

**REVIEW OF THE REGULATION OF HUMAN TISSUE AND TISSUE-BASED THERAPIES: PAPER THREE: ADDITIONAL MATTERS RELATING TO THE THERAPEUTIC AND NON-THERAPEUTIC USE OF HUMAN TISSUE**

**Proposal**

1. This paper seeks agreement to a new regulatory framework for the oversight and management of the therapeutic and non-therapeutic uses of human tissue.

**Executive Summary**

2. This is the third in a suite of three papers which seeks agreement to a new regulatory framework for human tissue and tissue-based therapies, including agreement to:
  - repeal the Human Tissue Act 1964 and replace it with new Human Tissue legislation; and
  - regulate tissue-based therapeutic products under the trans-Tasman Joint Agency.
3. This paper addresses the remaining issues not covered in Paper One and Paper Two. The items in the paper are typically discreet and endeavour to cover off issues that I consider would cloud the issues addressed in the other two papers.
4. The key proposals in this paper are:
  - The regulation of human tissue-based therapeutic products under the trans-Tasman Joint Agency and joint regulatory scheme.
  - The regulation of the non-therapeutic use of human tissue via a standard for the retrieval, use, retention and disposal of human tissue for non-therapeutic purposes (education, audit, research, pathology) and additional provisions for schools of anatomy.
5. The paper also includes proposed requirements for the import and export of human tissue; sale and purchase of human tissue; a mechanism to control activities that raise ethical, cultural, spiritual and safety risks.

## Background

### ***In-principle decision on the regulation of tissue-based therapies under the trans-Tasman Joint Therapeutic Products Agency***

6. Currently tissue banks and organ procurement processes in New Zealand are not formally regulated. Instead they operate under voluntary codes of practice.
7. I have given in-principle support to the regulation of tissue-based therapeutic products under the trans-Tasman Joint Therapeutic Products Agency and regulatory scheme (the 'Joint Agency and regulatory scheme'). This paper seeks your confirmation of the in-principle decision.

## Proposals for reform

8. A diagram illustrating the proposed regulatory structure for tissue and tissue-based therapies (both therapeutic and non-therapeutic uses of tissue) is provided in **figure one**.

### ***(i) Therapeutic use of tissue***

9. At present, tissue-based therapies (including organs, tissues and cells for transplantation as well as cell-based therapies) are not formally regulated in New Zealand, with providers instead operating under voluntary codes of practice. As part of the Human Tissue Review, the Ministry of Health considered the merits of various approaches to the formal regulation of tissue-based therapies. The main regulatory options were:
  - creating an entity structure under the Health Act 1956, which would lead to tissue being regulated in parallel to the current system for blood and blood products under the New Zealand Blood Service
  - developing standards for tissue-based therapies under the Health and Disability Services (Safety) Act 2001, which would lead to providers and manufacturers of such therapies being audited for compliance with standards approved by the Minister of Health
  - regulating tissue-based therapies under the Joint Agency and regulatory scheme.
10. The Therapeutic Products Interim Ministerial Council (TPIMC) has agreed that responsibility for audit and licensing of blood and blood products will be regulated under the Joint Agency and regulatory scheme. New Zealand needs to make a final decision about whether standard setting for blood will sit under the Joint Agency and whether tissue-based therapies (eg., the therapeutic use of whole organs) should be regulated independently or under the Joint Agency. Australia has already made the decision that all aspects of the regulation of blood and tissue will be undertaken by the Joint Agency on behalf of that country.

