

# HAEMOVIGILANCE ADVISORY COMMITTEE

---

## Committee Terms of Reference

---

Approved by NBA General Manager

June 2016

# Contents

<b>Introduction .....</b>	<b>3</b>
<b>Rationale .....</b>	<b>3</b>
<b>Scope .....</b>	<b>3</b>
<b>Outcomes and objectives .....</b>	<b>4</b>
<b>Relationship to other NBA committees .....</b>	<b>4</b>
<b>Membership .....</b>	<b>6</b>
Chair.....	6
Members.....	6
Expert advisors and working groups .....	7
Observers.....	7
Quorum of the HAC .....	7
Remuneration and allowances .....	7
Undertaking/conflict of interest.....	7
<b>Working arrangements .....</b>	<b>7</b>
Role of chair.....	7
Role of members .....	8
Role of NBA.....	8
Role of observers .....	9
Role of expert advisors and working groups .....	9
Meetings .....	9
Out of session activities.....	9
Conduct.....	10
Ad-hoc sub-committees .....	10
<b>Attachment 1: How the NBA runs the National Haemovigilance Program .....</b>	<b>11</b>
Collection and submission of haemovigilance data .....	11
National haemovigilance reports .....	11
National haemovigilance reporting process.....	12
Exceptional reports and reporting processes.....	12
Publication processes .....	12

# Introduction

The Initial Australian Haemovigilance Report 2008 recommended the establishment of an enduring national haemovigilance program in Australia guided by a Haemovigilance Advisory Committee (HAC). This document details the governance arrangements and Terms of Reference (TOR) for the HAC. These governance arrangements and TOR are approved by the NBA's General Manager on behalf of the Jurisdictional Blood Committee. Operational costs for HAC are funded by all Australian governments. The HAC will report to the NBA's General Manager.

## Rationale

Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety. A well-functioning haemovigilance system should be able to collect, review, analyse and report adverse event information related to both recipients and donors.

The Haemovigilance Advisory Committee is established to enable and promote the capture, analysis and reporting of serious transfusion-related adverse events occurring in Australian public and private health service organisations.

## Scope

The scope of the Haemovigilance Program should include all blood and blood related products, including fresh blood, plasma derived and recombinant products that are supplied and distributed by the National Blood Authority under the National Blood Agreement. The scope of the HAC can also extend to donor haemovigilance.

The HAC has been established to:

- review analysis of the available haemovigilance data
- provide recommendations for further analysis, research and best practice initiatives based on evidence where possible
- provide expert advice and guidance on:
  - required data sets for haemovigilance
  - data standards and definitions
  - strategies that can be implemented to address haemovigilance issues
  - directions and priorities for the program
  - evaluating processes and developing recommendations for the national haemovigilance reports
  - other advice in relation to the NBA's haemovigilance activities
- support participation in the National Haemovigilance Program and implementation of the Strategic Framework for the National Haemovigilance Program (Version 1, September 2014) at <http://www.blood.gov.au/haemovigilance-reporting>
- provide input to the National Safety and Quality Health Service Standard 7 (NSQHS Standard 7) and integrate the NSQHS Standard 7 with the HAC program
- manage HAC sub-committees
- network with other NBA committees to share information
- support appropriate use and stewardship of blood and blood products

# Outcomes and objectives

The objective of the HAC is to provide advice to the NBA on ways to:

- provide recommendations on activities that need to be addressed to implement the National Haemovigilance Program
- provide direction and support for the ongoing National Haemovigilance Program
- improve the quality, comparability and imputability of Australian haemovigilance data
- support the requirements and ongoing programs for:
  - the Strategic Framework for the National Haemovigilance Program
  - Patient Blood Management appropriate use
  - the Statement on National Stewardship Expectations for the Supply of Blood and Blood Products
  - the NSQHS Standard 7

The purpose of the HAC is to provide high level advice and assistance to the NBA General Manager and other staff to assist in achieving the following goals:

