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# National blood supply change proposal form

National Blood Authority

February 2025

## Introduction

In Australia, blood products and services supplied under the [National Blood Agreement 2003](https://www.blood.gov.au/national-blood-agreement) (Agreement) are provided without direct cost to patients, based on clinical need and appropriate clinical practice. The Agreement specifies that the cost of these products and services be shared by Commonwealth (63%) and states and territories (37%), with the funding from each state and territory proportioned by the volume supplied to each state and territory.

The *National Blood Authority Act 2003* established the National Blood Authority (NBA) to administer the national blood arrangements outlined in the Agreement. Blood and blood related products included in the national blood arrangements are agreed to by Australian governments and listed on the [National Product Price List](https://www.blood.gov.au/blood-products/national-product-price-list) (NPPL).

## What is a national blood supply change proposal?

A national blood supply change proposal (change proposal) is a proposal made to the NBA to add a new product to, or to remove or amend an existing product on the NPPL. The process for initiation, evaluation and implementation of change proposals is outlined under Schedule 4 of the Agreement.

For more information on change proposals and the processes involved, please refer to the Information for Proponents on the NBA website: [National Product Price List | National Blood Authority](https://www.blood.gov.au/blood-products/national-product-price-list).

## PART A: Administrative details

Please provide details as follows:

### Proponent:

|  |  |
| --- | --- |
| Company/organisation/individual name in full: | Click here to enter |
| ABN (if applicable): | Click here to enter |

Contact Person:

The contact person should be someone familiar with the change proposal and is able to provide/coordinate additional information as required

|  |  |  |
| --- | --- | --- |
| Title: Click here to enter | First name: Click here to enter | Last name: Click here to enter |
| Position | Click here to enter |
| Physical Address | Click here to enter |
| Postal Address:(if different from above) | Click here to enter |
| Email: | Click here to enter |
| Phone: | Click here to enter |
| Mobile: | Click here to enter |

PART B: Description of change proposal

This section of the form should provide an overview of the change proposal and the value or significance this will bring to governments and the Australian blood sector. The aim is to support an assessment of the change proposal against the National Blood Agreement objectives and current government policies.

### Type and purpose of the change proposal

1. **Is the change proposal a request to:**

[ ]  Add a new product or service to the NPPL

[ ]  Delete a product or service currently listed on the NPPL

[ ]  Substitute a product or service on the NPPL

[ ]  Modify a current product or service on the NPPL

[ ]  Add a new indication for an existing product or service on the NPPL

[ ]  Add a new collection or processing activity to the NPPL

1. **What is the overall or primary purpose of the change proposal?**

[ ]  Safety intervention

[ ]  New therapy

[ ]  More effective therapy

[ ]  More efficient process

[ ]  Cost saving measure (including introduction of competition)

[ ]  Other – please state

Click here to enter text.

1. **Please summarise your change proposal, including proposed indications for use.**

Click here to enter text.

### Previous change proposal(s) associated with this change proposal

1. **Has a change proposal been submitted previously to the NBA for consideration?**

[ ]  Yes [ ]  No

If yes, please provide details, and clearly identify new information or circumstances for this change proposal.

Click here to enter text.

1. **Has the proponent had a pre-submission meeting with the NBA?**

[ ]  Yes [ ]  No

If yes, please provide the date(s) of the pre-submission meeting.

Click or tap here to enter text.

1. **Has funding been sought from other government sources?**e.g., Pharmaceutical Benefits Scheme, Medicare Benefits Schedule, National Health Reform Agreement.

[ ]  Yes [ ]  No

If yes, please provide details of those change proposals, and the outcomes.

Click here to enter text.

### Value and significance

1. **Provide a description below of why the change proposal is needed**
e.g., clinical need, public health significance, number of patients who stand to benefit and its contribution to the primary policy objectives and secondary policy aims of the National Blood Agreement.

Click here to enter text.

1. **Supporting documentation (e.g. letter of support from clinical expert groups or patient advocacy groups) can optionally be supplied as attachments to the change proposal. If such documentation is being supplied, please provide details below.**

Click or tap here to enter text.

### Other issues

1. **Provide details below of any other significant policy issues relating to the change proposal**e.g., consideration of any medico-legal or ethical issues that may need to be addressed.

Click here to enter text.