11. I propose that tissue-based therapeutic products be regulated under the Joint Agency and regulatory scheme. The advantages of bringing these products under the scheme are as follows:
  - provides consistency with the regulation of other therapeutic products, including prescription and non-prescription medicines, medical devices, blood and blood products, and complementary and alternative medicine.
  - enables efficiency gains due to the development of a single regulatory environment for both countries with respect to tissue-based therapies.
  - allows greater control over the cost of monitoring and compliance, as fees would be set by the TPIMC itself under the Joint Agency, not by independent contracted auditors under the Health and Disability Services (Safety) Act.
12. Ministry of Health officials have held discussions with a number of those involved in tissue banking and tissue-based therapies in New Zealand on the proposal to bring cellular and tissue-based therapies under the Joint Agency and regulatory scheme. Generally there is support for the proposal as people recognise that formal regulation in this area is needed. Some concerns were expressed that New Zealand will have less influence than Australia under the Joint Agency and regulatory scheme. Some concern has been expressed by the health sector about the potential indirect and direct costs associated with: the new fee structure; the change in culture of the regulator; and the potential for increased compliance costs due to a change in interpretation of guidelines and existing standards.
13. Under the proposed scheme New Zealand will have an equal say at the Ministerial level on the Ministerial Council, which oversees the scheme and appoints members to the expert advisory committees. New Zealand officials will ensure that there are appropriate New Zealand experts on any expert advisory committees established by the Joint Agency, including interim committees. In addition, the risks of change will be addressed via the change management process for moving to the Joint Agency environment, and the process to establish and apply the rules that the Agency will operate under.

**(ii) *Non-Therapeutic use of tissue***

*Development of a standard*

14. Currently the non-therapeutic use of tissue is largely unregulated, with the exception of schools of anatomy. There was general agreement from submitters, including DHBs, other health care providers, researchers and individuals that an overarching framework or standard for the non-therapeutic use of tissue (research, education, audit, non-coronial post-mortem examination and anatomical examination) is needed. The Ministry's subsequent discussions with the sector have also confirmed this view. The reasons given for developing such a standard were the need for clarity, consistency and to allow for monitoring of the processes around tissue use. It was also felt that such a standard would increase public confidence in tissue

practices, including the importance of tissue being managed in a culturally appropriate manner.

15. I propose that new legislation provide for a standard to be developed, or an existing standard/s approved, for the non-therapeutic use of tissue. This would be provided for via a regulation-making power in new Human Tissue legislation.<sup>1</sup>
16. In addition, I propose that the standard must include requirements for ethical approval of research using human tissue. While it is currently common practice for researchers to seek ethical approval for research using human tissue, there is no legislation that requires this. Given the possible commercial uses of human tissue and the sensitivity around its use, I consider there should be some requirement for ethical oversight of research in this area, with the ability to specify exemptions. The ability to specify exemptions is important given the broad definition of tissue, which will include established cell lines. Some research using tissue is non-contentious and does not currently require ethical approval, such as some laboratory research that uses established cell lines. It would be quite onerous on researchers and ethics committees if ethical approval were to be required.
17. I envisage that this would be a minimum standard covering the collection, use, retention and disposal/return of all human tissue for non-therapeutic purposes.

*Additional provisions for schools of anatomy*

18. Under the Human Tissue Act 1964, the Governor-General in Council authorises the establishment of schools of anatomy where the study and practice of anatomy may be carried on in connection with any university or school of medicine and in a place or places and subject to such conditions as the Minister thinks fit. That authority may be revoked at any time. In addition, the Minister may from time to time appoint one or more members of the Police as an Inspector of any school of anatomy and they must make a quarterly return to the Minister of all bodies which have been removed for anatomical examination, including the name and age of the person. The Minister also issues licences to practise anatomy to any medical practitioner employed to teach in a school of anatomy.
19. I propose that under new Human Tissue legislation, schools of anatomy would be covered by the standard proposed above (refer paragraphs 15 to 18). In addition, I propose:
  - to retain authorisation of schools of anatomy by the Minister of Health in order to maintain public confidence in the process of anatomical examination

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<sup>1</sup> There is a recent precedent for such a provision in the Health (National Cervical Screening Programme) Amendment Act 2004.