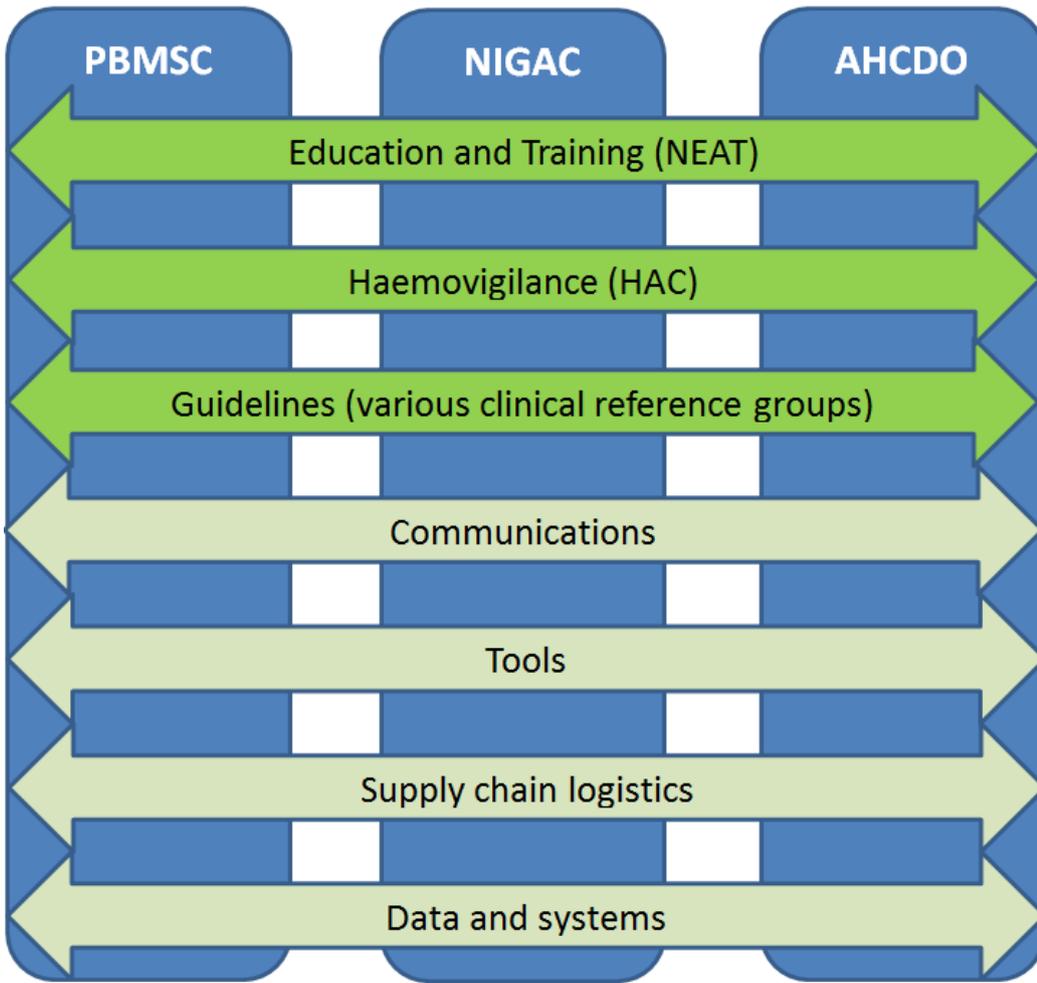
- The Strategic Framework for the National Haemovigilance Program is implemented at national, state and local levels
- Successful strategies are deployed to assist health care professionals to monitor and improve processes relating to adverse events
- Haemovigilance and other best practice initiatives lead to genuine changes in clinical practice and improvements in patient outcomes

## Relationship to other NBA committees

The HAC will communicate, through the NBA secretariat and cross membership to other NBA committees to manage any common areas of interest. The NBA has three key product related committees. These are:

- Patient Blood Management Steering Committee (PBMSC) which predominantly focus on the appropriate use of fresh products (and avoidance of unnecessary exposure).
- National Immunoglobulin Governance Advisory Committee (NIGAC) which focus on appropriate use of immunoglobulin products.
- Australian Haemophilia Centre Directors' Organisation (AHCDO) which focus on appropriate use of clotting factors.

