

SCHEDULE 4 –PROCESS FOR INITIATION, EVALUATION AND IMPLEMENTATION OF NATIONAL BLOOD SUPPLY CHANGE PROPOSALS

Objective

The objective of the process described in this Schedule is to provide appropriate evidence based evaluation and advice to Governments to support decisions about changes to products or services funded under the national blood supply.

Scope

The process set out in this Schedule applies to national blood supply change proposals as defined in this Agreement.

Where any change requires Therapeutic Goods Administration (TGA) approval, such approval must be obtained prior to the change being proposed and considered through the process set out in this Schedule.

This process does not apply to changes within the Australian blood sector which do not have any implications for the national blood supply.

Initiation of proposals

The initiation of a proposal (including those resulting from changes to mandatory TGA requirements) may come from a range of sources, including suppliers, TGA, other bodies with responsibilities in relation to safety and quality, the NBA, the Jurisdictional Blood Committee, or users of products or services.

Proposals from suppliers will need to be made in writing to the NBA, in its role as secretariat for the Jurisdictional Blood Committee. In putting forward a proposal, and throughout the process of consideration and evaluation, the supplier will need to provide information required by the NBA, Jurisdictional Blood Committee or other body undertaking the process.

All proposals initiated by suppliers or the NBA will be submitted by the NBA to the Jurisdictional Blood Committee. The NBA may, if it considers it appropriate, also submit to the Jurisdictional Blood Committee additional information or advice on the present or future production, supply, cost or other implications of the proposal, or on options for implementation of the proposal.

Consideration of proposals

All proposals will be considered initially by the Jurisdictional Blood Committee. The Jurisdictional Blood Committee will consider whether evidence based evaluation, or further information or advice of any other sort, is required in relation to the proposal. If so, the Jurisdictional Blood Committee will consider the nature and scope of the required

evaluation, information or advice, and the entity best suited to provide the evaluation, information or advice.

The Jurisdictional Blood Committee may request any of the following in relation to a proposal:

- (a) evidence based evaluation by MSAC on the safety, clinical effectiveness or cost effectiveness of the proposal, as determined by the Jurisdictional Blood Committee;
- (b) in relation to a proposal resulting from changes mandated by the TGA – evaluation, information or advice from the TGA, MSAC, the NBA or any other relevant body or person to confirm whether the change is necessary for the health care of identifiable groups of patients, whether there is any reasonable scope for limiting indications within those patient groups, and whether any reasonable alternative for the proposal is available;
- (c) information or advice from the NBA in relation to the production, supply or cost implications of the proposal, including costing based on established standardised costing approaches such as reference pricing, cost-plus or cost-effectiveness;
- (d) information or advice from the NBA or any other relevant person or body in relation to options for implementation of the proposal; and
- (e) any other evidence based evaluation, information or advice from any relevant person or body in relation to the proposal.

The terms of reference for any request for evaluation, information or advice will be as decided by the Jurisdictional Blood Committee. Entities to whom requests are made will not make a recommendation as to whether the proposal should be accepted and public subsidy extended to the proposal, unless specifically requested to do so by the Jurisdictional Blood Committee in the terms of reference.

The Jurisdictional Blood Committee may decide that no further evaluation, information or advice is required in relation to a proposal – for example, because:

- (a) the proposal does not have a material effect on clinical care and outcomes, or have a material effect on production, supply or cost under the national blood supply;
- (b) the proposal is outside the scope of the national blood supply; or
- (c) the Jurisdictional Blood Committee decides to rely on existing information.

Resolution of proposals

When the Jurisdictional Blood Committee considers that it has received sufficient evaluation, information and advice in relation to a proposal to enable it to do so, it will:

- (a) submit the proposal to the Ministerial Council for decision, accompanied by such information, advice and recommendations the Jurisdictional Blood Committee considers appropriate; or
- (b) where the Jurisdictional Blood Committee considers consideration of the proposal by the Ministerial Council is not warranted, for example because the proposal does not have a material effect on clinical care and outcomes, or have a material effect on production, supply or cost under the national blood supply:

- (i) decide that the proposal should be funded under the national blood supply, in which case it may also decide the option (if any) to be adopted for implementation; or
- (ii) decide that the proposal should not be funded under the national blood supply.

If a proposal is submitted by the Jurisdictional Blood Committee to the Ministerial Council for decision, the Ministerial Council may:

- (a) decide that the proposal should be funded under the national blood supply, in which case it may also decide the option (if any) to be adopted for implementation;
- (b) decide that the proposal should not be funded under the national blood supply; or
- (c) remit the proposal to the Jurisdictional Blood Committee for further information or advise the Ministerial Council considers appropriate.

Implementation of proposals

When it is decided that a proposal is to be funded under the national blood supply, the NBA will conduct contract and price variation negotiations with suppliers to implement the proposal, within the framework of the relevant supply contracts.

The option (if any options are available) adopted for implementation will be as decided by the Ministerial Council, or if not decided by the Ministerial Council, as decided by the Jurisdictional Blood Committee, or if not decided by the Jurisdictional Blood Committee, as decided by the NBA.

The price change associated with the implementation of the proposal will be reflected by the NBA as appropriate in the annual production and supply plans and budgets, and the annual national product price list, or reviews of these, developed by the NBA under Schedule 2 of this Agreement.