

NATIONAL BLOOD AGREEMENT

AN AGREEMENT made the _____ day of _____,
between:

The COMMONWEALTH OF AUSTRALIA ('the Commonwealth'); and

The STATE OF NEW SOUTH WALES; and
The STATE OF VICTORIA; and
The STATE OF QUEENSLAND; and
The STATE OF WESTERN AUSTRALIA; and
The STATE OF SOUTH AUSTRALIA; and
The STATE OF TASMANIA; and
The NORTHERN TERRITORY OF AUSTRALIA; and
The AUSTRALIAN CAPITAL TERRITORY
(collectively called 'the States and Territories')

PURPOSE -

The Commonwealth and the States and Territories agree that there is a need to implement a coordinated national approach to policy setting, governance and management for the Australian blood sector. To ensure the highest quality, effectiveness and efficiency for the Australian blood sector, they further agree that the national approach should have the following key features:

- (a) national agreement on the objectives of Governments for the Australian blood sector;
- (b) a primary policy setting and governance role for Commonwealth, State and Territory health Ministers, supported by a Jurisdictional Blood Committee of senior officials;
- (c) a National Blood Authority, to manage the national blood supply;
- (d) joint funding of the national blood supply by the Commonwealth and the States and Territories; and
- (e) a nationally agreed framework for the management of safety and quality issues within the Australian blood sector.

To further these purposes the Parties have entered this Agreement as a policy and administrative agreement which is not intended to give rise to any legal or justiciable obligation whatsoever upon any of the Parties, either as between them or as between a Party and any other person.

THE PARTIES AGREE AS FOLLOWS -

**PART 1 – OBJECTIVES OF GOVERNMENTS FOR THE AUSTRALIAN
BLOOD SECTOR**

1. The primary policy objectives for the Australian blood sector are:
 - (a) to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and
 - (b) to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

2. In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:
 - (a) to meet international obligations and standards;
 - (b) to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma;
 - (c) to promote national self-sufficiency;
 - (d) to provide products to patients free of charge and based on clinical need and appropriate clinical practice;
 - (e) to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards;
 - (f) to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sector;
 - (g) to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector;
 - (h) to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs;
 - (i) to ensure public support and confidence in the Australian blood sector; and
 - (j) to work towards optimal access to blood products and blood related products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction.

PART 2 – THE MINISTERIAL COUNCIL, THE STANDING COMMITTEE AND THE JURISDICTIONAL BLOOD COMMITTEE

The Ministerial Council

3. The Ministerial Council referred to in this Agreement will be the Australian Health Ministers' Conference, unless the Parties determine by agreement between them that another Ministerial Council will have responsibility for this Agreement.
4. The Ministerial Council will be responsible for:
 - (a) the general oversight of the Australian blood sector;
 - (b) the determination of national policy in relation to the Australian blood sector;
 - (c) the oversight of coordination, cooperation and information exchange between bodies with safety and quality or national supply roles within the Australian blood sector, to ensure that safety and quality and national supply issues are addressed by relevant bodies in a timely, efficient and effective manner;
 - (d) the oversight of the implementation of this Agreement; and
 - (e) other specific roles allocated to the Ministerial Council in this Agreement.
5. In relation to the Commonwealth legislation under which the NBA is established, the Ministerial Council will be responsible for:
 - (a) issuing policy principles to the NBA through the Commonwealth Minister in accordance with the legislation, in relation to the performance of the NBA's functions;
 - (b) other decisions or matters under the legislation which, by express reference in the legislation to the Ministerial Council or to this Agreement, are the responsibility of the Ministerial Council;
 - (c) requesting and receiving information from the Commonwealth Minister concerning the Minister's general administration of the legislation;
 - (d) at the request of the Commonwealth Minister, or as the Ministerial Council considers appropriate, making recommendations to the Commonwealth Minister on specific decisions or matters arising, or on the general principles to be applied, in the general administration of the legislation.
6. The responsibility of the Ministerial Council for determining national policy in relation to the Australian blood sector does not affect the proper policy roles of each of the Parties within their own jurisdictions, or the proper policy roles of other Ministerial councils in their own areas of responsibility.
7. The Ministerial Council may authorise the Standing Committee, the Jurisdictional Blood Committee or other appropriate persons or bodies to carry out particular responsibilities under this Agreement on its behalf.

8. For the purposes of this Agreement and the Commonwealth legislation referred to in clause 17, the Ministerial Council will conduct its affairs in accordance with the procedures set out in Schedule 5, or as otherwise determined by the Ministerial Council.

The Standing Committee

9. The Standing Committee referred to in this Agreement will be the Australian Health Ministers' Advisory Council, unless the Parties agree between them that another standing committee of senior officials should be the Standing Committee for the purposes of this Agreement.
10. The Standing Committee will be responsible for:
 - (a) establishing the Jurisdictional Blood Committee in accordance with this Agreement; and
 - (b) supporting the Ministerial Council in carrying out its responsibilities under this Agreement, in any manner required by the Ministerial Council.

