

## REVIEW OF THE HUMAN TISSUE ACT 1983

### ***DISCUSSION PAPER: BLOOD DONATION AND THE SUPPLY OF BLOOD AND BLOOD PRODUCTS***

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## **PART 1: INTRODUCTION**

### ***[1.1] Review of the Human Tissue Act***

The Human Tissue Act presently deals with a variety of matters, the common element of which is the use of tissue, including blood, from either a living or dead body for medical, scientific or therapeutic purposes. The origins of the present Act are found in the Corneal and Tissue Grafting Act which was enacted in 1955 to overcome perceived legal difficulties in allowing for corneal grafting, a then relatively new technology. In 1966 the Act became the Tissue Grafting and Processing Act, its terms being widened to accommodate the removal of tissue for “therapeutic” as well as transplant purposes.

In 1977 the Australian Law Reform Commission inquired into the appropriate legislative means of providing laws for the preservation and use of human bodies and for the removal, preservation and use of organs and tissue for the purpose of surgery, medical therapy, transplantation, education and research. The ALRC drafted model legislation, which was the basis for the 1983 Act. The original Act dealt with:

- donations of tissue by living adults and children and post mortem examinations;
- blood donations;
- removal of tissue after death;
- post mortem examinations;
- prohibition on trading in tissue.

In 1985, increasing concern over the transmission of contaminants such as HIV led to amendments to the Act to ensure that donors of blood and semen were adequately screened prior to donation. Amendments in 1987 were made to protect suppliers of semen, blood and blood products from litigation in relation to the transmission of contaminants through blood and semen in circumstances where the supplier has taken reasonable care to prevent such transmission. Provisions were also introduced to regulate private suppliers of blood and semen.

Since these amendments, the Act has remained substantially unchanged.

The need for a review of the Human Tissue Act has been apparent for some time. In 1994, the Regulation made under the Act was the

subject of review pursuant to the provisions of the Subordinate Legislation Act 1989. In the course of reviewing the Regulation, submissions were received from various interest groups and members of the public which highlighted issues concerning the provisions of the Act. Other submissions have been received from the medical profession and members of the public from time to time.

With the majority of the Act being based on recommendations made in 1977, it is appropriate that the community's attitudes to those provisions be re-examined. It may be that there has not been a sufficient change in circumstances for major alterations to the statutory framework. However, there may be several minor but nonetheless important issues to be dealt with in the existing statutory framework.

### ***[1.2] The review process***

The Department of Health is issuing this discussion paper to review the provisions of the Human Tissue Act relating to the supply of blood and blood products. The discussion paper deals with issues surrounding blood donations, regulation of the supply of both homologous and autologous blood and blood products, and the statutory defence extended to suppliers of blood and blood products in respect of actions for the transmission of blood borne contaminants. The purpose of the discussion paper is to raise issues in relation to the Act which have been brought to the Department's attention either by members of the public, the medical profession, community groups and other interested parties, as well as issues which the Department has encountered in the course of administering the Act. In relation to each issue, a range of options are presented for the purposes of initiating discussion. It is hoped that this will provide a sound basis for the consideration of legislative proposals.

### ***[1.3] National Competition Principles Agreement***

In April 1995, the Council of Australian Governments agreed to the National Competition Principles Agreement. This commits Commonwealth, State and Territory Governments to consider the potential anti-competitive effect of all legislation. The guiding principle of the Agreement is that legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the cost; and

- the objectives of the legislation can only be achieved by restricting competition (NSW Government Policy Statement of Legislation Review, June 1996 at p 24).

The Human Tissue Act 1983 currently restricts competition in relation to the supply of blood and blood products by requiring persons who carry on a business of supplying blood and blood products to be authorised by the Director-General of the Department of Health. Competition is further restricted by only allowing authorised suppliers to supply autologous blood. Hence, only persons who are exempt suppliers under the Act are able to engage in the supply of homologous blood and blood products: see Part III for a discussion of these requirements.

This Discussion Paper raises questions as to whether these restrictions result in net benefits to the community in terms of the protection of the public from the spread of infectious diseases and other public health risks (thus addressing the first criterion) and whether there are alternative means of safeguarding public health other than through the restriction of competition (thus addressing the second criterion). Persons making submissions in relation to Part III of this Discussion Paper are invited to address the above principles in the course of those submissions.

#### **[1.4] Submissions**

Written submissions are invited on the issues raised in this Discussion Paper. There is no special form for submissions. However, a contact name and address for each submission is requested. Submissions should be forwarded to:

**ADDRESS:** Legal and Legislative Services - Legal Branch  
NSW Department of Health  
Locked Mail Bag 961  
NORTH SYDNEY NSW 2059

**CLOSING DATE FOR SUBMISSIONS:** 30 April 1998

Any queries regarding submissions should be directed to Legal and Legislative Services - Legal Branch on (02) 9391 9616.