PART C: Population, intervention, comparator, outcome (PICO)

Please discuss the proposed population(s), intervention, comparator(s), and outcome(s) of the proposed intervention.

### Population

1. **Describe the population in which the proposed health technology or service is intended to be used**

Click or tap here to enter text.

### Intervention

1. **Name of the proposed health technology or service**

Click or tap here to enter text.

### Comparator(s)

Please discuss the selection of an appropriate comparator for this change proposal to be compared against. Generally, the current product or treatment for the condition to be addressed by the change proposal should be taken as the comparator.

1. **What is the nominated comparator(s)?**

Click or tap here to enter text.

1. **Why is the chosen comparator(s) appropriate?**

Click or tap here to enter text.

### Outcome(s)

1. **Please describe the expected outcome(s) of the proposed health technology or service**

Click or tap here to enter text.

PART D: Regulatory requirements – safety and effectiveness

### TGA registration

Registration/licensing of the product and indication(s) for use with the Therapeutic Goods Administration (TGA) may be required for a change proposal to be considered. The requirement for TGA registration/licencing before consideration of a change proposal will be at the discretion of the NBA.

1. **Has TGA registration / other approval been sought?**

[ ]  Yes [ ]  No

If yes, please attach a copy of relevant documentation where applicable:

|  |  |
| --- | --- |
|  | **Attached** |
| * Sponsor’s submission to TGA
 | [ ]  Yes | [ ]  No |
| * Letter of registration with details of marketing approval and registration
 | [ ]  Yes | [ ]  No |
| * TGA Clinical Evaluator’s Report (including any expert reports)
 | [ ]  Yes | [ ]  No |
| * The TGA Delegate’s Overview (advice to the Advisory Committee on Medicines)
 | [ ]  Yes | [ ]  No |
| * The ACM resolution (when available) and the relevant extract of the ACM minutes (if and when available)
 | [ ]  Yes | [ ]  No |
| * Any related assessment provided to you by TGA
 | [ ]  Yes | [ ]  No |
| * Any TGA-approved product information (showing the relevant license or registration number)
 | [ ]  Yes | [ ]  No |

If the product/service has been considered more than once by TGA, documentation relating to all TGA considerations should be attached.

1. **If the product or service has been mandated/registered/licenced by the TGA, on what date did this occur?**

Click here to enter text.

1. **If TGA approval has not been sought, please explain why this is not needed, or what exceptional circumstances may apply.**

Click or tap here to enter text.

1. **Is the change proposal supported by additional information / evidence as to safety and efficacy other than that already provided by the TGA?**

[ ]  Yes [ ]  No

**If yes, please list any additional evidence available.**

Click or tap here to enter text.

1. **Does the product / service meet all other applicable regulatory requirements – for example, the requirements of State or Territory laws in relation to blood collection, if relevant?**

[ ]  Yes [ ]  Pending [ ]  No

**If yes, please list any additional evidence available.**

Click or tap here to enter text.

1. **Does the proponent agree and authorise TGA to release information and/or copies of reports to the NBA and Australian governments?**

[ ]  Yes [ ]  No

If no, please provide reason why authority not granted.

Click here to enter text.

PART E: CLINICAL EFFECTIVENESS, SAFETY, AND OTHER BENEFITS

Provide information of the expected/proposed clinical outcomes of the new product/process/service and a summary of the experimental evidence supporting these expected outcomes. Please provide details of your literature search and attach copies of all relevant papers, both published and unpublished.

Australian governments will consider the quality of the evidence base, as well as the strength of the findings.

### Methodology

1. **Provide a description of the methodology used to obtain results and expected outcomes from the proposed change** e.g.,What measures of efficacy, effectiveness and safety are available?

Click here to enter text.

### Clinical effectiveness

1. **Please provide a description of the clinical efficacy of the proposed intervention, including in comparison to the nominated comparator(s)**

Including but not limited to clinical care and outcomes to patients. Note that reduction of current risks can be considered as beneficial.

Click here to enter text.

### Safety

1. **Where applicable, please specify any side-effects or reactions that have been associated with the product, and how frequently they occur, including in comparison with the nominated comparator(s)**

Click here to enter text.