- to remove the requirement for licensed anatomists, which is in the Human Tissue Act 1964. I consider that the schools of anatomy should be responsible for determining who can practise anatomy within the school
- a smaller inspection role for a person authorised by the Director-General of Health to carry out this role. This may be a member of the Police or another person deemed appropriate by the Director-General of Health. It is anticipated that the Police would continue in this role but the legislation would allow another person to undertake this role in the future, if this is considered appropriate. The authorised person would report any irregularities to the Minister of Health rather than mandatory reporting of all bodies removed for anatomical examination as currently happens. Schools of anatomy supported retaining an inspection role for the Police for public assurance purposes.
- that anatomical tissue may not be held on premises that are not authorised schools of anatomy unless the tissue has come from an authorised school of anatomy and has been authorised in writing by the 'person with lawful responsibility for the tissue' in that school of anatomy.

**Analysis of tissue for the purposes of obtaining information, including genetic information, about a particular condition, potential condition or trait of the individual**

20. The need for informed consent before genetic information can be obtained, stored, or used was highlighted as very important in the public consultation process.
21. There is currently a gap in relation to the use of tissue from living people for tissue analysis for the purposes of obtaining genetic information about an individual that occurred outside a health care setting. I therefore propose that new Human Tissue legislation cover consent for analysis of tissue taken from deceased people and living people where the Code of Health and Disability Services Consumers' Rights does not apply, for the purposes of obtaining information, including genetic information, about a particular condition, potential condition or trait of the individual from deceased. There are instances when it will be desirable to analyse tissue to obtain information about an individual without informed consent. I am therefore recommending the following limited exceptions from the requirement for informed consent.
  - for criminal justice purposes, including for the purposes of crime prevention, or criminal investigations or prosecution
  - purposes or functions of a coroner
  - implementing an order or direction of the court
  - if the results of an analysis of tissue are to be used to obtain scientific or medical information about that person for the medical benefit of another person (including a future person) and the following conditions are met:
    - It is not reasonably possible to trace the person if alive, or in the case of a deceased person a person nominated by that person prior to their death or the immediate family of that person (but reasonable attempts have been made to trace them); and

- there is no formal record of a person's objection to their tissue being used for this purpose
  - those matters covered by the "secondary principle" – exceptions to the requirement for informed consent (refer paper two).
22. I propose that the Ministry of Health, in consultation with other relevant agencies, undertake further work on clarifying the scope of the exemptions for drafting purposes.

### **Import and Export of tissue**

23. There was general support in the consultation process for more comprehensive oversight of the import and export of human tissue to address issues such as safety, cultural appropriateness, and ethical concerns. Many respondents also considered that any legislative framework should continue to permit the import and export of tissue for quality assurance, peer review, diagnostic, and transplantation purposes where adequate safety levels can be assured. I am proposing that requirements in relation to the import and export of human tissue be implemented using a code of practice and that new Human Tissue legislation include a regulation making power that enables the prescribing of standards/requirements on the import and export of human tissue, if this is considered necessary. This would be enforced by the Ministry of Health.

### **Sale and Purchase of Human Tissue**

24. It has long been considered a matter of common law that there is no property in the body of a deceased person. That is, no one is able to 'own' the body of a deceased person and determining what happens to a human body after death cannot be decided on the basis of anyone owning the dead body. Current New Zealand law prohibits the sale and purchase of some human tissue:
- The Health Act 1956 prohibits trade in blood and blood products and requires the New Zealand Blood Service to recognise the gift status of blood, although it does allow the Minister of Health to authorise the sale and purchase under special circumstances.
  - The Human Assisted Reproductive Technology Act 2004 prohibits the sale and purchase of gametes and embryos, although allows some cost recovery for those involved in surrogacy arrangements.
  - Other tissue, such as organs for transplantation, cannot be sold or purchased as a matter of common law.
25. Part 3A of the Health Act 1956 contains provisions covering trading and collection in blood and controlled human substances. A number of respondents to the Human Tissue Discussion Document expressed the view that blood should be brought within the new regulatory framework for Human Tissue. I support this view and recommend that the new Human Tissue Act amend the Health Act 1956 by transferring the provisions in Part 3A of the

Health Act to new Human Tissue legislation, where appropriate and extending these provisions to cover trading in human tissue (including blood).