The Jurisdictional Blood Committee

11. The Standing Committee will establish the Jurisdictional Blood Committee in accordance with this Agreement.
12. The Jurisdictional Blood Committee will:
 - (a) be comprised of senior officials representing all the Parties;
 - (b) be established as a sub-committee of the Standing Committee; and
 - (c) report annually and on an *ad hoc* basis to the Standing Committee.
13. In carrying out its responsibilities under this Agreement, the Jurisdictional Blood Committee will be responsible to the Ministerial Council, and will carry out its responsibilities in accordance with any policies, guidelines, instructions or procedures issued to it by the Ministerial Council.
14. The Jurisdictional Blood Committee will be:
 - (a) the committee of senior officials with specific responsibility to support the Ministerial Council in carrying out its responsibilities under this Agreement, including through:
 - (i) the provision of advice to the Ministerial Council, or the coordination of advice to the Ministerial Council from other sources;
 - (ii) the development of issues for consideration by the Ministerial Council;
 - (iii) the consideration and settling of less significant issues within the responsibility of the Ministerial Council, or arising in the implementation of Ministerial Council decisions, as authorised by the Ministerial Council;

- (iv) carrying out particular responsibilities of the Ministerial Council if authorised by the Ministerial Council to do so; and
 - (b) responsible for the other specific roles allocated to the Jurisdictional Blood Committee in this Agreement.
- 15. Subject to Clause 13, the Jurisdictional Blood Committee will otherwise determine its own procedures for carrying out its responsibilities under this Agreement. The Jurisdictional Blood Committee will notify the Standing Committee and the Ministerial Council of such procedures once determined. Decisions of the Jurisdictional Blood Committee which have material financial implications for a Party under this Agreement, or which have a material effect on clinical care and outcomes in a Party's jurisdiction, or which have material implications which would restrict the supply or alter the range of blood products, blood related products or blood related services to a Party under this Agreement, must be decided at a meeting attended by that Party and must be agreed to by that Party. Any change to the procedures in this paragraph requires the unanimous agreement of the Parties.
- 16. Secretariat support for the Jurisdictional Blood Committee will be provided by the NBA or such other body as is determined by the Ministerial Council, within the resources allocated for this purpose by the Ministerial Council.

PART 3 – ADMINISTRATIVE ARRANGEMENTS FOR THE NATIONAL BLOOD SUPPLY

Establishment of National Blood Authority by Commonwealth legislation

- 17. The Commonwealth will use best endeavours to have enacted by the Parliament of the Commonwealth the legislation required to establish the NBA, to set out the powers, functions and administrative arrangements for the NBA, and to deal with other matters relating to the NBA which require legislation, in accordance with this Agreement and the draft Bill approved by the Parties, the main features of which are set out in Schedule 1. If there are any amendments to the terms of the draft Bill introduced during the passage of the legislation which depart in a material respect from the main features of the legislation set out in Schedule 1 the Commonwealth will consult with and obtain the approval of the other Parties to any such amendments.
- 18. The Commonwealth will use best endeavours to ensure that the Commonwealth legislation is amended in accordance with policy decisions made by the Parties through the Ministerial Council. The Commonwealth will not initiate or support any legislative amendment which departs in a material respect from the features of the Commonwealth legislation set out in Schedule 1 without the policy approval of the other Parties. The Commonwealth will consult with and obtain the approval of the other Parties to the draft text of amending legislation referred to in this clause.

19. The Commonwealth may initiate legislative amendments to the Commonwealth legislation which do not materially affect the features of the Commonwealth legislation set out in Schedule 1, to give effect to general Commonwealth administrative changes or consequential legislative changes. The Commonwealth will use best endeavours to consult with and obtain the approval of the other Parties to the draft text of amending legislation referred to in this clause.
20. The Commonwealth agrees to notify the Parties in the event that a disallowance motion is moved in relation to any disallowable instrument made under the Commonwealth legislation that establishes the NBA.
21. The relevant Commonwealth Minister will be responsible for the administration and oversight of the Commonwealth legislation, including the high level oversight of the NBA, in accordance with normal principles of responsible government and administrative law applying to the Commonwealth executive, and the policy direction of the Ministerial Council.

Commencement of national blood supply arrangements

22. Unless otherwise agreed by the Parties, the national blood supply arrangements established in accordance with this Agreement will commence on 1 July 2003 or on a later date decided by the Ministerial Council.

National blood supply roles of Ministerial Council

23. The specific roles of the Ministerial Council in relation to the national blood supply are:
 - (a) approving national supply and production planning and budgeting proposals from the NBA, in accordance with Schedule 2;
 - (b) approving funding for national blood supply change proposals following evidence-based evaluation in accordance with clause 28 and Schedule 4;
 - (c) approving specific contingency or risk management strategies for the national blood supply; and
 - (d) to oversee the NBA's management of the national blood supply.
- 23A. (1) The Ministerial Council may determine arrangements in relation to the overseas provision of blood.
 - (2) In particular, but without limiting the matters that can be covered by arrangements determined under this paragraph, the arrangements may specify:
 - (a) the roles of the Ministerial Council, Jurisdictional Blood Committee, NBA and the States and Territories in relation to the overseas provision of blood; and
 - (b) funding of the overseas provision of blood, by parties to this Agreement or by other persons.

(3) Where arrangements determined under this paragraph are inconsistent with the terms of this Agreement, the arrangements prevail over the terms of this Agreement.

(4) In this paragraph, *overseas provision of blood* means: the supply and use of blood products, blood related products and blood related services that are part of the national blood supply which are supplied either:

- (a) in Australia for use outside Australia; and
- (b) outside Australia.

National blood supply roles of Jurisdictional Blood Committee

24. The specific roles of the Jurisdictional Blood Committee in relation to the national blood supply are:

- (a) if the Jurisdictional Blood Committee considers it appropriate to do so, to refer national blood supply change proposals for evidence-based evaluation in accordance with clause 28 and Schedule 4;
- (b) to participate in the process for development of NBA national supply and production planning and budgeting documents in accordance with Schedule 2;
- (c) to consider advice from the NBA, and to consider and advise the NBA of the joint jurisdictional position on matters relating to national blood supply issues;
- (d) to oversee the NBA's role in relation to contracts with bodies involved in the collection, production and distribution of products for the purposes of the national blood supply; and
- (e) to support the Ministerial Council in the oversight of the NBA's management of the national blood supply.