The NBA manages many of the functions that are common to all three committees without the need for additional input. These are depicted in light green below. There are some circumstances however, when specific committees are required (eg when there is a need for specialist input or when there is a need national consistency). Committees for these purposes are depicted in dark green below.



# Membership

## Chair

The Chair will be appointed by the NBA General Manager. The General Manager may nominate an alternative person to be a temporary Chair where the Chair is unable to attend a meeting or is otherwise temporarily unable to perform the role of Chair.

The position of Chair will be required to undergo a review process every two years, or at the discretion of the NBA General Manager (GM). The position will be filled by an existing committee member chosen by the NBA GM. Where possible, the Chair will continue as a member on the committee to maintain continuity.

## Members

Members are appointed by the NBA GM after the consultation with the HAC Chair. The HAC is a group comprising members with expertise and knowledge in the health sector, blood management and quality and safety. This group will enable a focussed approach to considering haemovigilance activities. In addition to the Chair the membership of the HAC comprises the following expertise and representation, noting that one person may represent the views of multiple organisations.

Participation in national haemovigilance and activities relevant to the work of the HAC is voluntary. Serious adverse event information, plus some agreed additional descriptive data, is captured and validated by local institutions and reported to State and Territory Department of Health quality units. These units will provide aggregated, coded and de-identified information via periodic reports to the NBA.

The HAC will consist of approximately 15 members plus Chair. Membership may consist of representation from a number of key organisations and stakeholder groups as follows.

- Australian Association of Pathology Practices (AAPP)
- Australia and New Zealand Society for Blood Transfusion (ANZSBT)
- Australian Private Hospitals Association (APHA)
- Australian Red Cross Blood Service (Blood Service)
- Jurisdictional Blood Committee (JBC) members or proxies
- Therapeutic Goods Administration (TGA)
- Transfusion Nurses Group
- Selected Clinical Speciality Colleges

Selection of representatives will take into consideration a requisite number of specific skills and attributes.

- Analysis and research expertise in statistical/healthcare epidemiology
- In-depth knowledge of blood sector
- Understanding of data to do analysis
- Clinical expertise in the blood sector
- Working knowledge of both the private & public health systems
- Working understanding of transfusion science/laboratory
- Expertise in healthcare safety and/or quality
- Jurisdictional representative

Not all stakeholders will be formally represented on the Committee at any one time and the Committee will be responsible for developing a strategy to ensure adequate consultation with unrepresented key stakeholders.

Membership will be required to undergo a rolling review process with a 'half-spill' each review, every two years, or otherwise at the discretion of the NBA GM. There will be a maximum term of membership not exceeding eight years.

Members are responsible for obtaining all approvals necessary from their current employer or organisation as appropriate to accept appointment as a member and undertake the role of member.

## Expert advisors and working groups

The HAC will be kept to minimum size to ensure that it is focused and manageable. Therefore, additional expert advice will be sought on an ad hoc basis from experts on specific issues as required and cleared by the Chair. There also may be times where small working groups are required to deliver specific programs to the HAC and this could consist of HAC members and/or expert advisors.

## Observers

Additional observers may be invited to attend from time to time. Observers are invited to participate in discussions but do not have voting rights on decisions.

## Quorum of the HAC

At least 8 members must be present before the HAC can conduct valid business.

## Remuneration and allowances

Remuneration and allowances for members of the HAC will be in accordance with the NBA's 'Domestic Travel Policy – 3<sup>rd</sup> Parties' and 'Remuneration of Non-NBA Staff Management Instruction or as approved by the NBA GM.

