National blood supply change proposal

Information for proponents

National Blood Authority

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Introduction

In Australia, blood products and services supplied under the National Blood Agreement 2003 (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 (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.

How to submit a proposal

Proponents wishing to submit a blood supply change proposal can find the proposal form on the NBA website: National Product Price List | National Blood Authority. Although not mandatory, it is recommended that the proponent meet with the NBA to discuss the proposal prior to submission. Please email productreview@blood.gov.au to request a pre-submission meeting.

The proposal form is designed to gather appropriate evidence for the NBA to make an evaluation and provide advice to Australian governments about proposed changes to products or services funded under the national blood arrangements.

Before filling out the proposal form, the proponent should read through and understand the Multi Criteria Analysis (MCA) framework found in Appendix 1. Proponents should ensure that all criteria points of the framework have been addressed in detail before submitting the form to the NBA. More information on the purpose of this framework is described in the assessment process below.

Once a proponent has completed the proposal form, email the form and supporting documents to productreview@blood.gov.au for the NBA to process.

Assessment process

Once a change proposal is submitted to the NBA, it is reviewed to determine whether evidence-based evaluation, or further information or advice of any other sort, is required in relation to the proposal. A proposal for a new product that is not already on the NPPL, or a material change to the nature of an existing product on the NPPL may require an MCA and a full health technology assessment (HTA). The scope of each type of assessment is described in Table 1.

Table 1: Assessment of national blood supply change proposals	
Cycle 1 **Multi-Criteria Analysis (MCA)**	The MCA framework has been developed to ensure that blood sector objectives are considered in a consistent manner when assessing national blood supply change proposals. The MCA is a high-level evaluation to determine if there is enough evidence to make a recommendation to Australian governments. The analysis relies on information contained within the proposal together with other desk-top research, information held by the NBA, and other information gathered from relevant stakeholders. A proponent can complete their own MCA and submit it to the NBA alongside the completed proposal form and supporting documents. This may reduce the time required to consider a change proposal.
Cycle 2 **Health Technology Assessment (HTA)**	The need for a HTA may be identified if one or more criteria from the MCA requires a more detailed evaluation. A HTA requires a comprehensive examination of scientific evidence to assess quality, safety, efficacy, effectiveness against relevant comparators and cost effectiveness of a proposed change to the NPPL. In these cases, the proposal may be referred to the Medical Services Advisory Committee (MSAC) for expert evidence-based assessment and advice.

The MCA framework is provided in Appendix 1. Proponents may choose to provide an assessment of their product against the MCA framework to add to their proposal, however the NBA will also conduct an independent review of the proposal against the MCA criteria.

Once the assessment step(s) are complete the proposal will be considered by Australian governments who may decide that the proposal:

- should be funded under the national blood arrangements and determine any associated implementation issues;
- should not be funded under the national blood arrangements; or
- requires further information or advice.

Proponents will be provided with the assessment reports and informed of the decision made by governments.

Implementation

If Australian governments agree that a new product is suitable for funding under the national blood arrangements, the NBA may undertake a procurement process following the Commonwealth Procurement Rules. It is important for proponents to know that agreement does not guarantee a particular product will be purchased. Rather, it is a policy decision that a product can be considered for future purchase.

Where there is one supplier of a product, the NBA may directly negotiate a value for money contract for the purchase of the product. Where there is more than one supplier of a product, the NBA will undertake a competitive procurement process to ensure that all potential suppliers of that product have equal opportunity to respond to the NBA tender and that any contracts are awarded based on a value for money evaluation. Where Australian governments agree to a change relating to a product that is already listed on the NPPL, the NBA may conduct contract and price variation negotiations with suppliers if required.

Frequently Asked Questions

How can a change proposal be submitted?

The proposal form to submit a change proposal can be found on the NBA's website: National Product Price List | National Blood Authority.

When can a change proposal can be lodged?

Proponents can submit a national blood supply change proposal at any time to productreview@blood.gov.au. Although not mandatory, proponents are encouraged to reach out to the NBA for an initial meeting prior to submission.

How are proposals assessed?

The NBA checks proposals to ensure that all required elements are captured. If the proposal is missing key information, the proponent will be contacted by the NBA and asked to provide further information.

Depending on the complexity of the change proposed, the NBA may:

- assess the proposal against the multi-criteria analysis (MCA) framework,
- refer the proposal to the Medical Services Advisory Committee (MSAC) for a health technology assessment (HTA), or
- recommend the proposal progress to a competitive procurement process.