26. I am proposing that the sale and purchase of tissue (includes blood) from both living and deceased people be prohibited but with provision for exemptions where desirable (ie. it is in the public interest to allow the sale or purchase of tissue). This is consistent with provisions relating to the trading in human blood in the Health Act 1956 and with feedback from the public consultation process. There was general support for a prohibition on the sale and purchase of human tissue, however, a number of respondents thought that there should be some allowance for cost recovery. Respondents generally agreed that the gift status of tissue (including blood) should continue to be recognised and trafficking in tissue should not be permitted.
27. I propose that the sale and purchase of human tissue from living or deceased people, offering to sell or purchase human tissue from a living or deceased person, involvement in arranging the sale or purchase of human tissue taken from a living or deceased person, including advertising for the sale and purchase of the tissue, would be prohibited under new Human Tissue legislation unless these activities have been authorised in writing by the Minister of Health. I am proposing that the Minister may also impose restrictions or conditions on such activities and that these must be specified in writing.
28. It is anticipated that the exemptions provision would be used to authorise entities such as the NZBS, DHBs, and private hospitals to purchase tissue, if necessary, for the purposes of audit, diagnosis or treatment or to receive payment to cover expenses incurred in the collection, transport or processing of tissue. Researchers may also seek authorisation to purchase tissue from entities or imported cell lines for research purposes under this provision. I am proposing that the Government's current policy of allowing welfare assistance for living donors would not be affected by this provision. These proposals are consistent with current practice.

### **Controlled Activities**

29. I am recommending that the new Human Tissue legislation include provision for a category of 'controlled activities'. Such a provision would enable the legislation to control new developments in science and research that present cultural, safety, and ethical risks. The majority of individuals and organisations who addressed this issue considered that such a provision was needed.
30. The purpose of the controlled activities provisions would be to put in place a prohibition or restrictions on certain procedures while providing a process for allowing exemptions. In other words, these controlled activities would be prohibited or restricted, but could be authorised after due consideration of an application made to the Minister of Health, or through an Order in Council.

31. Before approving a particular application under this provision or recommending that an activity be added or removed from the list of controlled activities, the Minister of Health would have to take into consideration<sup>2</sup>:
- ethical, cultural and spiritual implications
  - risks to health or safety of the public.
32. I also propose that the Minister of Health may establish a committee, or seek advice from an existing body or committee on whether he/she should permit an activity or whether an activity should be included or taken off the list of controlled activities. Any such body or committee would have to comply with relevant provisions in the New Zealand Public Health and Disability Act 2000, including the requirement to consult with interested parties and members of the public before tendering advice to the Minister of Health. This is consistent with the current controls in the Medicines (Specified Biotechnical Procedures) Amendment Act 2005. Xenotransplantation<sup>3</sup> is currently regulated under these provisions, however, it is envisaged that xenotransplantation would be regulated under new Human Tissue legislation, once this is enacted.
33. I am proposing that, initially, the Controlled Activities provision would include restrictions on xenotransplantation with the ability to add to the list by Order-in-Council, if necessary. This provision would be used to extend the controls on animal to human xenotransplantation until such time it is considered safe to move to therapeutic use, including in clinical trials. At that point it would be regulated under the trans-Tasman Joint Therapeutic Products Agency and regulatory scheme. It is proposed that research involving the mixing of human and animal cells/tissue would at the very least be covered by requirements relating to research in a standard for the non-therapeutic use of tissue and may be subject to greater controls under the controlled activities provision.