## Undertaking/conflict of interest

HAC members and observers will be required to complete undertakings and comply with the terms of those undertakings, in relation to conflicts of interest, confidentiality, document control and intellectual property. Members and observers will be required to declare any actual or potential, real or perceived Conflicts of Interest.

Relevant documents will be provided to members as part of their letter of offer.

## Working arrangements

The NBA provides the necessary support to allow the HAC to perform its functions. This includes secretariat support and other appropriate resources as requested by the Chair.

## Role of chair

The Chair's main role is to provide leadership to the HAC. The Chair will advocate consistency in key messages and ensure the HAC carries out its functions effectively and efficiently. Together with relevant NBA staff, the Chair will participate in the development of HAC agendas and ensure that HAC meetings are properly run. The Chair will also provide advice and guidance direct to the NBA GM or their delegate on issues as they arise outside of the HAC processes to ensure maintenance of momentum.

In undertaking the Chairperson's roles and responsibilities, the Chair should:

- ensure the HAC provides high level advice and assistance to the NBA

- foster coherence in advice provided to the NBA
- ensure the HAC has the necessary information to undertake its duties effectively
- undertake public relations activities in relation to HAC responsibilities if requested by the NBA GM
- work with the NBA to:
  - ensure the proper and efficient running HAC meetings,
  - ensure all necessary actions before and after meetings are completed, and
  - coordinate and manage out of session activities of the HAC.

## Role of members

It is the responsibility of each HAC member to contribute to the success of implementing the National Haemovigilance Program. Members of the HAC have been appointed based on their specific interests, individual knowledge and skills and ability to influence stakeholders in their area of expertise or peer group. Members will display their enthusiasm and determination to drive a consistent approach for national haemovigilance.

HAC members should:

- provide advice on strategies and initiatives that would influence the quality and uptake of haemovigilance practice
- participate in influencing the uptake of haemovigilance activities
- gather input on likely responses from their area of practice to suggested policy and/or initiatives and changes
- actively contribute to setting of the agenda for HAC meetings and give input or responses as agreed in meetings and as required out of session
- ensure that they have access to timely and accurate information, and are well prepared to consider the issues addressed at HAC meetings
- actively participate in the development of relevant materials to support any research required or to design haemovigilance activities
- monitor reports of progress on implementation of HAC activities
- express the views of the professional or consumer body they represent and in turn seek their endorsement for activities and initiatives.

## Role of NBA

The NBA GM is responsible for oversight of the HAC. For the purposes of day-to-day dealings with the HAC, the GM is represented by the Director responsible for the Data and Clinical Development program as notified by the GM to the Chair (subject to any specific powers under the *National Blood Authority Act (2003)* which require formal delegation).

The NBA will provide funding, project management, secretariat services and administrative support for the HAC. The NBA shall be responsible for:

- seeking relevant approvals and reporting
- establishing the governance framework and operating procedures
- managing contracts for any outsourced activities
- monitoring and managing project finances and resources to ensure they are sufficient
- booking venues and arranging travel, accommodation and meeting arrangements as required and where appropriate
- ensuring that an agenda is circulated, at least one week prior to the meeting, together with any supporting papers after approval from the Chair
- ensuring minutes of meetings are compiled and promptly provided to the Chair for approval
- circulating the minutes within two weeks of the meeting HAC members and observers, as appropriate, and

- following up on agreed action items from meetings
- ensuring regular review of the processes and documentation which underlie HAC activities in line with NBA and JBC requirements.

The NBA collates the national data for analysis and subsequent reporting. Regular national reports are printed and made publicly available.

The agreed process for how the NBA runs the National Haemovigilance Program as at **Attachment 1**

## Role of observers

HAC observers are invited to participate in discussions and provide their advice on the development and implementation of policy and drivers appropriate for national activities that support and encourage haemovigilance. The HAC will consider the strategic advice from the observers when considering the most appropriate design and implementation strategies for national haemovigilance.

