

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

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Portfolio: Health and Ageing

Summary of committee view

2.27 The committee seeks further information in order to assess this instrument's compatibility with the right to privacy and the rights of equality and non-discrimination.

Overview

2.28 This instrument specifies requirements relating to donor selection, donor testing and cell and tissue management, as related to infectious agents during the collection and processing for human blood, blood components, tissues and cellular therapy products and associated critical materials.

2.29 The instrument specifies the minimum donor screening and testing requirements considered necessary for the safety of human blood, cell and tissue products and also includes donor testing criteria.

2.30 The instrument also requires that donor's medical and social history be obtained before the use of any relevant products collected from the donor and specifies the minimum physical assessment and testing that must be undertaken to evaluate donor suitability.

Compatibility with human rights

2.31 The instrument is accompanied by a self-contained statement of compatibility that states that it is compatible with human rights as it does not raise any human rights issues.

2.32 However, section 9 of the Order relating to 'Requirements in relation to the medical and social history of prospective donors' is likely to engage the right to privacy (article 17 of the International Covenant on Civil and Political Rights (ICCPR)) and the rights of equality and non-discrimination (article 26 of the ICCPR).

2.33 Subsection 9(1) of the Order states:

In the case of a living donor, the blood, blood components, cells or tissues must only be collected from a living donor with whom an interview to obtain the donor's medical and social history has been conducted and recorded...

2.34 Noting the sensitivity of the information collected as part of this process (and any associated physical assessment or testing) the committee considers that the right to privacy is likely to be engaged.

2.35 The explanatory statement explains that the process of obtaining a donor's medical and social history:

...is important in order to be able to effectively assess the risk of infectious disease transmission associated with the use of blood or blood components, human tissues or human cellular therapy products from the donor.¹

2.36 However, the Order does not specify how the confidentiality of this information (and the results of any physical assessment or testing) is to be protected or how (and for how long) the information collected will be stored.

2.37 In addition, subsection 9(4) of the Order states that a donor who meets certain criteria² is subject to a period of ineligibility prior to donation. This differential treatment of potential donors is likely to engage the rights of equality and non-discrimination and therefore an explicit explanation as to how the differential treatment is justified needs to be provided.

2.38 The committee intends to write to the Minister for Health to seek 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 rights to equality and non-discrimination.**

1 Explanatory statement, p. 3.

2 For example, 'a donor who has ever injected, or been injected with, any drug for a non-medical reason', 'a donor whose sexual practices put them at an increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues', or 'an inmate of a prison'.