### **Powers of Inspection, Entry, Search and Seizure**

34. Under the Human Tissue Act 1964 the only powers of inspection are vested in the Inspectors of Anatomy (under section 8(1)). Inspectors of Anatomy are members of the Police and have a limited role in overseeing the practices of schools of anatomy.
35. I propose that under new Human Tissue legislation the Director-General of Health may authorise a person to enforce the restrictions contained in either the primary legislation or in regulations developed under the legislation, including regulations covering the non-therapeutic use of tissue (refer paragraphs 15 to 20) and the import and export of tissue (refer paragraph 21). The powers would allow for inspection of relevant records, entry and inspection of premises where tissue is collected, used or retained, entry and

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<sup>2</sup> This is consistent with the recommendations of the Royal Commission on Genetic Modification, 2002

<sup>3</sup> xenotransplantation is the transplantation of living biological material from one species to another, for example, a pig to a human. The term covers transplantation of solid organs, tissues, or clusters of specialised cells (such as pancreatic cells that produce insulin)

search in connection with a suspected offence and execution of warrants in connection with entry and search, and seizure in the course of inspection or search. It would be an offence for a person to intentionally obstruct or hinder an authorised person exercising his/her powers under the legislation.

### **Offence provisions and penalties**

36. I am proposing that the Ministry of Health work with the Ministry of Justice on clarifying the scope of any offences and appropriate penalties under new legislation and will report back to their respective Ministers on this issue.

### **Consultation**

37. Details of the public consultation process undertaken by the Ministry of Health are provided in Paper One of this suite of three papers.
38. The following government agencies have been consulted on this paper. Ministry of Justice; Ministry of Research Science and Technology; Ministry of Transport; Land Transport New Zealand, Police, Te Puni Kokiri; Ministry of Pacific Island Affairs; Treasury; New Zealand Customs; Ministry of Social Development, Ministry of Culture and Heritage; New Zealand Defence Force, Office of Disability Issues, Ministry of Women's Affairs; Ministry of Consumer Affairs, Department of Prime Minister and Cabinet, Office of the Health and Disability Commissioner; Office of the Privacy Commissioner.

### **Financial Implications**

#### ***Regulation of tissue-based therapeutic products under the trans-Tasman Joint Agency and joint regulatory scheme***

39. The Government's decision to formally regulate tissue-based products will create new costs for providers. Costs would be incurred regardless of who the regulator is. The Ministry considers that auditing and licensing of these services are essential public health activities.
40. It is expected that the major providers of tissue for therapeutic uses (the National Eye Bank and New Zealand Blood Service) who already meet international quality standards, would face few costs in bringing their services up to the standard required under the Joint Agency. The cost to DHBs who have small collections of tissue for therapeutic uses (mainly bone banks) of meeting the required standard may be higher. The compliance costs will reflect the size of the organisation and the level of risk of the functions being undertaken. However, until the code of Good Manufacturing Practice (cGMP) and any other relevant standards are finalised it is not possible to accurately estimate the costs to the sector of compliance.
41. There will also be costs associated with an application for a licence and audit for providers of all banked tissue e.g. blood, skin, corneas and providers of high risk tissue-based therapies such as tissue combined with non-tissue, and

cell-based gene therapy<sup>4</sup>. Based on initial advice from Medsafe's auditors the Ministry estimates the total annual audit and licensing costs for current tissue related activities under the Joint Agency and joint regulatory scheme to be less than \$0.3 million per annum (GST exclusive)<sup>5</sup>. The estimated audit and licensing costs for blood and tissue under the Trans-Tasman Joint Agency and joint regulatory scheme are indicative only and will become clearer once work has been completed on the cost recovery model under the Joint Agency and joint regulatory scheme.