## Role of expert advisors and working groups

Other influential clinical or educational stakeholders will be invited to contribute from time to time to the HAC in relation to policy changes, and design and implementation of haemovigilance program activities. Where clarification is required by the HAC, expert advisors will be asked to provide the HAC with advice to support their decisions around the priority activities.

## Meetings

The timing, agenda and mode of meetings will be determined by the NBA and the Chair, after any necessary consultation with members. Meetings will ordinarily be held at the NBA's premises in Canberra. It is intended that the HAC will meet in person at least 2 times per year. Meetings by teleconference of no more than two hours will be used when appropriate and expedient.

## Out of session activities

The HAC may, in accordance with a process determined by the Chair, undertake activities to give advice or assistance to the NBA out of session. Members may be called upon for ad-hoc advice via email between meetings. They will also be required to actively participate in the development of materials and provide input via the secure web-portal.

Contributions will be required on various documents including, but not limited to, statements of requirement for engaging consultants, education and training materials, meeting minutes and out-of-session papers.

Members may also be required to engage in forum style discussions. Members should not undertake out of session activities in their capacity as HAC members without the prior approval from the Chair and the NBA.

## Conduct

Members of HAC are expected to carry out their role in accordance with the highest ethical standards. A HAC member when undertaking HAC related functions should:

- act honestly, in good faith and in the best interests of the NBA
- use due care and diligence
- have regard to the interests of all stakeholders of the NBA
- contribute to NBA activities in a co-operative, impartial and productive way
- be independent in judgement and actions and take all reasonable steps to be satisfied as to the soundness of advice provided by the HAC
- agree with the NBA and Chair on an appropriate response and approach to external stakeholder interest or enquiries relating to the HAC work plan
- not make improper use of information acquired as a HAC member, both during and after the term of appointment, and
- not engage in conduct likely to bring discredit upon the NBA.

## Ad-hoc sub-committees

Ad-hoc sub-committees may be developed from time to time. The sub-committees are managed by the HAC. The sub-committees contribute to the national haemovigilance activities such as data analysis, recommendations, case studies and audits and provide advice to the NBA and JBC.

One or more liaison officers may be selected by NBA in conjunction with the HAC to undertake specific pieces of data analysis or research or consultation, or development of a technical sub-committee to further the work of the committee. Liaison officers and sub-committees will report to the HAC.

# Attachment 1: How the NBA runs the National Haemovigilance Program

## Collection and submission of haemovigilance data

The NBA will request data from State and Territory Departments of Health through the JBC. Data can be submitted through the NBA data portal on [www.govdex.gov.au](http://www.govdex.gov.au) or through other agreed means. To support a national approach to haemovigilance, States and Territories have agreed to progressively align their reporting systems with the agreed dataset requirements to contribute to a comprehensive national dataset. It is recognised that this will require all users of labile blood products to:

- Participate in the provision and analysis of data
- Investigate and report adverse events in accordance with the national dataset

To improve the quality, comparability and imputability of data, all information provided by States and Territories for national reporting should be validated and de-identified by the jurisdiction before submission. The means of collection and submission of haemovigilance data may change with the outcome(s) of the national haemovigilance system scoping exercise.

It should be noted that the current voluntary reporting process may eventually be complemented by a legislated reporting process, perhaps through the Therapeutic Goods Administration (TGA) or a successor body. The Australian Health Ministers' Conference (AHMC) agreed to the regulatory framework for Human Cell and Tissue Therapies proposed to it in November 2006 by the TGA. The agreed definition for the Human Cell and Tissue (HCT) Framework covers "all articles containing or consisting of, or derived from, human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient". The proposed legislation is being developed so that products other than HCTs can be incorporated in the future if required. To reflect the legislation will include the concept of biologicals rather than HCTs. The current implementation of the biologicals framework excludes blood, blood components and blood products. It is proposed that adverse event reporting for biological products will rely on existing processes established within the TGA. If/when blood, blood components and blood products are included in this framework it will become a legislated requirement for sponsors to report certain adverse transfusion reactions. The NBA and HAC will maintain relations with the TGA to coordinate haemovigilance reporting in Australia.