## **PART II: BLOOD DONATIONS**

### ***[2.1] The present provisions***

Part 3 of the Human Tissue Act sets out a legislative mechanism for consent to removal of blood from living persons.

Section 19 allows a person to consent to the removal of their blood for the purposes of its transfusion to another person or its use for other therapeutic, medical or scientific purposes. A parent or guardian may consent to the removal of blood from a child's body for the same purposes, provided that a medical practitioner advises the parent or guardian that the removal of blood is not likely to be prejudicial to the health of the child and the child is in agreement with the proposed removal. A consent to remove blood is only sufficient authority for the removal of blood at certain places, being a hospital, at premises used by the Australian Red Cross or other body approved by the Minister, or at other prescribed places.

### ***[2.2] Blood donations by children***

A child is defined in the Act as an unmarried person under the age of 18 years. The Department is advised that a donation by a healthy child of 16 years and over presents no risk to the child's health. The current requirement that medical advice be received by the parent or guardian that the removal of blood is not likely to be prejudicial to the health of the child may not be necessary for children over the age of 16 provided the parent/guardian's consent is still obtained.

#### ***Options for discussion***

1. Should the requirement that a medical practitioner advise the parent or guardian of a child from whom blood is to be removed that the removal will not be prejudicial to the health of the child be restricted to children under the age of 16 years?

### ***[2.3] Removal of blood at certain places***

Section 21 effectively prevents blood donations being taken at places other than those listed in the section, being hospitals, premises of the Red Cross or other approved body, or other prescribed places. Other provisions in the Act prevent persons other than CSL Ltd, public and private hospitals, the Red Cross and

persons authorised by the Director-General from carrying on a business of supplying blood and blood products. In relation to the latter (authorised suppliers), a premises inspection is part of the authorisation process as is the requirement that persons superintending and carrying out the collection of blood have certain qualifications. The issue of whether the Department should continue to authorise suppliers of blood is considered later in this discussion paper. However, assuming that such a system of authorisation continues, it may not be necessary to restrict the premises on which blood is removed. Alternatively, the premises of authorised suppliers should be added to the list of acceptable places where blood may be removed.

***Options for discussion***

2. Should the restriction as to the premises upon which blood may be removed pursuant to a valid consent be repealed?

OR

3. Should the restriction as to the premises upon which blood may be removed pursuant to a valid consent be retained, and the premises of authorised suppliers be included in the list of such premises?

## PART III: REGULATING THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

### [3.1] *The blood supply in NSW*

An important distinction in discussing the supply of blood in NSW is that between homologous and autologous blood. Homologous blood is blood which is removed from the body of a person for the purpose of its transfusion to *another* person or its use for other medical, or therapeutic treatment of a *another* person. Autologous blood is blood which is removed from the body of a person for the purpose of its transfusion to the *same* person or its use for other medical or therapeutic treatment of the *same* person from whom it was removed.

The main supplier of homologous blood and blood products in NSW is the Red Cross. At the time of writing, the Red Cross blood transfusion services were state based. However, the nationalisation of the state services was underway. When completed, this will result in a single National Australian Red Cross Blood Service.

Until recently, there were also several regional blood transfusion services administered by various public hospitals. A program of subsuming those services into the Red Cross BTS has been completed.

The main suppliers of autologous blood are the Red Cross and private pathology laboratories which are authorised by the Director-General. Public and private hospitals may also engage in the collection and supply of autologous blood and blood products.

The Red Cross supplies plasma for plasma fractionation to CSL Ltd, the body formed by the privatisation of the Commonwealth Serum Laboratories. CSL Ltd has a ten year contract with the Australian Red Cross whereby the Red Cross provides plasma for fractionation by CSL.<sup>1</sup> Most of the plasma fractions produced by CSL are distributed back to the states and territories in proportion to the amounts of plasma they have delivered to CSL.<sup>2</sup>

Part 3B of the Act, deals with the regulation of the supply of blood, blood products and semen. This discussion paper will deal only with

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<sup>1</sup> B McKay, R Wells, *Commonwealth review of Australian blood and blood product system: final report*, February 1995, para 3.10, p 7.

<sup>2</sup> *Ibid*, para 3.11, p 8

the question of blood and blood products, as semen donation and supply are dealt with in another discussion paper.<sup>3</sup>

**[3.2] Regulation of the supply of blood and blood products under the Human Tissue Act**

Section 21G of the Act states that a person shall not carry on a business of supplying blood or blood products or participate in the management of such a business unless the business has been authorised by the Director-General of the Department of Health.

“Blood product” is defined as a product or extract derived or extracted from blood by any process of manufacture.

The prohibition does not apply to “exempt suppliers”. Exempt suppliers are defined in section 4 of the Act as :

- the Australian Red Cross Society;
- the governing body of a public hospital or licensed private hospital;
- the Commonwealth Serum Laboratories (now CSL Ltd); and
- any other body declared by the Regulations to be an exempt supplier.

