ANZSBT Response to Australian Law Reform Commission Discussion Paper on the Review of Human Tissue Laws

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) is the professional society specifically representing medical practitioners, medical and research scientists and nurses in blood transfusion and patient blood management within Australia. Transfusion is a series of procedures beginning from collection of blood from suitably qualified donors, processing, transport and storage of blood components and administration to a patient under the care of health care professionals. The ANZSBT supports reform to streamline and unify regulation in the blood transfusion sector, but has concerns in legislative changes to leave future decisions, such as blood donor remuneration, at the discretion of regulators alone.

The National Blood Authority (NBA) has been listed as an organisation whose scope may need to be considered in this proposal. The NBA has an important role to play in the Australian blood sector, ensuring supply, managing demand data, horizon scanning and purchasing. The NBA has led internationally recognised guideline development for patient blood management and established the systems to manage demand for intravenous immunoglobulin. While the NBA does manage supply, it does not regulate use.

The NBA also has responsibility to "facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector." [National Blood Agreement, 35(f)] This includes management of haemovigilance processes. Haemovigilance is the system used to monitor, report and analyse adverse events relating to transfusion to monitor safety and enable improvement in blood products and transfusion practice. This model is different to pharmacovigilance in Australia, which is the responsibility of the regulator, the Therapeutic Goods Administration (TGA). It is entirely appropriate for the regulator to monitor and respond to issues relating to therapeutic goods, however medical procedures are beyond the scope of the TGA and a distinct national haemovigilance model can look at errors and recommend improvements within clinical practice, where most issues arise.

ANZSBT supports a national model of haemovigilance distinct from the TGA as is has the primary goal of improving the practice in health care rather than manufacturing facilities. Although established in 2003, the NBA has not yet developed a suitable national haemovigilance program. A national library of definitions, delayed reporting and compilation into a report do exist, however reports are driven by five different state systems (ACT, NT and Tasmania participate in the Victorian Serious Transfusion Incident Reporting program). The national arrangement is a collation of the efforts of jurisdictions. A single unified process would likely reduce effort and increase the likelihood of private hospital reporting since unlike state and territory healthcare systems, private hospital governance frequently have national procedures. While this has been an objective of the sector and the NBA, the current governance structures have not assisted in its development.

While the National Blood Agreement seeks equity, there are currently systemic differences in service provision dependent on jurisdiction. The Agreement allowed for continuation of services already provided in some jurisdictions which are not offered to all. For example, there is inconsistent availability of NBA funded (through Lifeblood) transfusion practitioners. Western Australia has had statewide antibody register rebuilt as this functionality was in place in 2003, while calls for a national antibody register have hit roadblocks for most of this time. ANZSBT supports nationally consistent approaches. Additional services to improve equity should be based on overcoming adverse determinants of health care and acknowledging specific genetic

and cultural needs of indigenous Australians and, in conjunction with New Zealand, people of South Pacific Islander backgrounds.

It is not clear from the discussion paper how NBA governance will change. ANZSBT would support a governance model for the NBA that does not require 100% agreement of all state and territories within the Jurisdictional Blood Committee, with a focus on providing the best outcomes for all Australians (see National Blood Agreement Clause 15).

ANZSBT agrees with the objectives outlined in proposal 5 and that their incorporation into legislation adds value to the interpretation by the regulator and those seeking to apply the legislation.

The emergence of new therapies (breast milk banks, faecal microbiota transplants, CAR-T and potentially allogeneic CAR-T cells) highlights the value of a wide definition for the scope of tissue covered. There is likely to be overlap and it is preferable that these be dealt with by regulation rather than leave gaps where legislation does not apply.

The Society agrees with proposal 14, to consistently legislate minimum requirements for consent prior to living donation. The extent to which donors can be informed will vary. Inclusion of blood donor consent within the scope of the regulator will enable consent requirements to be tailored in a risk-adapted way. It is noted that while donors generally donate with the expectation that their blood components will be transfused to people who need them, additional uses include use as testing reagents and research and for some uses commercial entities profit from using donated blood. The extent to which secondary use is allowed will need to be addressed. Samples taken for one purpose may be required for other uses. For example, blood donated for clinical transfusion may in very small proportion of cases will be needed to be used for reagents. More commonly blood taken for a clinical purpose may be used in routine quality control, or for research purposes.