The final decision as to whether a product is suitable for inclusion on the NPPL rests with Australian governments.

What is the role of the MSAC under the National Blood Agreement?

There is no formal role for the MSAC outlined in the National Blood Agreement. Where additional evidence is needed to consider a change proposal, it may be referred to the MSAC or another suitable body to undertake a health technology assessment.

Can a proponent request that a change proposal only undergoes MCA, and not MSAC assessment?

No. Depending on the complexity of the change proposed, the NBA may refer the proposal to MSAC for a HTA. The proponent is under no obligation to follow the MSAC process, however it will affect the ongoing consideration of their change proposal.

Can a proponent request a HTA from MSAC prior to submitting a change proposal to the NBA?

The NBA recommends proponents contact the MSAC Secretariat for further information on the MSAC application and assessment process. However, MSAC will typically not accept applications for blood and blood related products until they have been formally referred to MSAC by the NBA.

How long does the assessment/decision making process take?

The time needed to resolve a national blood supply change proposal depends on the complexity and novel nature of the proposal and if multiple rounds of assessment and consideration are needed.

Who decides if a product is included on the National Product Price List?

Following assessment of the proposal, national blood supply change proposals are resolved by Australian governments. Where a proposed change is minor (e.g. changes to product information or packaging size) the NBA may resolve the proposal without further consultation.

Who decides if a product can be regarded as a blood or blood-related product under the national blood agreement?

This is a decision for Australian governments.

In submitting a national blood supply change proposal, would decision makers look favourably on a particular package size or bundle?

These are commercial issues for prospective suppliers, and it is their responsibility to put forward their strongest proposal.

Appendix A:
Multi-criteria Analysis Framework

Criterion	**1. SECURITY OF SUPPLY**	
Definition	*The extent to which the proposed intervention/product effectively mitigates an existing or emerging risk to the security of supply in terms of: • meeting the annual supply plan; and/or • promptly responding to unexpected demand increases or supply shortfalls.*	
Scope	The risks/opportunities include for example*:* • New diseases or a change in disease incidence (e.g. influenza cases, dengue) • Presence of new blood borne contaminants • Manufacturing problems/issues • Annual surgical/treatment pattern(s) • Domestic and International plasma shortages or quality issues • Government policies/initiatives • Local, national or international disaster • Viability of suppliers in the market to supply product(s) in the event of other manufacturer failure.	
Rating Scale	Highly Positive	Is expected to mitigate a high risk to the security of supply
	Moderately Positive	Is expected to mitigate a moderate risk to the security of supply
	Mildly Positive	Is expected to mitigate a minor risk to the security of supply
	No impact	Is expected to have no effect on a security of supply risk
	Mildly Negative	Is expected to increase a security of supply risk to a minor level
	Moderately Negative	Is expected to increase a security of supply risk to a moderate level
	Highly Negative	Is expected to increase a security of supply risk to a high level

Criterion	2. COMPARATIVE HEALTH GAIN	
Definition	*The extent to which the proposed intervention/product provides better health outcomes compared to the comparator.*	
Scope	Superior Quality of Life (QoL) measures compared to the comparator: • Better functionality • Less pain • Fewer days off work • Better clinical outcome measures compared to the comparator: • More rapid improvement of haemoglobin levels • Better/faster correction of platelet levels • Fewer days in hospital/ICU • Reduced incidence/severity of side effects	
Rating Scale	Highly Positive	A significant incremental health gain for some patients demonstrated by randomised controlled clinical trials.
	Moderately Positive	An incremental health gain for some patients demonstrated by evidence based clinical standards and/or epidemiology, observational or analytical data.
	Mildly Positive	A theoretical incremental health gain.
	No impact	No incremental health gain.

Criterion	3. COMPARATIVE SAFETY GAIN	
Definition	*The extent to which the proposed intervention/product reduces the patient's real or potential risk of harm compared to the comparator*	
Scope	For example: • reduced infection rates • reduced risk of immunomodulation • reduced need for medication/services that may cause harm e.g. transfusion	
Rating Scale	Highly Positive	A significant incremental safety benefit for some patients demonstrated by randomised controlled clinical trials.
	Moderately Positive	An incremental safety benefit for some patients demonstrated by evidence based clinical standards and/or epidemiology, observational or analytical data.
	Mildly Positive	A theoretical incremental safety benefit.
	No impact	No incremental safety benefit.

