

# Part E: Looking Toward a New Regulatory Framework

This document has covered many complicated and interwoven issues. The final Part provides a summary of the proposed structure of the overall framework. Your comments and responses to the issues in this document will inform the shape of the overall framework, as well as the detail that is developed within it.

## E1 A new human tissue act

It is proposed that a new human tissue act be developed to regulate the collection and use of tissue from deceased persons for therapeutic and non-therapeutic purposes. In particular, it is proposed that the new human tissue act include:

- a requirement that tissue from deceased persons be treated with dignity and respect
- consent requirements for non-coronial post-mortem examinations, and anatomical examinations
- consent requirements for the collection of tissue for research and education, including when tissue is to be collected at the time of a non-coronial post-mortem examination
- provisions for the collection of tissue for therapeutic purposes – organ and tissue donation
- definitions of who is able to give consent for tissue use on behalf of a deceased person
- provisions regarding the sale and purchase of tissue
- provisions that allow challenging new tissue-based technologies to be controlled while they are assessed for acceptability and safety.

## **E2 Amendments to therapeutic products legislation<sup>50</sup>**

It is proposed that a comprehensive regime be put in place to ensure the safety of tissue-based therapeutic products. The proposed regime would add a new part to therapeutic products legislation and potentially develop standards as described below under the Health and Disability Services (Safety) Act. It is envisioned that, in time, the regime for the safety of tissue-based therapeutic products could come under the jurisdiction of the Joint Therapeutic Products Agency.

The amendments to therapeutic products legislation would include:

- a definition of tissue-based therapeutic products based on an assessment of the risk associated with a particular product
- a definition of the activities to be regulated
- a definition of the people to be regulated.

## **E3 Standards under the Health and Disability Services (Safety) Act 2001**

The Health and Disability Services (Safety) Act provides a framework for setting safety standards in the health and disability sector. When this Act was developed it was anticipated that tissue-based services would be regulated in the future and it has made provision for standards to be developed for this purpose. This document proposes that standards could be developed for:

- tissue banking
- whole organ retrieval and transplantation.

This document also proposes that a more comprehensive form of oversight for non-therapeutic use of tissue be developed. One option is that a tissue management standard be developed and monitored under the Health and Disability Services (Safety) Act. This would require an amendment to this Act, and the development of a standard. Your feedback on this proposal is welcomed, as are other suggestions for achieving the objective of comprehensive oversight without imposing unnecessary costs on the health and disability sector.

<sup>50</sup> Work is under way to replace the Medicines Act 1981, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The specific vehicle for tissue-based therapeutic products will be considered at a later date.

## **E4 Health Act 1956**

As part of the overall framework for the safety of tissue-based therapies, this document suggests that it may be appropriate to use the provisions in the Health Act 1956 to recognise particular entities as being authorised to collect controlled human substances. The Health Act could also be used to prevent trade in controlled human substances.

## **E5 Other regulations, codes or guidelines**

To complete the framework for human tissue, this document has asked for your comments on a number of other regulations, codes or guidelines, including the following.

- Health (Retention of Health Information) Regulations 1996 – following changes to the relevant regulation-making powers, we seek your initial comment on the issues to be addressed in requiring specimens to be retained in the same way as other health information.
- Health Information Privacy Code – in response to the increasing focus on genetic information, we seek your comment about the coverage of the Health Information Privacy Code in relation to genetic information, and specimens in particular.
- Import and export of tissue – it is suggested that the import and export of tissue could be covered by a code of practice.
- Your comment is also sought on whether or not more detailed guidance is needed to assist ethical decision-making about the use of foetal tissue for non-therapeutic purposes.