Proposal 16 proposes a child 16 years of age or older be considered an adult for the purpose of blood donation. In the broad context of the legislation, blood donation could be taken to include the commonly accepted use of donating into a blood bank for therapeutic purposes, but also includes the collection of blood for research purposes. ANZSBT supports the extension of blood donation consent to 16 years, noting that any change from the current practice will need to be supported by evidence for safety. Setting a specific age on the donation and use of blood for scientific and research purposes does not align with current NHMRC Statement on Ethical Conduct in Human Research and it would be preferable for donation for research be incorporated and align with research governance.

The requirement for committee approval for adults without decision making capacity could significantly impair transfusion research (Question 28). Transfusion research covers many settings and questions. A key area at present is in critical care, where patients are often lacking capacity or overwhelmed. There is a clear need for standardisation of research consent in this area due to variability across jurisdictions, however adding an additional consent function to take low risk samples adds unnecessary complexity to an already difficult research environment. Ideally. An appropriately constituted Human Research Ethics Committee (HREC) should have the authority to provide general authorisation of low risk samples (blood, urine, drain fluid, faeces, hair, etc.) In these circumstances, the HREC would usually consider the risks and benefits as seen by an ordinary person, noting that further participation in research may be subject to voluntary withdrawal by the patient or representative.

ANZSBT notes the current and proposed restrictions of trade have significant potential impact in the blood sector. At the present time, Australia collects blood only from voluntary non-remunerated donors. Australia also sources plasma products routinely from international manufacturers, predominantly collecting blood from United States of America, where monetary compensation is allowed. These may provide significant value to people on low incomes. In addition, Australia rarely sources blood from international services (for example to supply red cells to a patient with antibodies to a high incidence antigen). Mostly, these will come from non-remunerated donors and will not be considered traded. The proposed exceptions for goods registered by TGA and blood products would allow for supply of these products into the future. This would then not require a case specific process to exempt transfusion-related products from the trade restrictions, although if the exemption of blood products was strictly applied to only those products and suppliers then rare red cell cases as noted above could be excluded if any aspect of collection and processing was seen as trade.

The current prohibition on paid blood donors has been specifically raised in question 36c. As currently Australia sources a large proportion of intravenous immunoglobulin, largely derived from apheresis donors in the USA, ethical principles could be considered to have been applied inconsistently. The USA is the world's largest source of excess plasma in all likelihood due to the ability to attract paid plasma donors, while Australia, with one of the highest per capita volumes of plasma from non-remunerated donors in the world, struggles to supply even 50% of our own needs. Improving local supply could enhance supply security. The current prohibition is clearly open to debate.

In order to implement paid plasma donors, Australia would have to consider major reforms. The impact on whole blood and platelet donations would need to be considered. A review of who can collect plasma, manufacture products from it and the management of excess products (particularly the potential to export excess and Australia's current position of a monopoly fractionator) will need to be considered. The strategic vision of Red Cross Lifeblood may not align and Australia would need to consider whether to move away from a single donor collection organisation and allow commercial operators to establish donation facilities. Research would need to be offered to inform decision makers on anticipated donor behaviour and a plan established. Alternative or additional changes, such as allowing higher frequency plasma donations, would need to be considered. In the USA, the FDA allows plasma donations up to twice in a seven day period, compared with no more than once every 14 days in Australia, and the benefit may not be as clear implementing one without the other. Donor safety would need to be considered if changes to donation frequency are also considered (see Haugen M etal. Vox Sang. 2025 120:1205-15). Consideration would need to be given to trends in intravenous immunoglobulin use and in particular, new evidence from trials currently underway in Australia, as these may have a significant impact on demand and whether to proceed with such a proposal.

In short, allowing paid donors is an option, but should not be consider as s simple solution or in isolation. It is important to consider which decisions should be included in legislation and which should be allowed under delegated legislation / regulation.

Section 4.19 notes, "It is appropriate to have delegated legislation for the following purposes:

- to streamline and simplify primary legislation;

- the legislation is dealing with something that is likely to change regularly or frequently; and
- it is suitable for subject matter experts to make legislation about technical and detailed aspects of the law, rather than Parliament"

ANZSBT believes that none of these apply in this case. Rather, paid plasma donors is such a major strategic shift that it should be debated properly and considered specifically by Parliament with an overall plan for the sector formed by government(s), not set up as an option available to a regulator. A framework with single national legislation would facilitate this, rather than the current arrangements where each jurisdiction would need to debate and agree separately, if at any stage Australia chose to opt for this pathway.

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