### Other benefits

1. **Please provide a description of other benefits of the proposed intervention, including in comparison to the nominated comparator(s)**

Including but not limited to benefits for donors, for governments, supply and contingency measures, and financial benefits. Note that reduction of current risks can be considered as beneficial.

Click here to enter text.

PART F: IMPLEMENTATION

It is important that Australian governments understand the practicalities associated with implementing the change proposal and the implications for governments, funding, the blood sector, and the provision of products and/or services to the Australian community.

### Proposed timeframes for implementation

1. **Please provide details below of timings (if any) for the change proposal**
e.g., lead times to full implementation, timeframe from placing an order to delivery.

Click here to enter text.

1. **Please discuss below any demand management issues related with this change proposal**
e.g., is there a need to develop rules or guidelines to ensure that limited supplies (and funds) are directed to indications of greatest need and used in sustainable amounts? How would you recommend that this be managed?

Click here to enter text.

### Estimated utilisation

1. **Estimate the prevalence and / or incidence of the population that is proposed will be eligible to use the intervention in Australia**

Click here to enter text.

1. **Provide the percentage uptake of the proposed intervention by the proposed population in the first 5 years**

Click here to enter text.

1. **Estimate the number of patients who will utilise the proposed intervention for the first full year**

Click here to enter text.

1. **Estimate the average amount / volume of the proposed intervention that will be utilised per patient per year**

Click here to enter text.

PART G: RISK ANALYSIS

Proponents are asked to provide a summary of the major benefits and risks that the change proposal would have for the blood sector and the Australian community.

### Potential risks

1. **Please provide a description below of the major risks, including but not limited to risks to government, risks to recipients, risks of supply continuity and legal, regulatory and financial risks, and how they would be managed**
* Where are the main areas of uncertainty in the costs, benefits and risks?
* How do these risks compare to the risks for similar products and services?
* Are there side effects, or risks to the patient, or occupational health & safety issues?

Click here to enter text.

PART H: COSTING SUMMARY

The purpose of this section is to enable Australian governments to make a general assessment of the value of a change proposal for the Australian community. Detailed evidence on the costs and benefits may be required at a later stage for evaluation by expert advisors, NBA or Australian governments.

Although this is a change proposal for funding by governments under the national blood supply, there may be other costs associated with a change proposal spread across a variety of payers. For example, a product is purchased by the NBA and paid for by governments under the national blood supply may incur costs (or savings) to other areas e.g., Australian Red Cross Lifeblood distribution networks, hospitals, pathology costs, patients and their families, and in other sectors of society either government or non-government (e.g., patient transport, income support etc). Costs to blood and plasma donors may also be considered. There is also an opportunity cost associated with the use of resources that could otherwise be used for a different purpose.

Proponents should note that the general assessment of the value of a change proposal made by Australian governments does not preclude or pre-empt any steps required to be taken by the NBA in accordance with the Commonwealth procurement framework, including seeking to establish prices through a competitive procurement process, undertaking price benchmarking, or negotiating on price as part of contract negotiations.

### Costs

1. **Please discuss opportunity cost considerations associated with this change proposal.**

Click here to enter text.

1. **Please provide an estimate of the cost per unit**Unit refers to the unit of measurement appropriate for the particular product e.g., gram, International Unit (IU) etc. of the proposed product/service.

Click or tap here to enter text.

1. **How much will the change proposal cost?**
* Please list both costs and savings, rather than an aggregated amount and distinguish between costs under national blood supply funding, other costs to governments, and other costs to the health system/other sectors/patients and their families.
* If another product/service is to be modified or discontinued, to what extent are the costs associated with that recoverable?
* This analysis is to include all costs associated/incurred along with the intervention, not just the purchase of a product/service from its sponsor.
* Please describe the sources of data for the costings.

Click here to enter text.

