

SCHEDULE 4 MULTI-CRITERIA ANALYSIS (MCA) FRAMEWORK

TWO-CYCLE DECISION-MAKING PROCESS

The NBA has applied the process outlined in Schedule 4 of the National Blood Agreement to a two-cycle decision-making process (refer **Figure 1**). It is intended that the MCA Framework be the primary tool used to facilitate JBC's consideration of Schedule 4 proposals within this two-cycle decision-making process.

Cycle 1 Evaluation

To assist JBC's consideration of whether further evaluation, information or advice is required, the NBA, in consultation with other relevant advisors, undertakes a high-level evaluation of the proposal against the multi-criteria. This high-level evaluation relies on the information contained in the proposal, other desk-top research and information held by the NBA and other information gathered from relevant stakeholders. The main objective of this first cycle is to identify for the JBC whether there is sufficient evidence in which the NBA has adequate confidence for JBC to make a decision or recommendation. If further evidence and analysis is required against one or more of the criteria for a decision to be made, then this becomes a Cycle 2 evaluation.

Cycle 2 Evaluation

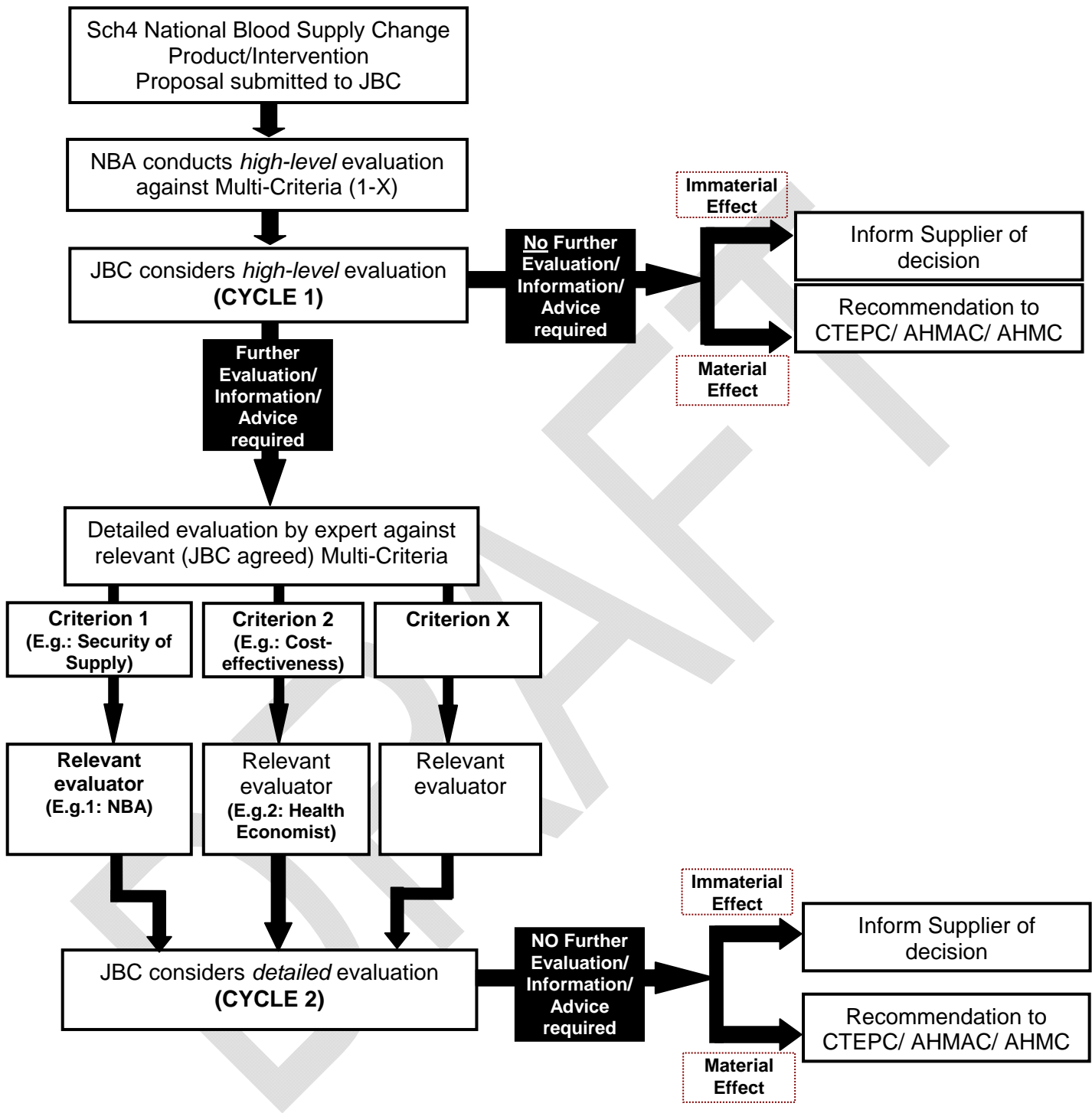
If JBC determines at Cycle 1 that one or more criteria requires detailed evaluation, then it will provide guidance regarding the nature and scope of the evaluation and the advisor(s)/entity(s) best suited to provide it. The NBA then coordinates the detailed evaluation of the relevant criteria by the relevant advisor(s)/entity(s) and provides a detailed evaluation report to JBC for consideration.