National blood supply roles of National Blood Authority

25. The specific roles of the NBA in relation to the national blood supply, which must be exercised in accordance with the Commonwealth legislation including any policy principles issued to the NBA by the Ministerial Council through the Commonwealth Minister in accordance with that legislation, are:

- (a) to liaise with and continuously gather information from State and Territory health authorities and other persons or bodies involved in the use of blood products or blood related products in relation to the demand for those products;
- (b) in consultation with each Party, and for the approval of the Ministerial Council or the Jurisdictional Blood Committee, to undertake annual supply and production planning and budgeting in accordance with the process set out in Schedule 2;
- (c) to use best endeavours to manage the national blood supply to provide a sufficient level of supply to meet the demand in all States and Territories

and to ensure that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction;

- (d) to negotiate, enter into, vary, administer and enforce funding and supply contracts with bodies involved in the collection, production and distribution of products for the purposes of the national blood supply (but in doing so, not to act directly as a supplier of blood products, blood related products or blood related services);
- (e) to administer payments to suppliers under funding and supply contracts;
- (f) based on its annual supply and production planning and budgeting, and on the funding and supply contracts with suppliers, to develop the national price list for products for the purpose of the joint funding arrangements for the national blood supply established under Part 5 and Schedule 3;
- (g) to refer national blood supply change proposals to the Jurisdictional Blood Committee for consideration for evidence-based evaluation in accordance with clause 28 and Schedule 4;
- (h) to administer provisions of the legislation establishing the NBA and other applicable legislation relevant to the administration or enforcement of funding and supply contracts;
- (i) to establish and manage contingency and risk mitigation measures in relation to the national blood supply, including specific strategies developed in consultation with the Jurisdictional Blood Committee and approved by the Ministerial Council;
- (j) to report annually, and on an *ad hoc* basis in relation to significant new developments, to the Ministerial Council and the Commonwealth Minister;
- (k) to provide information and advice to the Jurisdictional Blood Committee, and through the Jurisdictional Blood Committee to the Ministerial Council;
- (l) to liaise with, obtain information and advice from, and provide information and advice to, Commonwealth, State or Territory governments or government agencies, relevant non-government persons or bodies, and relevant international governments or other bodies, on matters relevant to the national blood supply;
- (m) to monitor the national and international environment in which the Australian blood sector operates for new technological, clinical, risk or other developments that may impact on the national blood supply;
- (n) under the direction of the Ministerial Council and the Jurisdictional Blood Committee, to facilitate and fund appropriate research, policy development or other action in relation to new developments by relevant government or non-government persons or bodies; and
- (o) to undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply.

National blood supply roles of States and Territories

26. The specific roles of the States and Territories in relation to the national blood supply are:
- (a) to foster the development and implementation of best practice planning and management systems for blood products and blood related products within each jurisdiction, to promote efficiency in use and minimisation of wastage;
 - (b) to ensure the provision of information and advice to the NBA, including through the Jurisdictional Blood Committee, in relation to demand for blood products or blood related products;
 - (c) to obtain information and advice from the NBA in relation to available levels and prices for the supply of particular products;
 - (d) to undertake best practice planning and management of the supply and use of blood products and blood related products within the State or Territory health system; and
 - (e) without affecting the application of the financial arrangement for the joint funding of the national blood supply by the Parties through the NBA set out in clause 30 and Schedule 3, as between the States and Territories, each State and Territory is responsible for bearing the State or Territory share of the blood and blood product costs incurred in the treatment of that State or Territory's residents anywhere in Australia (other than treatment of patients falling within the funding pool for high cost patients using haemostatic factors set out in Schedule 3), through arrangements established by agreement between States and Territories consistent with other arrangements for meeting the cost of cross border delivery of health services.

Role of State and Territory representatives on NBA Board

27. The Parties acknowledge that the purpose of the State and Territory representatives on the NBA Board is to allow for representation of the collective interests of all States and Territories having due regard to the individual views of each State and Territory.

Process for evidence-based evaluation of new products and services

28. The Parties agree that decisions to be made under this Agreement about changes to products or services funded under the national blood supply should be supported by appropriate evidence based evaluation, information and advice, as determined by the Jurisdictional Blood Committee, in accordance with the process set out in Schedule 4.

Management of national blood supply emergencies

29. The Commonwealth Minister may issue policy principles to the NBA in relation to the performance of the NBA's functions in emergency situations which are not

covered by the normal planning and operational processes of the national blood supply, and which require immediate action to ensure the availability of blood products, blood related products and blood related services to persons who need them. The Commonwealth Minister will consult with other members of the Ministerial Council prior to or as soon as possible after issuing such policy principles.

PART 4 – FINANCIAL ARRANGEMENTS FOR THE NATIONAL BLOOD SUPPLY

30. The key principles agreed between the Parties for the joint funding of the national blood supply are:
- (a) national blood supply costs to be jointly funded by the Commonwealth and the States and Territories in agreed proportions;
 - (b) funding to be determined on a price-volume basis according to products supplied to each State and Territory;
 - (c) products to be priced on the basis of a single national price list, for the purposes of the joint funding of the national blood supply;
 - (d) the national price list to include a charge for capital costs and other extraordinary items as agreed by the Ministerial Council;
 - (e) joint funding of the operating costs of the NBA on the basis of a fixed Commonwealth-State/Territory funding ratio, with the funding proportion as between States and Territories to be determined on a population basis; and
 - (f) unforeseen financial liabilities arising within the national blood supply are to be considered on a case by case basis by the Ministerial Council.
31. To give effect to these principles, the detailed method for calculation of the Parties' funding commitments, and the specific process for the provision of funding, will be as set out in Schedule 3.

