



NATIONAL BLOOD AUTHORITY
AUSTRALIA

HAEMOVIGILANCE ADVISORY COMMITTEE

Terms of Reference

July 2019

Role

Purpose

The Haemovigilance Advisory Committee (HAC) is established by the National Blood Authority (NBA) Chief Executive under section 38 of the *National Blood Authority Act 2003* (the NBA Act) to provide advice and guidance to the National Blood Authority NBA in relation to the development and implementation of the *Strategic Framework for National Haemovigilance* (Strategic Framework) consistent with the NBA's responsibilities specified in:

1. Part 2, section 8(1)(f) of the NBA Act to 'carry out national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services';
2. Part 5, clause 35(c) of the *National Blood Agreement* to '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'; and
3. Part 5, clause 35(f) of the *National Blood Agreement* to 'facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector'.

The HAC may contribute to national haemovigilance activities including, but not limited to, data analysis, research, case studies and audits in order to identify opportunities for improvement and contribute to national reporting if required.

Background

Introduction

The transfusion of blood and blood products is a core part of healthcare service delivery to patients. While the use of blood and blood products can be lifesaving, there are also risks associated with the transfusion. Incidents can occur and some of these can have serious consequences to patients if not well managed.

The *National Safety and Quality Health Service Standards - Blood Management Standard* (2nd ed, 2017) (the Standard) requires health service organisations to report adverse events as follows:

- Action 7.7 The health service organisation uses processes for reporting transfusion-related adverse events, in accordance with national guidelines and criteria
- Action 7.8 The health service organisation participates in haemovigilance activities, in accordance with the national framework.

What is haemovigilance?

The Standard defines haemovigilance as:

a set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients, to their follow-up. It includes monitoring, reporting, investigating and analysing diverse events related to the donation, processing and transfusion of blood, as well as development and implementation of recommendations to prevent the occurrence or recurrence of adverse events'. (NSQHS 2017)

Scope

The scope of haemovigilance in Australia and the HAC includes all fresh blood products. Other blood products (e.g. plasma derived and recombinant products that are supplied and distributed by the NBA under the *National Blood Agreement*) are managed under separate projects. The scope of the HAC and haemovigilance can also extend to donor haemovigilance (data reporting only).

The Strategic Framework was endorsed by the Jurisdictional Blood Committee (in September 2014 and amended from time to time as per the NBA website). It defines the scope of national haemovigilance arrangements to emphasise activities that contribute to national standardisation. The HAC will provide guidance and advice to the NBA and in particular on the Strategic Framework and accompanying work plan for future haemovigilance activities.

Operations of the Committee

Chair

The Chair of HAC will be appointed at the discretion of the NBA Chief Executive. The NBA Chief Executive may nominate an alternative person to be a temporary Chair when the Chair is unable to attend a meeting or is otherwise unable to perform the role of Chair.

The position of Chair will usually undergo a review process every three years, or at the discretion of the NBA Chief Executive. Where possible, the former Chair will continue as a member of HAC to maintain continuity.

The Chair's main role is to provide leadership to the HAC. The Chair will promote and advocate consistency in key messages and ensure the HAC carries out its functions effectively and efficiently. The Chair will also provide advice and guidance direct to the NBA Chief Executive or their delegate on issues that might arise outside the HAC processes.

Members

HAC members are appointed by the NBA Chief Executive. The HAC is a group comprising members with expertise and knowledge in the health sector, blood management, quality and safety and consumer issues. This group will enable a focussed approach to considering haemovigilance activities.

The HAC will normally comprise up to 12 members including the Chair. Membership should consist of nominees from key stakeholders with balanced representation from different clinical disciplines, organisations, and jurisdictions. One person may represent the views of multiple stakeholders due to their membership of more than one organisation (for example, the Blood Service *and* a college/society). A membership list is at **Appendix A**.

Membership will undergo a rolling review process with a 'half-spill' usually every three years or otherwise at the discretion of the NBA Chief Executive. 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. Members who are a nominated representative of an organisation must identify a proxy to attend meetings in their absence.

NBA Support

The NBA Deputy Chief Executive or other delegate will be responsible for the day-to-day dealings with the HAC.

The NBA will provide funding, project management, secretariat services and administrative support for the HAC. The NBA will collate national data for analysis and subsequent reporting as appropriate and after consideration and advice by the HAC. Regular national reports will be made publicly available once data is sufficiently complete and subjected to appropriate quality assurance and advice. Subject to provision of data to the NBA, the NBA will endeavour to make the national reports available annually.

The secretariat will service and support the HAC and in particular, will:

- Support the Chair;
- Schedule meetings;
- Coordinate papers for meetings;
- Draft meeting minutes and action items;
- Monitor and report on actions from meetings; and
- Prepare formal correspondence on behalf of the Committee.

Meetings

The timing, agenda and mode of meetings will be determined by the NBA and the Chair, after any necessary consultation with members. Meetings of no more than two hours will usually be held via teleconference, dependent on the agenda. It is intended that the HAC will hold a minimum of two meetings annually with at least one being face-to-face.

At least five members must be present for meetings of the HAC before the HAC can conduct valid business.

Additional observers may be invited to attend HAC meetings from time to time.

Expert advisers and working groups

Additional expert advice will be sought on an ad hoc basis from experts on specific issues as required and cleared by the Chair. This could include, but is not limited to nominees from the Therapeutics Goods Administration, the Australian Commission on Safety and Quality in Health Care, and the Australian Institute of Health and Welfare.

There may be times when small working groups are required to deliver specific programs to the HAC. These working groups can consist of HAC members and/or expert advisors. The working groups may contribute to national haemovigilance activities including, but not limited to, data analysis, research, case studies and audits. The working groups will provide advice to the HAC and NBA as required.

Remuneration and allowances

HAC members are to be paid the remuneration and allowances as determined by the Remuneration Tribunal in accordance with the NBA Act and the *Remuneration Tribunal Act 1973*.

Undertaking/Conflict of Interest

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

HAC members must declare any conflicts of interest at the start of each meeting or before discussion of the relevant agenda item or topic. Details of any conflicts should be appropriately minuted.

Members will use a form of declaration notified by the NBA.

Conduct

Members of HAC hold a public office and accordingly are expected to carry out their role as members in accordance with the highest ethical standards. A HAC member should:

- a. act honestly and in good faith;
- b. use due care and diligence;
- c. only use their office for a proper purpose;
- d. not make improper use of information acquired as a HAC member, both during and after the term of appointment;
- e. be fair, honest and courteous in interactions with other members, NBA and stakeholders;
- f. contribute to NBA activities in a co-operative, impartial and productive way; and
- g. not engage in conduct likely to bring discredit upon the NBA or the Program.

A member must not express any opinion, make any commitment, or otherwise purport to represent or act on behalf of the NBA, unless specifically requested by the Chair or the NBA Chief Executive to do so.