Other Considerations

When a decision is reached about a change to products or services funded under the national blood supply, the option (if any options are available) adopted for implementation will be as decided by the Ministerial Council, or by the JBC, or by the NBA. In conjunction with the MCA evaluation, the NBA assesses the commercial and procurement considerations related to the proposal, and provides advice for the consideration of JBC/AHMC. For example, NBA advice may cover:

- Existing NBA tendering or contract arrangements
- Strategies and planning for future procurements
- Market analysis (e.g. availability and price of other similar products in the market, patent or other issues relating to the market position of particular suppliers, etc)
- Practicality and possible strategy for implementation of particular Schedule 4 outcomes
- Procurement, contract or implementation risk and opportunity assessment

Figure 1: Schedule 4 two-cycle decision-making process



CRITERIA IN THE MCA FRAMEWORK

The MCA compares the proposed product/intervention against the best alternative treatment (the comparator).

In some cases MCA consideration may be based on a scenario of particular conditions or restrictions implemented through best practice or clinical governance mechanisms (e.g. clinical guidelines, authorisation processes, data collections) and/or through supply mechanisms (e.g. eligibility criteria under NBA supply contracts).

It should be noted that the criteria are not weighted. Research undertaken by the NBA uncovered a similar MCA approach to health technology decision-making in Canada. Canada chose not to weight the criteria because it yielded no improvement in predictive capacity. This was thought to suggest that raters implicitly weight each item in assigning their overall judgement. Furthermore, different factors might be more or less important in different situations.

Key:

P – Primary National Blood Agreement Objective

S – Secondary National Blood Agreement Objective

Criterion	1. SECURITY OF SUPPLY (P)	
Definition	<p><i>The extent to which the proposed intervention/product effectively mitigates an existing or emerging risk to the security of supply in terms of:</i></p> <ul style="list-style-type: none"> • <i>meeting the annual supply plan; and/or</i> • <i>promptly responding to unexpected demand increases or supply shortfalls.</i> 	
Scope	<p>The risks/opportunities include:</p> <ul style="list-style-type: none"> • 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 <u>high</u> risk to the security of supply
	Moderately Positive	Is expected to mitigate a <u>moderate</u> risk to the security of supply
	Mildly Positive	Is expected to mitigate a <u>minor</u> 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 <u>minor</u> level
	Moderately Negative	Is expected to increase a security of supply risk to a <u>moderate</u> level
	Highly Negative	Is expected to increase a security of supply risk to a <u>high</u> level