PART 5 – ADMINISTRATIVE ARRANGEMENTS FOR SAFETY AND QUALITY IN THE AUSTRALIAN BLOOD SECTOR

Cooperative nature of the national safety and quality framework

32. The Parties acknowledge that:
- (a) there is a broad spectrum of safety and quality issues within the Australian blood sector, which fall within the areas of responsibility of a range of government and non-government bodies having complementary roles; and
 - (b) ensuring that safety and quality issues are addressed in a timely, efficient and effective manner will require liaison, coordination, cooperation and appropriate information exchange between relevant bodies.

33. The Parties acknowledge that the Therapeutic Goods Administration has primary responsibility for the regulation of products and establishing production standards for the Australian blood sector, through the national statutory framework for the regulation of therapeutic goods in Australia.

Safety and quality roles of the Jurisdictional Blood Committee

34. The specific roles of the Jurisdictional Blood Committee in relation to safety and quality in the Australian blood sector are:
- (a) to seek appropriate evidence based advice from relevant bodies on the safety, quality, efficiency or cost effectiveness of existing or proposed new blood products, processes, services or interventions;
 - (b) to arrange for evidence-based guidelines to be prepared by relevant bodies to promote safe, efficient and effective collection, distribution, storage and use of blood and blood products;
 - (c) to monitor and facilitate coordination, integration, cooperation and information exchange between relevant bodies relating to matters under clause 34 (a) or 34 (b); and
 - (d) other monitoring, facilitation, coordination, referral, integration and information exchange activities as considered appropriate by the Jurisdictional Blood Committee.

Safety and quality roles of the NBA

35. The specific roles of the NBA in relation to safety and quality in the Australian blood sector, which must be exercised in accordance with the Commonwealth legislation including any policy principles issued to the NBA by the Ministerial Council through the Commonwealth Minister in accordance with that legislation, are to:
- (a) ensure that funding and supply contracts for the national blood supply include appropriate obligations on suppliers to meet safety and quality standards, and enforce those obligations;
 - (b) maintain a systematic approach to identifying new developments, and providing a clearinghouse and coordination function for information in relation to new developments;
 - (c) facilitate coordination, integration, cooperation and information exchange between the NBA and other bodies with a safety and quality role in the Australian blood sector, and between those other bodies;
 - (d) provide information and advice to the Jurisdictional Blood Committee, and through the Jurisdictional Blood Committee to the Ministerial Council;
 - (e) act on behalf of the Jurisdictional Blood Committee to purchase and/or organise activities under clauses 34 (a), (b) and (c); and
 - (f) facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector.

Development of specific safety and quality strategies by the Parties

36. The Parties agree to identify opportunities to develop and implement specific safety and quality strategies for the Australian blood sector, including in the following areas:
- (a) the development, implementation and review of evidence-based national clinical practice guidelines for blood products, blood related products and blood related services to ensure best practice in the management and use of such products and services;
 - (b) specific administrative systems to bring about quality improvements in the management and use of blood products, blood related products and blood related services within the public and private health systems;
 - (c) the promotion of best practice management and use of blood products, blood related products and blood related services by persons (including health professionals) and organisations involved in the management or use of such products and services in the health system;
 - (d) the development, implementation and review of appropriate indicators and means of measurement of best practice management and use of blood products, blood related products and blood related services; and
 - (e) the implementation of indicators and measures of best practice management and use of blood products, blood related products and blood related services referred to above into health system management and funding arrangements.

PART 6 – REVIEW OF ARRANGEMENTS ESTABLISHED BY THIS AGREEMENT

37. The Parties agree that arrangements established by this Agreement will be reviewed in a two-stage review process over a period of six years from the commencement of those arrangements:
- (a) a first review to be completed by the end of the third year of the operation of the arrangements (which is intended to be the year ending on 30 June 2006); and
 - (b) a second review within the fifth year of the arrangements (which is intended to be the year ending on 30 June 2008);
- or as otherwise determined by the Ministerial Council.
38. The Ministerial Council on the advice of the Jurisdictional Blood Committee will:
- (a) determine the terms of reference, process and administrative arrangements for the reviews;
 - (b) appoint an independent person or persons to conduct the reviews;
 - (c) consider the findings of the first review and decide upon any changes required to the arrangements established under this Agreement as a result of those findings; and
 - (d) consider the findings of the second review and decide upon the future of the arrangements established under this Agreement in light of those findings.

PART 7 – OPERATION AND INTERPRETATION OF AGREEMENT

Commencement

39. The operation of this Agreement commences as follows:
- (a) clause 17 - upon execution of this Agreement by the Commonwealth and all States and Territories; and
 - (b) all other clauses – upon passage of the Commonwealth legislation referred to in clause 17 through both houses of the Commonwealth Parliament.