## National haemovigilance reports

Aggregated haemovigilance data, supplied through State and Territory Departments of Health, will be analysed for national trends and other indicators. The scope of national haemovigilance reports will be to refer to data on voluntarily reported adverse transfusion events, adverse event capture and data systems and to state key observations and recommendations on the data. Reports will also refer to the national data in the context of previous national and international haemovigilance data. The function of national haemovigilance reports will be to identify the incidence and causes of voluntarily reported adverse transfusion events and make recommendations for national quality and safety investments that can lead to genuine improvements in patient safety outcomes in Australia. National haemovigilance reports are issued by the NBA after advice from the HAC and any endorsement that may be required from the JBC. It is desirable to publish national reports annually, but this is not anticipated until State and Territory Departments of Health have the opportunity to refine the haemovigilance data reporting processes. Following publication of a national report, the NBA General Manager will table HAC recommendations present in the report for discussion by the JBC and the development of actionable items as part of the JBC and HAC annual work program.

## National haemovigilance reporting process

All national haemovigilance data is held and managed by the NBA in a secure manner to prevent disaggregation and identification of patients, clinicians or facilities, and to meet relevant privacy requirements. Data provided by State and Territory Departments of Health is aggregated and analysed for national trends and other indicators. The initial national haemovigilance data analysis by the NBA will be presented for discussion to the HAC. It is the role of the HAC to advise on further data analysis and revision and to develop conclusions and national recommendations based on the resulting evidence. The HAC may also advise on stakeholder and sector consultation and dissemination of the conclusions and recommendations. It is the role of the NBA to draft, finalise and publish periodic national haemovigilance reports for public dissemination. Depending on the reporting intervals from States and Territories, an annual reporting period for national haemovigilance may represent the optimum interval to work towards. The report will be presented to the JBC prior to publication. The NBA will require the approval of the appropriate JBC representative for publication of any and all jurisdiction-specific data, conclusions or recommendations. The NBA will require JBC members to note the publication of all data, conclusions or recommendations that do not relate to their jurisdictions alone.

## Exceptional reports and reporting processes

State and Territory representatives, through the JBC, may exceptionally request haemovigilance reports that relate only to their jurisdiction. The NBA cannot guarantee the availability of, or depth of analysis contained within, such exceptional reports. In accordance with section 25(l) of the National Blood Agreement (2003) the NBA may author other reports, presentations, case studies, commentaries or research articles in relevant academic or professional body forums to further the goals of national haemovigilance in Australia. The HAC will provide advice to the NBA on the content of such publications and on the proposed publication route. The JBC is required to endorse the use of any jurisdiction specific content in reports, presentations, case studies, commentaries or research articles as a condition of their publication.

## Publication processes

The NBA is responsible for the publication process for national haemovigilance reports and other reports, presentations, case studies, commentaries or research articles in relevant academic or professional body forums. Publication processes will be managed in accordance with NBA policies and management instructions, which guide the construction of internal and external publications. They are developed to ensure that all publications are of a similar high standard and follow a consistent format, and outline the procedures for developing, drafting, approving, printing and releasing NBA publications. Other reports, presentations, case studies, commentaries or research articles in relevant academic or professional body forums will be published in line with that publisher's specifications. It is the role of the NBA to distribute national haemovigilance reports according to the NBA stakeholder engagement strategy. It is anticipated that the published reports will be made available to all identified primary stakeholders, who will be encouraged to comment on the scope of the report and its recommendations. The NBA will actively engage with the health, education and quality and safety sectors to disseminate national recommendations widely, effectively and efficiently and will seek written feedback from primary stakeholders on published national haemovigilance reports as part of the haemovigilance stakeholder engagement strategy.