42. My preferred option is for these costs to be absorbed by DHBs as part of the cost of carrying out their normal business. However, as the estimated audit and licensing costs for blood and tissue under the trans-Tasman Joint Agency and joint regulatory scheme are indicative only consideration will need to be given to how the costs will be met for small agencies if the actual costs are materially higher than estimated. The ability for the New Zealand Blood Service and the National Eye Bank to pass on the costs of meeting the audit and licensing requirements to DHBs and private providers needs further investigation to ensure consistency with current regulation around charging for blood (which allow for costs arising from collection and processing to be passed on but not the raw donated ingredient).
43. Implementation of regulation under the joint regulatory scheme would be over a three to five year time period to give providers time to comply with relevant standards. The application of fees for tissue-based therapeutic products could also be staged to assist suppliers with adjusting to the new scheme.

#### ***Regulation of the non-therapeutic use of tissue – development of a standard***

44. The cost of developing a standard for the non-therapeutic use of tissue ((research, education, audit, non-coronial post-mortem examination and anatomical examination) is estimated to be approximately \$80,000 (GST exclusive) and can be met within existing Vote Health baselines.

#### **Legislative Implications**

45. This is the third paper in a suite of three papers that contain proposals for new Human Tissue legislation. The new legislation will repeal the Human Tissue Act 1964. Legislative change is necessary because increasingly issues are raised that either fall outside the scope of the current legislation or are subject to legal interpretation.
46. The decision to declare blood and tissue as therapeutic products within the ambit of the trans-Tasman Joint Agency and regulatory scheme will be made by the Joint Ministerial Council or its interim equivalent under the agreement

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<sup>4</sup> The Ministry is not aware of any therapeutic tissue-based activities that would fall into class 3 activities currently being undertaken in New Zealand.

<sup>5</sup> Based on 13 providers currently banking tissue (including the New Zealand Blood Service, New Zealand Eye Bank, and 11 District Health Boards.

between the governments of Australia and New Zealand for the establishment of the joint scheme.

47. The proposals in this paper will:

- repeal any existing legislation or any part of existing legislation, which imposes controls on xenotransplantation and this matter will be addressed under the Controlled Activities provision (refer paragraphs 27 to 31)
- not limit the jurisdiction of the Coroners Act (The Coroners Bill is currently before the Justice and Electoral Committee)
- repeal Part 3A of the Health Act 1956, which covers trading and collection of blood and controlled human substances.
- not limit the jurisdiction of the Code of Health and Disability Services Consumers' Rights.

### **Human Rights/Bill Of Rights**

48. The proposal providing for the Director-General of Health to authorise a person to enforce the restrictions contained in either the primary legislation or in regulations developed under the legislation (paragraph 37) may give rise to issues of inconsistency with section 21 of the New Zealand Bill of Rights Act 1990. The Ministry of Health will work with the Ministry of Justice with the aim of developing this regulatory regime in compliance with the Bill of Rights Act.

### **Gender Equity**

49. There are no specific gender equity issues associated with these proposals.

### **Disability Perspective**

50. The New Zealand Disability Strategy requires that the perspectives of disabled people be included in ethical and bioethical debates (Action 1.4). Under the proposed Controlled Activities provisions (refer paragraph 28) the Minister of Health must have taken into account ethical, cultural and spiritual implications before approving particular applications that fall within the list of Controlled Activities or recommending to the Governor-General that an activity be added or removed from the list of controlled activities. Before making a decision or recommendation the Minister may seek advice from either a committee she has established for that purpose or an existing body or committee. Any such body would be required to consult with interested parties and members of the public before tendering advice to the Minister of Health.

### **Publicity**

51. I recommend that the suite of Cabinet papers relating to a new regulatory framework for human tissue and tissue-based therapies and the Regulatory Impact Statement/Business Compliance Cost Statement be published on the

Ministry of Health website. I also recommend that a copy of each of the three papers be forwarded to the Health Select Committee.

## **Recommendations**

52. It is recommended that you:
1. **Note** that this is the third in a suite of three papers that seek agreement to a new regulatory framework for the oversight and management of the therapeutic and non-therapeutic use of human tissue.
  2. **Note** that this paper addresses the remaining issues not covered in the other two papers and that have been addressed in a separate paper because they are quite discreet and would have clouded the complex issues addressed in the other papers.
  3. **Note** that the proposals in this paper require the repeal of the Human Tissue Act 1964 and a new Human Tissue bill to be drafted.