Definitions

40. In this Agreement, unless a contrary intention is apparent:

‘Agreement’ means this document, including the schedules, as amended from time to time;

‘Australian blood sector’ means all aspects of the supply and use of blood products, blood related products and blood related services in Australia or from Australian sources, including but not limited to the national blood supply;

‘blood products’ means products used or intended for use for human therapeutic or diagnostic purposes which consist of human blood or components of human blood, or which are derived from human blood;

‘blood related products’ means products used or intended for use for human therapeutic or diagnostic purposes which are alternative or complementary to the use of blood products, except where the Parties agree that such products are not to be regarded as blood related products for the purposes of this Agreement;

‘blood related services’ means services, equipment or procedures, other than blood products or blood related products, which:

- (a) are used in the collection, supply or use of blood products;
 - (b) are alternatives to the use of blood products;
 - (c) reduce the need for blood products; or
 - (d) otherwise affect the demand or supply of blood products;
- except where the Parties agree that such services are not to be regarded as blood related services for the purposes of this Agreement;

‘Jurisdictional Blood Committee’ means the Jurisdictional Blood Committee of senior officials representing each of the Parties established in accordance with Part 2 of this Agreement;

‘MSAC’ means the Medical Services Advisory Committee;

‘Ministerial Council’ means the council of Ministers of the Parties referred to in Part 2 of this Agreement;

‘National Blood Authority’ or **‘NBA’** means the National Blood Authority established by Commonwealth legislation in accordance with this Agreement;

‘national blood supply’ means:

- (a) blood products which are derived from blood collected by voluntary, non-remunerated, homologous blood donation in Australia;
- (b) blood products, other than those referred to in paragraph (a), which are determined by the Ministerial Council to form part of the national blood supply for the purposes of this Agreement; and
- (c) blood related products and blood related services which are determined by the Ministerial Council to form part of the national blood supply for the purposes of this Agreement;

supplied through arrangements managed by the NBA and funded jointly by the Parties, (or as otherwise determined by the Ministerial Council in arrangements determined under paragraph 23A) in accordance with this Agreement;

‘national blood supply change proposal’ means a proposal, made in accordance with the procedures set out in Schedule 4, that any of the following should occur:

- (a) the addition of a new blood product, blood related product or blood related service to be funded through the national blood supply;
- (b) the removal of a blood product, blood related product or blood related service from funding through the national blood supply; or
- (c) a change in the means of collection, production or supply of a blood product, blood related product or blood related service;

‘Party’ means a jurisdiction which is a signatory to this Agreement;

‘safety and quality’, in relation to the Australian blood sector, means all matters relating to the safe, appropriate, effective or optimal supply and use of products and services forming part of that system;

‘Standing Committee’ means the standing committee of senior officials of the Parties referred to in Part 2 of this Agreement; and

‘supply’, in relation to blood products or blood related products, means all steps involved in the collection, processing, packaging, distribution and delivery of products up to the point at which they are first delivered to a hospital, health practitioner or other health service provider to be used for human therapeutic or diagnostic purposes or to be stored ready for such use.

Amendment

41. Where a Party considers that an amendment to this Agreement would be desirable, it may initiate consultations with the other Parties in relation to the amendment through the Ministerial Council or the Jurisdictional Blood Committee.
42. Any amendment to this Agreement will be made in writing and executed by all Parties, and will include the date on which the amendment will come into force.

Dispute resolution

43. Where a dispute arises under or in relation to this Agreement:
 - (a) the members of the Jurisdictional Blood Committee or the Ministerial Council will negotiate to resolve the dispute; and
 - (b) if the negotiations fail, the Ministerial Council will refer the dispute to the Parties or their nominated representatives to seek a resolution.

Withdrawal and termination

44. A Party to this Agreement may withdraw from this Agreement, by giving no less than 12 months written notice of intention to withdraw to the other Parties. The withdrawal of a Party shall not release that Party from meeting its agreed funding commitments for the financial year in which the withdrawal takes effect unless this is otherwise agreed by all the Parties with due regard paid to the Parties investments and on-going liability. Following notification of a Party's intention to withdraw from this Agreement, the terms of the withdrawal in other respects will be agreed by the Ministerial Council, on a basis which aims to ensure continuity of supply to patients and fair attribution of costs of supply to all Parties including the withdrawing Party following the withdrawal.
45. Following notification of a Party's intention to withdraw from this Agreement, the remaining Parties will decide any necessary amendments to this Agreement, or how this Agreement is to be applied, in light of the withdrawal to ensure the continuing effectiveness of the arrangements established under this Agreement for the remaining Parties. These matters will be decided by the Ministerial Council, reconstituted as necessary for the purposes of this Agreement in light of the withdrawal of the Party.
46. A Party may withdraw from this Agreement immediately by written notice to the other Parties if the Commonwealth legislation establishing the NBA referred to in clause 17 departs in any material respect from the draft Bill approved by the Parties, the main features of which are set out in Schedule 1. Clause 44 will not apply to the withdrawal of a Party under this clause. Following notification of a Party's intention to withdraw from this Agreement under this clause, the terms of the withdrawal will be agreed by the Ministerial Council, on a basis which aims to ensure continuity of supply to patients and fair attribution of costs of supply to all Parties including the withdrawing Party following the withdrawal.

47. This Agreement may be terminated at any time in writing by agreement of all the Parties and under any conditions agreed by all the Parties.

Publication of the Agreement

48. The Parties agree that this Agreement is to be made publicly available by the Commonwealth by the following means:
- (i) by tabling in both Houses of the Commonwealth Parliament during the passage of the Commonwealth legislation to establish the NBA; and
 - (ii) by publication on relevant Commonwealth government websites.
49. Any future amendments to this Agreement made in accordance with clauses 41 and 42 are also to be made publicly available by the Commonwealth by publication on relevant Commonwealth Government websites.