Criterion	4. COMPARATIVE COST-EFFECTIVENESS	
Definition	*The extent to which the proposed intervention/product is cost-effective, i.e. makes better use of available resources.*	
Scope	Preferred comparative cost effectiveness presented as cost-minimisation analysis (CMA) or cost utility analysis (CUA). Quality Adjusted Life Years (QALY) combines extension of life and quality of life in a single index that allows comparison across health interventions	
Rating Scale	Highly Positive	CMA demonstrates significant savings against comparator
	Positive	CMA demonstrates savings against comparator
	Neutral	CUA demonstrates a minimal cost per QALY
	Negative	CUA demonstrates a moderate cost per QALY
	Highly Negative	CUA demonstrates a significant cost per QALY

Criterion	5a. FINANCIAL IMPLICATIONS FOR THE NATIONAL BLOOD BUDGET	
Definition	*The extent to which the proposed intervention/product impacts on the total National Blood Budget over one or more years.*	
Scope	Presented as the projected annual net cost or saving to the National Blood Budget. Analysis to consider health care resources subsidised through the National Blood Supply. Must take into account any potential controls on access such as specific patient group(s) or clinical indication(s).	
Rating Scale	Highly Positive	Estimated savings of over $20 million p.a.
	Moderately Positive	Estimated savings of between $5 and $20 million p.a.
	Mildly Positive	Estimated savings of up to $5 million p.a.
	No impact	Cost neutral (+/- $1 million p.a.)
	Mildly Negative	Estimated additional net cost up to $5 million p.a.
	Moderately Negative	Estimated additional net cost between $5 and $20 million p.a.
	Highly Negative	Estimated additional net cost over $20 million p.a.

Criterion	5b. FINANCIAL IMPLICATIONS FOR GOVERNMENT HEALTH BUDGETS	
Definition	*The extent to which the proposed intervention/product impacts on the total National Health Budget.*	
Scope	Presented as the projected annual net cost or saving to the health sector. Analysis to include health care resources funded through all government health budgets in Australia, including health insurance subsidies.	
Rating Scale	Highly Positive	Estimated savings of over $20 million p.a.
	Moderately Positive	Estimated savings of between $5 and $20 million p.a.
	Mildly Positive	Estimated savings of up to $5 million p.a.
	No impact	Cost neutral (+/- $1 million p.a.)
	Mildly Negative	Estimated additional net cost up to $5 million p.a.
	Moderately Negative	Estimated additional net cost between $5 and $20 million p.a.
	Highly Negative	Estimated additional net cost over $20 million p.a.

Criterion	6a. SELF-SUFFICIENCY – RELIANCE ON DOMESTIC PRODUCTION	
Definition	*The extent to which the proposed intervention/product impacts our reliance on products manufactured in Australia from Australian plasma.*	
Scope	Reliance or impact on donations collected by Lifeblood from Australia's voluntary and non-remunerated blood and plasma donors.	
Rating Scale	Highly Positive	Total replacement of an imported product with a locally produced product
	Moderately Positive	Replacement of an imported product with >50% of a locally produced product
	Mildly Positive	Replacement of an imported product with up to 10% of a locally produced product
	No impact	No impact
	Mildly Negative	Replacement of a locally produced product with up to 10% of an imported product
	Moderately Negative	Replacement of a locally produced product with >50% of an imported product
	Highly Negative	Total replacement of a locally produced product with an imported product

Criterion	6b. SELF-SUFFICIENCY – EFFICIENCY OF DOMESTIC PRODUCTION	
Definition	*The extent to which the proposed intervention/product maximises the use of domestically collected blood and plasma.*	
Scope	Examples include: • Use of by-products • Improvement in yield • Extraction of different proteins • Frees up domestically collected products for other uses	
Rating Scale	Highly Positive	Increases the utilisation of domestically collected blood and plasma by >5%
	Moderately Positive	Increases the utilisation of domestically collected blood and plasma by between 3% and 5%
	Mildly Positive	Increases the utilisation of domestically collected blood and plasma by up to 2%
	No impact	Does not change the use of domestically collected blood and plasma
	Mildly Negative	Decreases the utilisation of domestically collected blood and plasma by up to 2%
	Moderately Negative	Decreases the utilisation of domestically collected blood and plasma by between 3% and 5%
	Highly Negative	Decreases the utilisation of domestically collected blood and plasma by >5%

