and material submitted as commercial in confidence and will not publish this information.

Forward your response to the NBA (Attention Consultation Coordinator) by email: iprptender@blood.gov.au

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

# Attachment A – Questions for response

## 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.

Please separate the details for different products where appropriate.

## RFI Response

|  |
| --- |
| 1. COMPANY DETAILS
 |
| Company Name |  |
| 1. PRODUCT RANGE & AVAILABLITY
 |
| B1. Products available for supply in AustraliaWhat products does your company have registered, or have in the process of being registered, through the TGA for supply in Australia from 1 July 2017?*For each product, provide the information requested below.**You may wish to provide a product Information sheet, in which case your response can refer to the relevant section on the sheet.*  |
| Product Type | *Note: Please indicate the product type e.g. Factor rVIII.* |
| Product Name |  |
| ARTG Status | *Note: If product is not currently registered for supply in Australia:*1. *Identify if a submission for registration was submitted to TGA and the expected date of inclusion on the Australian Register of Therapeutic Goods (ARTG).*
2. *If no submission has been made as yet, please indicate what documentation has been prepared for the submission including:*
* *Explanation of evidence available against TGA requirements for registration*
* *Likelihood of meeting TGA requirements for registration*
* *Proposed timelines for registration*
1. *If there are no plans to register the product in Australia, please explain why not and the basis on which assurance of ability to provide reliable national supply could be given.*
 |
| Manufacturing Process | *Note: Provide information on source material, where material is sourced from, and major manufacturing processes or steps.* |
| Adverse Events/Regulatory Action | *Note: Please advise the following:*1. *What data is available on the number and type of adverse events in relation to this product?*
2. *Are you aware of current or intended investigations or regulatory restrictions in any jurisdiction, including but not limited to Australia, Europe or United States? If so, provide details.*
 |
| Vial Sizes |  |
| Shelf Life |  |
| Storage Temperature |  |
| Ancillary Equipment | *Note: Please list any ancillary equipment and how this equipment is provided e.g. reconstitution and infusion kits provided as a separate package upon request.* |
| Additional Features | *Note: Please list any additional features you consider are of value to users of the product, including patients, clinicians, and those who are involved in ordering and distribution.* |
| Future Features | *Note: are there any planned enhancements or advances in technology that will improve safety, efficacy or convenience of this product over the next six years?* |
| B2. Support servicesDescribe the support services your company provides for scientific or clinical personnel, or for patients, using the products (e.g. initial or ongoing training and education, demonstration kits, product information material, product advice, dose calculators and devices for managing patient use of the product). What additional support services could your company provide? |
|  |
| 1. DEMAND & SUPPLY
 |
| C1. Changes in supply or demandFrom your company’s knowledge of the market and clinical practice, do you anticipate any changes either globally or within Australia that may affect global or Australian supply or demand? If so, how might this affect NBA or global supply arrangements in the future? |
|  |
| C2. Global production scheduling and operationWhere is the product manufactured and how often? E.g. number of batches per year and batch quantity. |
|  |
| C3. Planning and production cycleProvide a detailed description of the planning and production cycle from initial scheduling of production to delivery into Australian inventory. This should include shelf life on production, country specific packaging, shipping, custom clearance and quarantine as required. In addition please advise the level of flexibility in this schedule when additional product is required for emergency purposes. |
|  |
| C4. Production and supply assuranceHas your company experienced any batch failures or other major production or supply issues (e.g. quarantine or recall) for the products? How were these managed? What production and supply contingency arrangements do your company have in place or intend to have in place? Please include in your response the definition used for a batch failure, and production or supply delay, within these contingency arrangements. |
|  |
| C5. Minimum/maximum volumesAre there any minimum or maximum limits to the volumes of products your company can supply? If so, advise these limits, within what time period, and the reason for them. What price or other value for money benefit would agreement to these limitations give to the NBA? |
|  |
| 1. LOGISTICS
 |
| D1. Distribution arrangementsNoting suppliers under NBA contracts may be required to deliver products to hospital, clinic, pathology service, home delivery patients, Blood Service or other approved locations anywhere in Australia, please outline what your company’s distribution arrangements for supply in Australia would be under any contract with the NBA, and where geographically stock would be held. |
|  |
| D2. Logistics innovationWhat possible advances in inventory or logistics processes or systems is your company aware of that may be relevant for the products over the next six years? Are these likely to be available for supply within Australia? |
|  |
| 1. CONTRACT FEATURES
 |
| E1. Term of supply arrangementsWhat term of NBA supply contract would your company prefer, and why? What price or other value for money benefit would agreement to this term give to the NBA? |
|  |
| E2. Number of suppliersIf there are multiple potential suppliers for a particular product, which number of suppliers engaged under NBA contract arrangements would enable your company to tender on the most advantageous terms for the NBA, and why:(a) one supplier(b) two suppliers |
|  |
| E3. Supply risk mitigation |
| E3.1. Under current NBA contract requirements suppliers must maintain in Australia the equivalent of up to 3 months demand of in country reserve to minimise supply risk. Please provide your company’s views on whether these arrangements adequately minimise Australian supply risk for your company’s products. |
|  |
| E3.2. Does your company have a suggestion for an alternative approach to addressing supply risks for Australia? If so please outline this approach and explain the benefits for minimising supply risk.  |
|  |
| E4. Price |
| E4.1. Please provide information on the price of your company’s products in the United States and European markets.  |
| *Note: Prices should be in source currency and exclude value added taxes* |
| E4.2. Please provide information on the likely price Australian dollars (GST Exclusive) at which your company would offer the products under NBA supply arrangements for supply from 1 July 2017. Please also indicate the basis for price increases over time that your company would be likely to propose. Please indicate whether any ancillary equipment is included in this price. |
|  |
| E4.3. More generally, what contract features, or overall aspects of the supply arrangements, would tend to reduce the price under which your company would be willing to supply, and why? |
|  |
| E4.4. What contract features, or overall aspects of the supply arrangements, would tend to increase the price under which your company would be willing to supply, and why? |
|  |
| 1. NEW PRODUCTS

This section relates to new product types or variants of, or direct alternatives for, products covered by this RFI.  |
| FI. Does your company have any new products in development (preclinical development or phase I, II and III clinical trials anywhere in the world), or in supply overseas but not yet in Australia, which may be registered and available for supply in Australia over the next six years?Please provide details of the products and planned timetable to register in Australia. If you have no plans to register in Australia, please explain why not. |
|  |
| F2. What is the intended use of the new products? What might be the variability in how the products might be used in practice? |
|  |
| F3. What are the potential advantages of the new products? |
|  |
| F4. Are there potential disadvantages or limitations of the new products?  |
|  |
| F5. What is the price per unit of the new products in overseas markets?What is the likely price per unit of the new products if introduced in Australia (in Australian dollars)?How might the new products affect the cost of treatment compared to current products? |
|  |
| F6. Please provide any additional information or views about the new products that may be useful for NBA forward planning |
|  |
| 1. ADDITIONAL INFORMATION
 |
| G1. Do you have any additional comments or suggestions you would like to make in relation to the current or potential future imported plasma and recombinant arrangements and/or products, including feedback on or possible improvements to the NBA tender or consultation process? |
|  |