SIGNED for and on behalf of the COMMONWEALTH OF AUSTRALIA by

.....
(Signature) (Date)
Senator the Hon Kay Patterson MP
Minister for Health and Ageing

SIGNED for and on behalf of the STATE OF NEW SOUTH WALES by

.....
(Signature) (Date)
The Hon Craig Knowles MP
Minister for Health

SIGNED for and on behalf of the STATE OF VICTORIA by

.....
(Signature) (Date)
The Hon Bronwyn Pike MP
Minister for Health

SIGNED for and on behalf of the STATE OF QUEENSLAND by

.....
(Signature) (Date)
The Hon Wendy Edmond MP
Minister for Health
Minister Assisting the Premier on Women's Policy

SIGNED for and on behalf of the STATE OF WESTERN AUSTRALIA by

.....
(Signature) (Date)
The Hon R C Kucera APM MLA
Minister for Health

SIGNED for and on behalf of the STATE OF SOUTH AUSTRALIA by

.....
(Signature) (Date)
The Hon Lea Stevens MP
Minister for Health
Minister Assisting the Premier in Social Inclusion

SIGNED for and on behalf of the STATE OF TASMANIA by

.....
(Signature) (Date)
The Hon David Llewellyn
Minister for Health and Human Services

SIGNED for and on behalf of the AUSTRALIAN CAPITAL TERRITORY by

.....
(Signature) *(Date)*
Mr Jon Stanhope MLA
Minister for Health and Community Care
Minister for Ageing
Minister for Disability Services

SIGNED for and on behalf of the NORTHERN TERRITORY OF AUSTRALIA by

.....
(Signature) *(Date)*
The Hon Jane Aagaard MLA
Minister for Health and Community Services

SCHEDULE 1 – MATTERS TO BE INCLUDED IN COMMONWEALTH LEGISLATION ESTABLISHING NBA

The Commonwealth will use its best endeavours to enact legislation that will:

- (a) establish a National Blood Authority as part of the executive Government of the Commonwealth and subject to the following Commonwealth corporate governance regimes:
 - i) the *Financial Management and Accountability Act 1997*;
 - ii) the *Public Service Act 1999*;
 - iii) the *Auditor-General Act 1997*;

- (b) establish a Board for the National Blood Authority comprising:
 - i) an independent chair;
 - ii) a Commonwealth representative;
 - iii) up to two State/Territory representatives, to represent the collective interests of the States and Territories;
 - iv) a public health expert with expertise in blood matters;
 - v) a community representative;
 - vi) a commercial/financial expert;

- (c) provide that all Board members will be nominated and selected by the Ministerial Council with the formal appointment for up to 4 years to be made by the Commonwealth Minister, and with jurisdictional representatives nominated by the relevant jurisdictions on a basis which will allow rotation of membership between the relevant jurisdictions;

- (d) provide for the appointment of a General Manager with responsibility for the day to day operations of the NBA, who is to be the head of the NBA for the purposes of the *Financial Management and Accountability Act* and the *Public Service Act*, and who is to take into account any recommendations of the Board in carrying out the functions of the NBA;

- (e) establish the functions of the National Blood Authority to give effect to this Agreement;

- (f) establish the roles of the Ministerial Council in relation to the NBA to give effect to this Agreement;

- (g) enable the NBA to establish advisory committees to assist it in the performance of its functions; and

- (h) enable the NBA to access information from national blood supply suppliers and other relevant persons, and provide for appropriate confidentiality to apply to such information.

SCHEDULE 2 – NATIONAL BLOOD SUPPLY AND PRODUCTION PLANNING AND BUDGETING PROCESS

The process of national blood supply and production planning and budgeting will involve the following steps. The specific schedule and process for these steps will be developed by the NBA in consultation with the Parties, and will be approved by the Jurisdictional Blood Committee.

Step 1: Demand and supply information gathering

This will involve the NBA obtaining information from the Parties and from suppliers, as follows. To the extent necessary these processes may be conducted in parallel in an iterative way, to allow for the effect that supply information (eg quantity, price) may have on demand, and vice versa.

Gathering of demand information by the NBA

- The NBA gathers demand information from States and Territories (including in relation to demand within the private health system).
- States/Territories provide information based on best practice planning/management systems implemented in accordance with clause 26(a) of this Agreement.

The NBA may determine the best process for gathering information, which may be through a specific committee established by the NBA, through bilateral liaison with each Party, or through other means.

Gathering of production and supply information by the NBA

- The NBA gathers information on forecasts of donations and potential supply levels, including costs and prices within the contractual framework, from all relevant suppliers of products or services.

The NBA may determine the best process for gathering information, which may be through a specific committee established by the NBA, through bilateral liaison with each supplier, or through other means.

Step 2: Formulation of annual plans by the NBA

- Based on information gathered, the NBA formulates annual production and supply plans and budgets, and annual national product price lists.
- In doing so the NBA must seek to optimise adequacy, safety, security and affordability of supply, and to meet its obligation under clause 25(c) of this Agreement to use best endeavours to manage the national blood supply to provide a sufficient level of supply to meet the demand in all States and Territories.

- The NBA consults with the States and Territories, and if necessary with suppliers, in relation to draft annual production and supply plans and budgets, and annual national product price lists.

Step 3: Approval of annual plans by the Jurisdictional Blood Committee and the Ministerial Council

- The NBA submits formulated annual production and supply plans and budgets, and annual national product price lists to the Jurisdictional Blood Committee for review. The Jurisdictional Blood Committee may request the NBA to revise any aspect of the documents, and the NBA must comply with such a request.
- Once satisfied, the Jurisdictional Blood Committee submits the annual production and supply plans and budgets, and annual national product price lists to the Ministerial Council for approval.

