



Medicines (Restricted Biotechnical Procedures) Amendment Act 2002

Public Act 2002 No 14
Date of assent 27 May 2002
Commencement see section 2

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The Parliament of New Zealand enacts as follows:

1 Title

- (1) This Act is the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002.
- (2) In this Act, the Medicines Act 1981 is called “the principal Act”.

2 Commencement

This Act comes into force on the day after the date on which it receives the Royal assent.

3 Expiry

This Act expires on the expiry of Part 7A of the principal Act.

4 Purpose

The purpose of this Act is to provide for temporary measures, pending the development of a comprehensive legislative regime, to control the use of germ-cell genetic procedures, cloning procedures, and xenotransplantation procedures in respect of human beings to ensure that—

- (a) a procedure of that kind does not pose an unacceptable risk to the health or safety of the public and that any risks are appropriately managed; and
- (b) any ethical, cultural, or spiritual issues raised by a procedure of that kind are adequately addressed.

5 Interpretation

Section 2(1) of the principal Act is amended by adding to the definition of **animal** the words “; but does not include a human being”.

6 Part 7A inserted

The principal Act is amended by inserting, after section 96, the following Part:

“Part 7A

“Restrictions on specified biotechnical procedures

“96A Interpretation

In this Part, unless the context otherwise requires,—

“**biological material** means—

- “(a) the whole or part of any organ, bone, tissue, or cell; or
- “(b) blood or body fluids

“**cloned human organism** means an artificially formed zygote or an artificially formed embryo whose genetic structure is a copy (whether identical or not) of another zygote or embryo, or of a foetus, or of a dead or living human being, or of a still-born child

“**cloning procedure** means the insertion or injection into a human being of a cloned human organism

“**genetically modified embryo** means a zygote or an embryo whose genetic structure has, as a result of artificial processes, been modified

“**genetically modified gamete** means an ovum or a sperm whose genetic structure has, as a result of artificial processes, been modified

“**germ-cell genetic procedure** means the artificial insertion or injection into a human being of—

“(a) a genetically modified gamete; or

“(b) a genetically modified embryo; or

“(c) a zygote or an embryo derived from a genetically modified gamete

“**specified biotechnical procedure** means—

“(a) any germ-cell genetic procedure; or

“(b) any xenotransplantation; or

“(c) any cloning procedure

“**xenotransplantation**—

“(a) means a medical procedure that involves the insertion or injection into a human being of any matter that consists of, or includes, living biological material of an animal, whether or not that biological material also includes biological material of a human being; and

“(b) includes the transfusion into a human being of any human blood or any human body fluid if the blood or the fluid has, as part of a biotechnical procedure, been in contact with living biological material of an animal.

“96B Restrictions on specified biotechnical procedures

“(1) No person may conduct a specified biotechnical procedure otherwise than in accordance with an authorisation under section 96C or section 96D.

“(2) Subsection (1) applies to a person who continues, after the commencement of this section, to conduct a specified biotechnical procedure that was begun before that commencement.

“(3) Every person commits an offence and is liable on summary conviction to imprisonment for a term not exceeding 6 months or to a fine not exceeding \$200,000 who contravenes subsection (1).

“96C Authorisation of particular procedures

- “(1) The Minister may, by notice in writing, authorise a person or a body of persons to conduct a particular specified biotechnical procedure.
- “(2) The Minister may issue a notice under subsection (1) only if satisfied that the conduct of the procedure concerned meets each of the criteria specified in section 96E(1).
- “(3) An authorisation granted by a notice under subsection (1) may be granted unconditionally or subject to any conditions that are specified in the notice.
- “(4) The Minister may, at any time, by written notice, do any 1 or more of the following in relation to an authorisation granted under subsection (1):
- “(a) vary the authorisation:
 - “(b) vary or revoke any condition subject to which the authorisation was granted:
 - “(c) make the authorisation subject to new conditions:
 - “(d) revoke the authorisation.
- “(5) As soon as practicable after giving a notice under subsection (1) or subsection (4), the Minister must publish the notice in the *Gazette* and present a copy of the notice to the House of Representatives.

“96D Authorisation of class of procedure

- “(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, authorise the conduct of 1 or more classes of specified biotechnical procedure.
- “(2) The Minister may make a recommendation under subsection (1) only if satisfied that the conduct of every class of procedure concerned meets each of the criteria specified in section 96E(1).
- “(3) An authorisation granted by an Order in Council under this section may be granted unconditionally or subject to any conditions specified in the order.