## **Oversight and Monitoring of Tissue for Therapeutic Purposes**

4. **Confirm** that tissue-based therapies in New Zealand should be formally regulated under the trans-Tasman Joint Therapeutic Products Agency and joint regulatory scheme.

## **Oversight and monitoring of the non-therapeutic use of human tissue and blood from living and deceased people**

### ***New Human Tissue Bill***

5. **Agree** to include a requirement that a standard be developed or an existing standard approved to govern the collection, use, retention and disposal of human tissue for non-therapeutic purposes (education, research, pathology, anatomy, tissue banking) and that the standard have the status of regulation under new legislation.
6. **Agree** that the standard must cover requirements for ethical approval for all research that uses human tissue.
7. **Agree** to the following additional regulatory requirements for schools of anatomy:
  - 7.1 authorisation of schools of anatomy by the Minister of Health
  - 7.2 an inspection role for a person authorised by the Director-General of Health to carry out this role. This may be a member of the Police or another person deemed appropriate by the Director-General of Health. This person would report any irregularities to the Minister of Health rather than mandatory reporting of all bodies removed for anatomical examination as currently happens

- 7.3 a prohibition on the holding of anatomical tissue on premises that are not authorised schools of anatomy unless the tissue has come from an authorised school of anatomy and has been authorised in writing by the ‘person with lawful responsibility for the tissue’ in that school of anatomy.

### **Analysis of tissue for the purposes of obtaining information about a particular condition, potential condition or trait of the individual**

8. **Agree** to include a requirement for specific consent for the analysis of tissue taken from both living people, if not covered by the Code of Health and Disability Services Consumers’ Rights, and deceased people where the analysis is for the purpose of providing information, including genetic information, about a particular condition, potential condition, or trait of the person, subject to the following exemptions:
- 8.1 for criminal justice purposes, including for the purposes of crime prevention, or criminal investigations or prosecution
  - 8.2 purposes or functions of a coroner
  - 8.3 implementing an order or direction of the court
  - 8.4 if the results of an analysis of genetic material are to be used to obtain scientific or medical information about that person for the medical benefit of another person (including a future person) and the following conditions are met:
    - 8.4.1 it is not reasonably possible to trace the person if alive, or in the case of a deceased person a person nominated by that person prior to their death or the immediate family of that person (but reasonable attempts have been made to trace them); and
    - 8.4.2 there is no formal record of a person’s objection to their tissue being used for this purpose
  - 8.5 those matters covered by the “secondary principle” – exceptions to the requirement for informed consent.
9. **Agree** that the Ministry of Health, in consultation with other relevant agencies, undertake further work on clarifying the scope of the exemptions detailed in recommendation 8.

### **Controlled Activities**

10. **Agree** that the legislation provide for a category of ‘controlled activities’ to enable the new legislation to respond to emerging developments in science and research by prohibiting or placing restrictions on activities and that this provision provide for the following:
- 10.1 prohibition or restrictions may be placed on certain procedures by Order in Council, on the recommendation of the Minister of Health after consideration of the ethical, cultural and spiritual implications and risks to public health or safety

- 10.2 the Minister of Health may authorise a particular activity that falls under a controlled activity after consideration of the ethical, cultural and spiritual implications and risks to public health or safety
- 10.3 the Minister of Health may establish a committee to advise, or request that an existing body or committee advise, on whether the Minister should permit an activity or whether an activity should be included or taken off the list of controlled activities. Any such body or committee would have to comply with relevant provisions in the New Zealand Public Health and Disability Act 2000, including the requirement to consult with interested parties and members of the public before tendering advice to the Minister of Health.

### **Import and export of tissue**

11. **Agree** that requirements in relation to the import and export of human tissue be implemented using a code of practice and that new Human Tissue legislation include a regulation making power that enables the prescribing of standards/requirements on the import and export of human tissue, if this is considered necessary.