Implementation/review of annual plans

- Once approved by the Ministerial Council, the NBA implements the annual production and supply plans and budgets and annual national product price lists in contracts with suppliers, and in NBA funding arrangements under Schedule 3 of this Agreement.
- The NBA maintains continuous monitoring of demand and supply against the approved annual production and supply plans and budgets, and reports quarterly to the Jurisdictional Blood Committee.
- The NBA reports to the Jurisdictional Blood Committee on ad hoc basis on major departures of supply, demand or price from the approved annual production and supply plans and budgets, and annual national product price lists.
- Subject to approval by the Jurisdictional Blood Committee and Ministerial Council of changes to the approved annual production and supply plans and budgets, and annual national product price lists, these documents operate for the purposes of the national blood supply arrangements under this Agreement for the duration of each year.

Transitional arrangements

The Parties may agree arrangements for the transitional implementation of the processes described in this Schedule following the commencement of the NBA's operations.

SCHEDULE 3 – JOINT FINANCING ARRANGEMENTS FOR NATIONAL BLOOD SUPPLY

Payment ratio for product usage on price-volume basis

General principle

The Parties will pay for the supply of national blood supply products according to the volume of products supplied to each State and Territory, on the basis of a national product price list as specified in Schedule 2 and this Schedule.

Except in relation to products supplied to patients falling within the funding pool for high cost patients using haemostatic factors, as described below, the cost of products supplied will be shared between the Commonwealth and the relevant State or Territory in accordance with a payment ratio determined in accordance with this Schedule.

Transitional payment ratios for 2003-04 and 2004-05

For 2003-04 and 2004-05, the payment ratios for each of the States and Territories will be determined on a transitional basis as follows:

- (a) the transitional ratios for the financial years 2003-04 and 2004-05 will be agreed by the Parties prior to 1 July 2003;
- (b) subject to (c) below, the transitional ratios will be agreed on the basis of the transition from the actual ratio of State or Territory spending to Commonwealth spending in 2002-03, to the ratio 63% Commonwealth 37% State or Territory in 2005-06, with an even 1/3 of the transition occurring in each financial year;
- (c) the transitional ratios of each State and Territory determined under (b) will be determined so that the overall total Commonwealth to total State and Territory ratio for 2003-04 and 2004-05 is 63% Commonwealth to 37% States and Territories; and
- (d) for the purposes of determining the transitional ratios, the Commonwealth, State or Territory spending in a financial year will be the total spending by that entity on blood products, blood-related products, and blood related services covered by the National Blood Supply under this Agreement in that period, excluding, without limitation, costs of capital, costs of the National Reserve of Plasma Products, the NBA's operating costs, and products or services not covered by the National Blood Supply under this Agreement

Payment ratios for 2005-06 and subsequent years

For 2005-06 and subsequent years, the payment ratio will be 63% for the Commonwealth and 37% for each State and Territory.

Funding pool for high cost patients using haemostatic factors

Purpose

The purpose of the funding pool is to reduce the financial risk to States and Territories of the on-going costs of treating specific high cost patients with a limited range of products (haemostatic factors), in accordance with clinical guidelines developed by an advisory Clinical Reference Group to the NBA.

Funding

In accordance with the agreed funding ratio for 2005-06 and subsequent years, the Commonwealth will contribute 63% of the treatment costs for these patients. The States and Territories will pay their share of the pool (37%) on a total population per capita basis.

Claims from the Pool

States and Territories will be able to claim from the pool the treatment costs of the specified patients that exceed a national threshold applying to a particular financial year. The size of the pool will be determined by the level of the threshold and the estimated treatment costs of patients above that threshold. The threshold for the financial year 2003-04 is \$125,000, and the threshold for later years will be determined by the Ministerial Council on advice from the NBA through the Jurisdictional Blood Committee.

Any excess funds in the pool at the end of a financial year will be carried forward to the next year. Any unmet claims will be taken into consideration in setting the threshold and the size of the pool for the next financial year.

Review of Pool Size and Threshold

The NBA will monitor the operation of the pool in consultation with the Clinical Reference Group and the Jurisdictional Blood Committee. The Jurisdictional Blood Committee will make a recommendation to the Ministerial Council each year on the size of the pool and the threshold for the next financial year, having regard to the operation of the pool to date.

National product price list

The national product price list for the joint funding of the national blood supply by the Parties will be developed by the NBA and approved by the Ministerial Council in accordance with Schedule 2.

The national product price list will be based on the prices for national blood supply products or services under the NBA's contractual arrangements with suppliers, but may include allowance for additional items, as follows.

The NBA's contracting arrangements with national blood supply suppliers will include arrangements for the financing of future capital costs. Where a charge on capital is not included in the supply price of a product, the Ministerial Council may approve the inclusion of a proportional capital charge on the product price within the national product price list.

The national product price list will also include provision for a charge to meet other extraordinary items as determined by the Ministerial Council.

NBA operating costs

The Commonwealth and the States and Territories will share NBA operating costs and extraordinary items agreed by the Ministerial Council on the ratio 63% Commonwealth, 37% total payment by States and Territories. The ratio between States and Territories to meet the total 37% payment will be determined on a per capita basis using the latest ABS population data.

NBA operating costs will be as agreed by the Ministerial Council annually through the planning process described in Schedule 2, including adjustments made during the course of a year in accordance with Schedule 2.