“96E Criteria for authorisations

- “(1) The Minister may grant or recommend an authorisation sought by an application under section 96G only if satisfied that the application relates to the conduct of a specified

biotechnical procedure or class of specified biotechnical procedure that meets each of the following criteria:

- “(a) the conduct of the procedure or class of procedure does not pose an unacceptable risk to the health or safety of the public:
 - “(b) any risks posed by the conduct of the procedure or class of procedure will be appropriately managed:
 - “(c) any ethical issues have been adequately addressed:
 - “(d) any cultural issues have been adequately addressed:
 - “(e) any spiritual issues have been adequately addressed.
- “(2) A reference in any of paragraphs (c) to (e) of subsection (1) to issues is a reference to issues raised—
- “(a) by the conduct of the procedure or class of procedure to which the application relates; and
 - “(b) by any technology involved in that conduct.
- “(3) If the Minister is not satisfied that the conduct of the procedure or class of procedure to which the application relates meets any 1 or more of the criteria specified in subsection (1), the Minister—
- “(a) may direct that advice on the question whether or not the conduct of the procedure or class of procedure meets that criterion (or, as the case may be, those criteria) be obtained from persons who, in the Minister’s opinion, are appropriately qualified, or have the appropriate expertise, to advise on the question; and
 - “(b) after obtaining that advice, may resume his or her consideration of the application on the basis of that advice.

“96F Advice on applicability of criteria

- “(1) For the purpose of obtaining advice of the kind referred to in section 96E(3)(a) in relation to an application, the Minister may do any 1 or more of the following:
- “(a) establish a committee to advise on the criteria in question:
 - “(b) request a body or a committee or an association of persons formed or recognised by or under an enactment to advise on the criteria in question:
 - “(c) request the person who made the application under section 96G (in this section referred to as the **applicant**) to obtain advice on the criteria in question from a committee consisting of persons nominated by the Minister.

- “(2) A committee or body or an association of persons that is to provide advice for the purposes of section 96E(3)(a) may provide that advice only after it has—
- “(a) given interested parties and members of the public a reasonable opportunity to make submissions in writing or orally, or both; and
 - “(b) taken any such submissions into account.
- “(3) Sections 74 to 86 of the New Zealand Public Health and Disability Act 2000 apply, with all necessary modifications, to the establishment and procedures of a committee that is to be established or that has been established under subsection (1)(a) as if it were an inquiry board under that Act.
- “(4) The Minister may agree with an applicant whose application relates to the work of a committee, body, or association established or requested under subsection (1)(a) or (b) that the applicant will pay, or contribute towards the payment of, any costs incurred or to be incurred by the committee or body or association in the examination of aspects of the applicant’s application that, in the Minister’s opinion, could have significant commercial benefits (whether or not that examination also benefits the public).
- “(5) The Minister may agree with an applicant whose application relates to the work of a committee of persons nominated by the Minister under subsection (1)(c) that the Minister will pay, or contribute towards the payment of, any costs incurred or to be incurred by the committee in the examination of aspects of the applicant’s application that, in the Minister’s opinion, are likely to benefit the public (whether or not that examination also has commercial benefits).
- “(6) If the Minister is, under subsection (4), attempting to reach an agreement with the applicant, the Minister may direct the committee, body, or association concerned not to consider any matters relating to the applicant’s application until agreement under subsection (4) has been reached; and the committee or body or association must give effect to that direction.

“96G Applications

- “(1) A person may, by application to the Minister, request the Minister to grant an authorisation under section 96C or to recommend an authorisation under section 96D(1).

- “(2) An application under subsection (1) must be in a form approved by the Director-General and must be accompanied by the prescribed fee.
- “(3) If the Minister has, under section 96F(1)(c), requested a person who applies under subsection (1) to obtain any advice, the Minister may defer consideration of the person’s application until the person has obtained that advice.

“96H No compensation

No compensation is payable by the Crown to any person for any loss or damage arising from the restrictions imposed by section 96B.

“96I Enforcement powers

- “(1) Sections 63(1), 63 (2)(a) to (d), (h), (k), and (3), 66, 68, 74(1), and 85 apply to any investigation or, as the case requires, any prosecution of an offence against section 96B as if—
- “(a) **medical device** included any substance or thing used as part of, or in connection with, a specified biotechnical procedure (within the meaning of this Part):
- “(b) there were inserted in section 63(2)(a), after the word ‘manufactured’, the word ‘used,’:
- “(c) there were inserted in section 63(2)(b), after the word ‘manufacture’, the word ‘use,’:
- “(d) there were inserted in section 66(1)(a), after the word ‘sale’, the words ‘or for use in a specified biotechnical procedure (within the meaning of Part 7A)’:
- “(e) there were inserted in section 66(1), after the words ‘dealing with the importation’, the word ‘use,’.
- “(2) To avoid any doubt, subsection (1) does not limit the application of any of sections 75, 76, 79, and 84 to any matter concerning, or arising out of, the commission, investigation, or prosecution of an offence against section 96B.

“96J Expiry of Part

- “(1) This Part expires on the close of 30 June 2003.
- “(2) The Governor-General may, by Order in Council, before the date specified in subsection (1), on the recommendation of the Minister, specify a later date in substitution for that date, but that substituted date may not be later than 30 June 2005.

“(3) An Order in Council made under this section is a regulation for the purposes of the Regulations (Disallowance) Act 1989.”

Legislative history

21 May 2002	Divided from Genetically Modified Organisms and Restricted Biotechnical Procedures Bill (Bill 175–2) as Bill 175–3B
22 May 2002	Third reading
27 May 2002	Royal assent

This Act is administered in the Ministry of Health.