Criterion	2. COMPARATIVE HEALTH GAIN	
Definition	<i>The extent to which the proposed intervention/product provides better health outcomes compared to the comparator.</i>	
Scope	<p>Superior QoL measures compared to the comparator:</p> <ul style="list-style-type: none"> • better functionality • Less pain • Fewer days off work <p>Better clinical outcome measures compared to the comparator:</p> <ul style="list-style-type: none"> • 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 <u>significant</u> incremental health gain for some patients demonstrated by randomised controlled clinical trials and/or evidence based clinical standards and/or epidemiology, observational or analytical data.
	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 (P)	
Definition	<i>The extent to which the proposed intervention/product reduces the patient's real or potential risk of harm compared to the comparator</i>	
Scope	<p>For example:</p> <ul style="list-style-type: none"> • reduced infection rates • reduced risk of immunomodulation • reduced need for medication/services that may cause harm e.g. Transfusion 	
Rating Scale	Highly Positive	A <u>significant</u> incremental safety benefit for some patients demonstrated by randomised controlled clinical trials and/or evidence based clinical standards and/or epidemiology, observational or analytical data.
	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 (S)	
Definition	<i>The extent to which the proposed intervention/product is cost-effective, i.e. makes better use of available resources.</i>	
Scope	<p>Presented as cost-minimisation analysis or incremental cost-effectiveness ratios (including incremental cost-utility ratios).</p> <p>Includes a consideration of comparative costs, including the full spectrum of cost offsets.</p> <p>LYG – Life Year Gained QALY – Quality Adjusted Life Year CEA – Cost Effectiveness Analysis</p>	
Rating Scale	Highly Positive	CEA demonstrates net savings per LYG/QALY of >\$140k (significantly lower than typical range)
	Moderately Positive	CEA demonstrates net savings per LYG/QALY of between \$70k and \$140k (moderately lower than typical range)
	Mildly Positive	CEA demonstrates an incremental cost per LYG/QALY of between \$0 and \$70k (slightly lower than typical range)
	On par with current practice	CEA demonstrates an incremental cost per LYG/QALY of between \$70k and \$80k (within the typical range)
	Mildly Negative	CEA demonstrates an incremental cost per LYG/QALY of between \$80k and \$160k (slightly higher than typical range)
	Moderately Negative	CEA demonstrates an incremental cost per LYG/QALY of between \$160k and \$320k (moderately higher than typical range)
	Highly Negative	CEA demonstrates an incremental cost per LYG/QALY of over \$320k (significantly higher than typical range)

Criterion	5a. FINANCIAL IMPLICATIONS FOR THE NATIONAL <u>BLOOD</u> BUDGET (P)	
Definition	<i>The extent to which the proposed intervention/product impacts on the total National <u>Blood</u> Budget.</i>	
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 pa
	Moderately Positive	Estimated savings of between \$5 and \$20 million pa
	Mildly Positive	Estimated savings of up to \$5 million pa
	No impact	Cost neutral (+/- \$1 million pa)
	Mildly Negative	Estimated additional net cost up to \$5 million pa
	Moderately Negative	Estimated additional net cost between \$5 and \$20 million pa
	Highly Negative	Estimated additional net cost over \$20 million pa

Criterion	5b. FINANCIAL IMPLICATIONS FOR GOVERNMENT <u>HEALTH</u> BUDGETS (P)	
Definition	<i>The extent to which the proposed intervention/product impacts on the total National <u>Health</u> Budget.</i>	
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 pa
	Moderately Positive	Estimated savings of between \$5 and \$20 million pa
	Mildly Positive	Estimated savings of up to \$5 million pa
	No impact	Cost neutral (+/- \$1 million pa)
	Mildly Negative	Estimated additional net cost up to \$5 million pa
	Moderately Negative	Estimated additional net cost between \$5 and \$20 million pa
	Highly Negative	Estimated additional net cost over \$20 million pa