NBA operating costs agreed by the Ministerial Council may include allowance for unforeseen liabilities incurred by the Commonwealth through the NBA which are not funded through the National Managed Fund, or other contingency or risk mitigation measures approved by the Ministerial Council and funded through the national product price list.

National Reserve of Plasma Products

The Commonwealth and the States and Territories will share the product and management costs of the national reserve of plasma products on the ratio 63% Commonwealth, 37% total payment by States and Territories. The ratio between States and Territories to meet the total 37% payment will be determined on a per capita basis using the latest ABS population data.

The budget for the national reserve product and management costs will be as agreed by the Ministerial Council annually through the planning process described in Schedule 2, including adjustments made during the course of a year in accordance with Schedule 2.

Extraordinary items and liabilities

The basis of funding extraordinary items will be decided by the Ministerial Council on a case by case basis. Options for funding include a charge on the national product price list, or an allowance within NBA operating costs, as referred to above.

Liabilities of the Parties arising prior to the commencement of the national blood supply arrangements established in accordance with this agreement will not be funded in accordance with the arrangements under this agreement.

All liabilities incurred by the NBA arising from or in connection with the national blood supply arrangements established in accordance with this agreement will be jointly funded by the Parties on the ratio 63% Commonwealth, 37% total payment by States and Territories. The basis for apportionment of the State and Territory component of such liabilities will be determined by the Ministerial Council.

The Parties agree that this Agreement does not affect the operation of the National Managed Fund established by a Memorandum between the Parties and the Australian Red Cross Blood Service.

Payment process

Funds paid by the Parties will be held by the NBA in an imprest account established as a special account under the Commonwealth's financial management framework. Funds in the imprest account will be used by the NBA to meet contractual payments to suppliers, to meet expenses of carrying out its other functions, and to meet its operating expenses. Any interest earned on funds held in the imprest account will be credited to that account.

States and Territories will make payments, and the Commonwealth will credit amounts, into the NBA imprest account quarterly in advance, based on forecast levels of product demand in the relevant NBA production and supply plan developed under Schedule 2. Payments will include a quarterly amount to meet NBA operating costs and other extraordinary expenses, and the national reserve product and management costs, calculated as equal quarterly instalments of the annual amount payable by each State or Territory.

Payments will be adjusted for any shortfall or surplus payment from the previous quarter, based on actual volumes supplied to the relevant State or Territory in that quarter.

Payments in the final quarter of each financial year will be adjusted for each Party for the amount payable into, and the claims made against, the funding pool for high cost patients using haemostatic factors.

Payments and credits will be due by no later than 14 days before the end of the preceding quarter. Late payment will attract an interest charge calculated at the relevant Commonwealth, State or Territory Treasury bond rate.

For the purposes of this Schedule, a quarter will be taken to be a three month period ending on 31 January, 30 April, 31 July and 31 October.

Consequences of non-payment

Where a Party fails to make a payment or credit to the NBA by the due date, the NBA will initially seek to resolve the matter by direct negotiation with that Party.

If the NBA has been unable to resolve the matter within 14 days of the due date, it may refer the matter to the Jurisdictional Blood Committee for resolution.

If in the opinion of the Jurisdictional Blood Committee the matter is a serious case of non-payment or non-credit involving large amounts or multiple Parties, or if the Jurisdictional Blood Committee is unable to resolve the matter within 2 months of the due date, the Jurisdictional Blood Committee must refer the matter to the Ministerial Council for resolution.

No Party will be required to make any additional payment or credit to the NBA above the level properly payable by it under this Schedule as a result of another Party failing to make payment or credit in accordance with this Schedule.

In no circumstances will the NBA cease supply of blood products to a Party as a consequence of failure to make a payment or credit under this Agreement.

Transitional arrangements

The Parties may agree arrangements for the transitional implementation of the processes described in this Schedule following the commencement of the NBA's operations.

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.

SCHEDULE 5 –MINISTERIAL COUNCIL DECISION MAKING PROCEDURES

Proceedings of the Ministerial Council

In calling a meeting of the Ministerial Council, the secretariat endeavours to establish a mutually agreeable date, but in the absence of such agreement, agrees a date with the Chair, the Commonwealth and the host jurisdiction and other members are requested to accommodate this date where possible. Members may send a proxy to meetings if they are unable to attend themselves but are not required to do so. Extraordinary meetings of the Ministerial Council on specific issues may be convened between general meetings if a majority of Ministers agree.

The Chair will set the agenda following nominations received from Ministers and consideration of a draft agenda by meetings of the Standing Committee and the Jurisdictional Blood Committee preceding the Ministerial Council.

Decisions of the Ministerial Council

Decisions are reached on the basis of consensus and there is provision for members to abstain from, or disagree with, decisions made by the majority of members. Dissentions and abstentions on specific items are noted in the record of decisions.

Decisions which have direct and material financial implications for a Party under this Agreement, or which have a direct and material effect on clinical care and outcomes in a Party's jurisdiction, or which have direct and material implications which would restrict the supply or alter the range of blood products, blood related products or blood related services to a Party under this Agreement, must be decided at a meeting attended by that Party and must be agreed to by that Party. Any change to these procedures requires the unanimous agreement of the Parties.

Resolutions of the Ministerial Council

Only the resolutions and decisions of the Council shall be formally recorded. Dissentions or abstentions by Ministers on particular items are to be noted as part of the decision on that item. Ministers may also reserve their position on particular items pending further discussions or development of policy.

Proceedings out of session

The Ministerial Council may deal with items by correspondence between meetings. A member proposing such action should contact the current Chair, who, if he or she agrees, will refer the matter to the Secretariat for necessary action.