Criterion	7. BLOOD DONATIONS	
Definition	*The extent to which the proposed intervention/product impacts our current reliance on voluntary, non-remunerated donations.*	
Scope	Encompasses products from both domestic and international sources.	
Rating Scale	Highly Positive	Increases volume of product coming from voluntary, non-remunerated donations to a high level
	Moderatel y Positive	Increases volume of product coming from voluntary, non-remunerated donations to a moderate level
	Mildly Positive	Increases volume of product coming from voluntary, non-remunerated donations to a minor level
	No impact	No impact on volume of product coming from voluntary, non-remunerated donations
	Mildly Negative	Increases volume of product coming from paid donations to a minor level
	Moderatel y Negative	Increases volume of product coming from paid donations to a moderate level
	Highly Negative	Increases volume of product coming from paid donations to a high level

Criterion	**8. ACCESSIBILITY AND UTILITY**	
Definition	*The extent to which the proposed intervention/product improves or addresses barriers in a range of clinical settings for: • Patients access to treatment: and/or • Ease in health providers delivering treatment.*	
Scope	Factors include: • Can be used in rural/remote areas • Can be delivered by a wider range of appropriately skilled workers • Capacity to respond rapidly to changing circumstances and needs • More accessible treatment regime for patients • Easier/more acceptable treatment regime for patients	
Rating Scale	Highly Positive	Provides a high level of accessibility and/or utility
	Moderately Positive	Provides a moderate level of accessibility and/or utility
	Mildly Positive	Provides a minor level of accessibility and/or utility
	No impact	No impact on accessibility and utility or impact on accessibility (utility) offsets impact on utility (accessibility)
	Mildly Negative	Provides mildly reduced accessibility and/or utility
	Moderately Negative	Provides moderately reduced accessibility and/or utility
	Highly Negative	Provides highly reduced accessibility and/or utility

Criterion	**9. FEASIBILITY**	
Definition	*The extent to which the proposed intervention/product is sustainable, practical and workable in terms of existing infrastructure and resource availability*	
Scope	*For example, equipment and staff Includes consideration of relevant procurement and other implementation issues*	
Rating Scale	High	Proposal easily sustainable as only requires a very minor level of investment in infrastructure changes and/or additional equipment and/or staff training.
	Moderate	Proposal sustainable but will require a moderate level of investment in infrastructure changes and/or additional equipment and/or staff training.
	Low	Proposal not sustainable as requires a significant investment in infrastructure changes and/or additional equipment and/or staff training, which is unlikely to be forthcoming without additional funds.

Criterion	10. CLINICAL NEED	
Definition	*The extent to which there is evidence of expressed need in the community by key patient groups, clinicians and other key stakeholders of the proposed intervention/product.*	
Scope	Evidence includes: • Advice from clinical advisory groups and/or consumers including impact statements. • Reliable studies providing evidence of unmet need	
Rating Scale	Highly Positive	Expressed need from many different stakeholder groups
	Moderatel y Positive	Expressed need from a few stakeholder groups
	Mildly Positive	Expressed need from one stakeholder group
	No evidence	No evidence of an expressed need

Criterion	11. INTERNATIONAL PRACTICE	
Definition	*The extent to which the proposed intervention/product has been implemented successfully in countries with similar health systems/policies and is accepted practice.*	
Scope	• Should be based on unequivocal evidence • Examples of countries with similar health systems/policies are Canada, NZ, Netherlands, UK, and Scandinavia • Direct evidence includes peer reviewed publications • Indirect evidence includes seminar/symposia presentations • Evidence can be based on a different brand of the product, however must be same type of product with same clinical indications	
Rating Scale	Highly Positive	Mandated by a regulatory authority or accepted practice in the majority of similar countries with continuation supported
	Moderately Positive	Mandated by a regulatory authority or accepted practice in a few similar countries with continuation supported
	Mildly Positive	Mandated by a regulatory authority or accepted practice in one similar country with continuation supported
	Neutral	Product is subject of debate internationally or no information available
	Mildly Negative	Product has been unsuccessfully implemented in one similar country
	Moderately Negative	Product has been unsuccessfully implemented in a few similar countries
	Highly Negative	Practice has been ceased in at least one similar country.