Criterion	6a. SELF-SUFFICIENCY – RELIANCE ON DOMESTIC PRODUCTION (S)	
Definition	<i>The extent to which the proposed intervention/product impacts our reliance on products manufactured in Australia from Australian plasma.</i>	
Scope		
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 (S)	
Definition	<i>The extent to which the proposed intervention/product maximises the use of domestically collected blood and plasma.</i>	
Scope	<p>Examples include:</p> <ul style="list-style-type: none"> • 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. DONATIONS (S)	
Definition	<i>The extent to which the proposed intervention/product impacts our current reliance on voluntary, non-remunerated donations.</i>	
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 <u>high</u> level
	Moderately Positive	Increases volume of product coming from voluntary, non-remunerated donations to a <u>moderate</u> level
	Mildly Positive	Increases volume of product coming from voluntary, non-remunerated donations to a <u>minor</u> 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 <u>minor</u> level
	Moderately Negative	Increases volume of product coming from paid donations to a <u>moderate</u> level
	Highly Negative	Increases volume of product coming from paid donations to a <u>high</u> level

Criterion	8. ACCESSIBILITY AND UTILITY (S)	
Definition	<i>The extent to which the proposed intervention/product improves or addresses barriers in a range of clinical settings for:</i> <ul style="list-style-type: none"> • <i>Patients access to treatment: and/or</i> • <i>Ease in health providers delivering treatment.</i> 	
Scope	Factors include: <ul style="list-style-type: none"> • 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 <u>high</u> level of accessibility and/or utility
	Moderately Positive	Provides a <u>moderate</u> level of accessibility and/or utility
	Mildly Positive	Provides a <u>minor</u> 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 <u>mildly reduced</u> accessibility and/or utility
	Moderately Negative	Provides <u>moderately reduced</u> accessibility and/or utility
	Highly Negative	Provides <u>highly reduced</u> accessibility and/or utility

Criterion	9. FEASIBILITY	
Definition	<i>The extent to which the proposed intervention/product is sustainable, practical and workable in terms of existing infrastructure and resource availability</i>	
Scope	<i>For example, equipment and staff Includes consideration of relevant procurement and other implementation issues</i>	
Rating Scale	High	Proposal easily sustainable as only requires a very <u>minor</u> level of investment in infrastructure changes and/or additional equipment and/or staff training.
	Moderate	Proposal sustainable but will require a <u>moderate</u> level of investment in infrastructure changes and/or additional equipment and/or staff training.
	Low	Proposal not sustainable as requires a <u>significant</u> 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	<i>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.</i>	
Scope	Evidence includes: <ul style="list-style-type: none"> • Advice from clinical advisory groups • Reliable studies providing evidence of unmet need 	
Rating Scale	Highly Positive	Expressed need from many different stakeholder groups
	Moderately Positive	Expressed need from a few stakeholder groups
	Mildly Positive	Expressed need from 1 stakeholder group
	No evidence	No evidence of an expressed need

Criterion	11. INTERNATIONAL PRACTICE	
Definition	<i>The extent to which the proposed intervention/product has been implemented successfully in countries with similar health systems/policies and is accepted practice.</i>	
Scope	<ul style="list-style-type: none"> • 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 <u>majority</u> of similar countries with continuation supported
	Moderately Positive	Mandated by a regulatory authority or accepted practice in a <u>few</u> similar countries with continuation supported
	Mildly Positive	Mandated by a regulatory authority or accepted practice in <u>one</u> similar country with continuation supported
	Neutral	Product is subject of debate internationally or no information available
	Mildly Negative	Product has been unsuccessfully implemented in <u>one</u> similar country
	Moderately Negative	Product has been unsuccessfully implemented in a <u>few</u> similar countries
	Highly Negative	Practice has been ceased in at least <u>one</u> similar country.