### **Sale and purchase of tissue**

12. **Agree** that the sale and purchase of human tissue from living or deceased people, offering to sell or purchase human tissue from a living or deceased person, involvement in arranging the sale or purchase of human tissue taken from a living or deceased person, including advertising for the sale and purchase of the tissue, would be prohibited, unless these activities have been authorised in writing by the Minister of Health.
13. **Agree** that the Minister of Health may also impose restrictions or conditions on such activities and that these must be specified in writing.
14. **Note** that these provisions are modelled on Part 3A of the Health Act 1956.
15. **Agree** that new Human Tissue legislation revoke Part 3A of the Health Act 1956 which relates to trading in blood and controlled human substances as blood will come within the definition of tissue under the new legislation.

### **Powers of Inspection, Entry, Search and Seizure**

16. **Agree** that the Director-General of Health may authorise a person to enforce the restrictions contained in either the primary legislation or in regulations developed under the legislation, including regulations covering the non-therapeutic use of tissue (refer paragraphs 15 to 20) and the import and export of tissue (refer paragraph 21).
17. **Agree** that the powers would allow for inspection of relevant records, entry and inspection of premises where tissue is collected, used or retained, entry and search in connection with a suspected offence and execution of warrants in connection with entry and search, and seizure in the course of inspection or

search. It would be an offence for a person to intentionally obstruct or hinder an authorised person exercising his/her powers under the legislation.

18. **Note** that the Ministry of Health will work with the Ministry of Justice with the aim of ensuring the regulatory regime is compliant with the Bill of Rights Act.

### **Offences and penalties under new legislation**

19. **Agree** that the Ministry of Health work with the Ministry of Justice on clarifying the scope of any offences and appropriate penalties under new legislation and will report back to their respective Ministers on this issue.

### **Financial Implications**

20. **Note** that the estimated costs of implementing the recommended proposals are as follows:

#### *Regulation of tissue-based products under the Joint Agency*

- Costs associated with annual audits, licensing and compliance with codes of Good Manufacturing Practice and other relevant standards in relation to tissue are expected to be less than \$0.3 million per annum based on current tissue practice and it is expected these will be recovered from the user on a full-cost basis. The actual total cost will depend on the level of audit and licensing fees and on the requirements in codes/standards, which are yet to finalised.

#### *Development of a standard for the non-therapeutic use of tissue*

- This is estimated to cost around \$0.08 million (GST exclusive) and can be met within existing Vote Health baselines.

21. **Note** that the estimated audit and licensing costs for blood and tissue under the trans-Tasman Joint Agency and joint regulatory scheme are indicative only and consideration will need to be given to how the costs will be met by DHBs and small agencies if the actual costs are materially higher than estimated.

### **Legislative implications**

22. **Note** that the decision to declare tissue a therapeutic product within the ambit of the trans-Tasman Joint Agency and regulatory scheme will be made by the Joint Ministerial Council or its interim equivalent under the agreement between the governments of Australia and New Zealand for the establishment of the joint scheme.

23. **Agree** that New Human Tissue legislation will:

- 23.1 revoke any existing legislation or any part of existing legislation, which imposes controls on xenotransplantation and pick this up under the Controlled Activities provisions in new legislation

- 23.2 repeal Part 3A of the Health Act 1956, which covers trading and collection of blood and controlled human substances.
24. **Agree** that the legislative changes will be binding on the Crown.
25. **Invite** the Minister of Health (Hon Annette King) to issue drafting instructions to Parliamentary Counsel Office to give effect to Cabinet's decisions on those of the above recommendations to be effected through the new Human Tissue Act.
26. **Note** that the Human Tissue Bill has priority four on the Government's legislative programme

Annette King  
**Minister of Health**

Appendix one

**Figure. 1. Overview of the Regulation of therapeutic and non-therapeutic tissue use.**