The NBA may contact you to discuss and refine the costings further. The following table includes suggestions about some of the common types of costs to consider. Please modify as appropriate.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Implementation cost** | **After Implementation****Ongoing Annual cost estimate per year over 5 years** | **Who incurs the cost?** **e.g., blood funding, hospital, patient, family, society etc.** |
| **Staff resources required**(e.g., nursing and medical staff in or out of hospital, laboratory technicians, administration staff, transport staff, blood bank staff and any additional training requirements etc.) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Direct consumables**(e.g., filters, blood bags, Laboratory reagents) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Other Direct costs**(e.g., other associated treatments such as pharmaceuticals, regulatory costs and outsourced arrangements such as storage) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Wastage**(e.g., due to product expiry or quality control) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Additional overhead costs**(e.g., property operating expenses, administrative and management expenses, hospital bed days) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Transportation and distribution costs** | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Capital costs**(e.g., equipment/ information system software and hardware) | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Indirect costs** | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Total:** | Click here to enter text. | Click here to enter text. | Click here to enter text. |

1. **Options for implementation**

Please describe below any issues or options that need to be considered for implementing this change proposal. Particularly, if evidence on cost/effectiveness is incomplete, can further evaluation and review be built into the approach to funding and implementation?

For example:

* implementation on a trial basis at selected pilot sites, or a phased implementation process (e.g., this may be an option to gather further data on costs, practicalities, and effectiveness before governments consider full implementation);
* alternative clinical protocols (e.g., that use different amounts of product, with different implementation costs);
* range of clinical applications/indications (e.g., some applications/indications may be more cost effective than others); and
* implications of these scenarios for costs and effectiveness described above.

Click here to enter text.

### Economic evaluation

1. **Please name and attach any relevant economic evaluation studies, either from the literature or prepared by the proponent, including in comparison with the nominated comparator(s)**

If no relevant studies are available, please provide relevant information where possible regarding costings, and clinical effectiveness. If the preliminary assessment by Australian governments is favourable, then further input may be sought on these issues via an independent health economist.

Relevant economic evaluation work would include details of modelling work, costing studies, basis of Quality Adjusted Life Years (QALY) estimates, comment on applicability to Australian circumstances, and the impact on calculations of sensitivity analysis.

Click here to enter text.

PART I: CONSULTATION

1. Have you consulted with any external experts in the preparation of the change proposal? If so, please provide details below and indicate their area of expertise.

Click here to enter text.

PART J: BASIS FOR CHANGE PROPOSALS

Proponents should note that by submitting a change proposal, ownership of the copies of (but not the intellectual property in) the documents and information submitted will vest in the NBA. Upon making a submission, proponents will be taken to have granted Health Ministers, Australian governments, the NBA and any person acting on their behalf a permanent, non-exclusive, irrevocable, royalty free licence to use, modify and reproduce any part of the change proposal for a purpose relevant to their role. A relevant purpose can include a public process of consultation or competitive procurement.

Generally, change proposals will not be treated as being confidential. If a proponent wishes to claim confidentiality, the proponent must contact the NBA in writing to specifically request that the change proposal, or part of it, be treated as confidential and give reasons for the claim. The change proposal will only be treated as confidential to the extent that this is specifically agreed to by the NBA.

The NBA will handle any personal information contained in a change proposal in accordance with the *Privacy Act 1988* and the Australian Privacy Principles.

Proponents should also note that as an Australian Government agency, certain rights of access to information held by the NBA are provided under a range of legislation including:

1. *Freedom of Information Act 1982*
2. *Archives Act 1983*
3. *Auditor-General Act 1997, and*
4. *Ombudsman Act 1976.*

Parliament and courts also have rights to access information held by the NBA.

Nothing in the proponent information, change proposal form or the process of considering submissions creates, or is to be construed to create, any binding contract or other understanding (including any form of contractual, quasi-contractual, restitutionary rights or other legal relationship (express or implied) between the proponent and Health Ministers, Australian governments or the NBA or any person acting on their behalf.

Neither Health Ministers, Australian governments or the NBA or any person acting on their behalf gives any warranty or bears any obligation or liability for any action or decision made by an proponent or other person on the basis of any information provided in the guidelines, the change proposal form or in connection with the change proposal process.

PART K: DECLARATION

On behalf of Enter company or individual name here I hereby declare that:

* I have read and understand the proponent information and change proposal form and that this change proposal is submitted on the basis set out in those documents; and
* I conscientiously believe the statements contained in this change proposal to be true in every particular.

In making this Declaration I acknowledge that the giving of false and misleading information to the NBA is a serious offence under Division 137 of the *Criminal Code* (Cth).

|  |  |
| --- | --- |
| Signed: |  |
| Name (print): | Click here to enter |
| Position: | Click here to enter |
| Date: | Click to enter a date. |