Therapeutic Goods Order No. 88 - Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

FRLI: F2013L00854
Portfolio: Health
Tabled: House of Representatives, 30 May 2013 and Senate, 17 June 2013
PJCHR comments: Tenth Report of 2013, tabled 26 June 2013
Response dated: 18 December 2013

Information sought by the committee

3.57 The committee sought further information in relation to:

- how the confidentiality of information collected as part of the donor screening process (including the results of any physical assessment or testing) is to be protected and how (and for how long) the information collected will be stored, and whether this is consistent with the right to privacy; and
- further information as to how the differential treatment of individuals who meet one of the 'donor medical and social history criteria' in column 1 of table 1 is justifiable and consistent with the right to equality and non-discrimination.

3.58 The Assistant Minister's response is attached.

Committee's response

3.59 The committee thanks the Assistant Minister for her response.

3.60 In light of the information provided, the committee makes no further comments on this bill.

3.61 The committee notes it would have been useful had the information provided in this response been included in the statement of compatibility.

Senator the Hon Fiona Nash
Assistant Minister for Health
Senator for New South Wales
Deputy Leader of the Nationals in the Senate

Ref No: M13009090

Senator Dean Smith
Chair
Parliamentary Joint Committee on Human Rights
S1.111
Parliament House
CANBERRA ACT 2600

Dear Chair

I refer to correspondence of 26 June 2013 from the then Chair, Parliamentary Joint Committee on Human Rights, Mr Harry Jenkins MP, to the then Parliamentary Secretary of Health and Ageing, the Hon Shayne Neumann MP, seeking clarification about the operation of Therapeutic Goods Order No. 88 – *Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products* (TGO 88). The letter has been referred to me as Assistant Minister for Health with portfolio responsibility for this matter.

I congratulate you on your appointment as Chair of this important committee.

In its Tenth Report of 2013, the Committee indicated it would seek further information about:

- how the confidentiality of information collected from blood and tissue donors who donate their blood, cells or tissues for use in the manufacture of products covered by TGO 88 is to be protected and how (and for how long) the information collected will be stored, and whether this is consistent with the rights to privacy, and
- how the differential treatment of individuals who meet one of the 'donor medical and social history criteria' in Table 1 in TGO 88 is justifiable and consistent with the rights to equality and non-discrimination.

As you are aware, TGO 88 specifies minimum donor screening and testing requirements for the safe collection and manufacturing of blood, cells and tissues for use in recipients.

These requirements are designed to minimise the risk of contaminated blood or tissues being used in a recipient, and to minimise the risks of such products being contaminated during their manufacture, processing and transportation.

TGO 88 sets out requirements for collecting a donor's social and medical history before (or, in the case of a deceased donor, not more than seven days after) blood, cells or tissues are extracted or collected (refer to subsections 9(1) and (2) of TGO 88). TGO 88 itself does not set out requirements relating to the confidentiality of such information.

However, the entities involved in the collection, use and disclosure of such information in Australia must comply with applicable laws dealing with the protection of individual privacy.

These entities include organisations such as the Australian Red Cross Blood Service and the Australian Bone Marrow Donor Registry, which are 'organisations' within the meaning of that term in the Commonwealth *Privacy Act 1988* and are subject to the National Privacy Principles in that Act regarding personal and health information. State and territory government bodies, such as the Donor Tissue Bank of Victoria and the Queensland Bone Bank (within Queensland Health), are also involved in this collection, use and disclosure.

As state and territory authorities are not 'organisations' for the purposes of the *Privacy Act 1988* (subsection 6C(1) of that Act refers), those state and territory bodies engaged in the collection of donor information are not subject to the requirements set out in that Act. However, the state and territories have their own legislation, administrative requirements or policies relating to privacy or the protection of health information.

For example, the Donor Tissue Bank of Victoria (within the Victorian Institute of Forensic Medicine) is subject to Victorian legislation dealing with personal and health information, including the *Victorian Institute of Forensic Medicine Act 1985* (Vic), the *Human Tissue Act 1982* (Vic), the *Information Privacy Act 2000* (Vic) and the *Health Records Act 2001* (Vic).

For bodies required to comply with the *Privacy Act 1988*, there are a number of important requirements in relation to their treatment of donor information. These include, for example, that under National Privacy Principle 2, an organisation can generally only use or disclose personal information for the purpose for which it was collected, subject to certain exceptions, e.g. where the individual has consented to the use or disclosure or where the use or disclosure is required or authorised by law. Under National Privacy Principle 4, an organisation must take reasonable steps to protect the personal information it holds from misuse, loss and unauthorised access, modification and disclosure, and must destroy personal information or make it impossible to identify the person it relates to if it is no longer needed for any purpose.

The collection of a donor's social and medical history is a critical part of assessing whether it will be safe to use the donor's blood, tissues or cells in a recipient, and for this reason it is considered that the collection of this information is justified in relation to Article 17 of the International Covenant on Civil and Political Rights (the ICCPR).

Under subsection 9(4) of TGO 88, a person who meets any of the criteria listed in Table 1 of section 9 of the Order is ineligible to be a donor for the period specified in that table. For example:

- donors infected with Human Immunodeficiency Virus (HIV) or Hepatitis C virus, or who are at risk of prion disease (e.g. Creutzfeldt-Jakob Disease, a neurodegenerative disorder which is always fatal) are permanently ineligible to be donors;
- donors who have been injected with a drug for a non-medical reason are ineligible for a period of five years from their last such injection;
- donors whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues are ineligible for a period of 12 months from last contact;
- donors with a history of malaria are ineligible unless a validated immunological test, taken at least four months after the last visit to a malaria endemic area, is negative; and
- donors with an unexplained fever or infectious illness are ineligible for at least two weeks from the date they fully recovered from that event.

When the 'donor medical and social history' criteria are assessed, it can be seen that they do not discriminate on the basis of any non-health related status of the donor. In cases such as a person who was a prison inmate or has a tattoo or body piercing, the criteria and period of ineligibility are related to the increased risk of acquiring a blood borne transmissible infection for people in these situations. The criteria and the ineligibility periods are solely designed to ensure the safety of the supply of blood, blood components, tissues and cellular therapy products that are manufactured from donated blood and to minimise the risk of serious illnesses being transmitted to recipients through such products.

The criteria in TGO 88 are consistent with international practice including the requirements for the collection of human blood, cells and tissues in Europe, America and Canada, though exclusion periods can vary significantly.

A review of blood donor deferrals relating to sexual activity commissioned by the Australian Red Cross Blood Service, which reported in May 2012, referred to the fact that three legal challenges in Australia, in which it was argued that the policy of the Blood Service of deferral of donors engaging in male-to-male sex was discriminatory on the grounds of sexuality and lawful sexual activity, were unsuccessful, and that the findings in these cases were consistent with international legal challenges.[1]

For the important public health reasons set out above, the treatment of potential donors under TGO 88 would appear to be justifiable, and consistent with the rights to equality and non-discrimination in Articles 2.1 and 26 of the ICCPR. If you would like to discuss this matter further, I invite you to contact Mr Bill Turner from the Office of Scientific Evaluation, Therapeutic Goods Administration, by telephone on (02) 6232 8187.

Yours sincerely

18 DEC 2013

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1 Pitt. V. (Ed) (2012). *Review of Australian blood donor deferrals relating to sexual activity*. p4. <http://www.bloodrulesreview.com.au/files/upload/blood_review_report_may_2012_electronic_version.pdf.