Exempt suppliers may supply both homologous and autologous blood and blood products. The Human Tissue Act and Regulation place no requirements upon exempt suppliers in respect of their premises, equipment, practices, storage facilities, labelling, record keeping or testing of blood. Exempt suppliers are only required to ensure that donors of homologous blood sign certificates regarding their medical suitability to donate blood. Testing of donated blood for prescribed contaminants is not mandatory for exempt suppliers, but is necessary for them to claim the benefit of the statutory defence which protects them (in certain circumstances) against legal action as a result of the spread of a prescribed contaminant through blood supplied by them.

The Human Tissue Regulation 1995 has recently been amended to render a body an exempt supplier of blood products to the extent that the body supplies blood products that are therapeutic goods within the meaning of the Therapeutic Goods Act 1989 (Cth) and that are registered or exempt goods within the meaning of that Act.

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<sup>3</sup> *Review of the Human Tissue Act 1983, Discussion Paper, Assisted Reproductive Technologies.* NSW Department of Health. October 1997. Copies of this paper can be obtained from the Department’s Better Health Centre on telephone (02) 9954 1193.



The Human Tissue Act does not, therefore, restrict the supply of pharmaceuticals which contain blood or blood products provided they are exempt or registered goods under the Commonwealth Act.

Persons other than exempt suppliers who wish to engage in the supply of blood and blood products must apply to the Director-General of the Department of Health for authorisation. Part 3B of the Act contains a number of procedural sections dealing with applications for authorisations, circumstances in which the Director-General may refuse to grant an application for authorisation, powers of inspectors, revocation and suspension of authorities and other such matters.

One important provision is subsection 21(3) which states that an authorisation is subject to such conditions and restrictions as are prescribed. The Human Tissue Regulation 1995 sets out many such conditions to which all authorisations are subject. One aspect of the Regulation which affects competition in the supply of blood and blood products is the restriction which states that authorised suppliers of blood are able only to collect, store and supply blood and blood products for the purposes of transfusing the blood back to the person from whom the blood was removed or for using the blood for therapeutic, medical or scientific purposes, involving the treatment of the person from whom the blood was removed, or the use of blood for cross-matching with other blood or blood products. That is, authorised suppliers are only able to supply autologous blood and blood products.

Other authorisation conditions require the supplier to obtain a medical certificate from the donor and to test all blood for prescribed contaminants. Suppliers are required to label all blood containers in a manner consistent with the Regulation and to abide by certain requirements in the storage and transportation of blood and blood products. Emergency resuscitation equipment must be maintained. Certain records must be kept and a quality assurance program must be implemented.

There is no doubt that these requirements impose significant costs upon authorised suppliers. However, it may not be correct to attribute these costs to the existence of the legislation. Many of the above requirements would be an integral part of good medical practice, and pathologists involved in the supply of blood and blood products may therefore maintain these standards in the absence of any legislative requirement to do so.

### Directed donations

Homologous supply includes what is sometimes referred to as “directed donations”, that is, a person who gives blood for transfusion to a specific friend or family member. This form of donation is sometimes favoured where the person who is to receive the blood does not wish to use blood from the general homologous pool and cannot, for some reason, supply their own blood. Under the Human Tissue Act and Regulation, directed donations may only be supplied legally by hospitals, the Red Cross or CSL Ltd (although CSL is not directly involved in such activities). Authorised suppliers are not able to engage in the supply of “directed donations”.

### **[3.3] Other Regulatory Controls on the Supply of Blood and Blood Products**

The Therapeutic Goods Administration of the Commonwealth Department of Health and Family Services (TGA) operating under the Therapeutic Goods Act 1989 (Cth) has determined standards applying to the production of plasma fractionated products. These standards apply to CSL Ltd and the Red Cross in respect of these products. However, the Commonwealth Act does not currently cover fresh blood products.<sup>4</sup> Consequently, there are no national standards enforceable by legislation in relation to fresh blood. A Report commissioned by the Commonwealth Department of Human Services and Health on the Australian Blood and Blood Product System (the McKay Wells Report), recommends the desirability of having national standards for such products and that a special unit be established in the TGA to develop and monitor compliance with standards for these products. The Report notes that all other member nations of the OECD except Ireland have implemented standards for fresh blood products.<sup>5</sup> However, it is understood that this recommendation has not been implemented at present.

Apart from the Human Tissue Act and Regulation, pathology laboratories are subject to other regulation which impacts upon their activities of blood collection and supply. In order to attract Medicare benefits, pathology laboratories must be accredited with the Commonwealth Department of Human Services and Health.<sup>6</sup> Such accreditation is conditional upon registration with the National

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<sup>4</sup> B McKay, R Wells, *op cit*, para 1.8, page 2.

<sup>5</sup> *Ibid*, para 3.23, p 10, para 10.2, p 25.

<sup>6</sup> Accreditation takes place under section 23 DNA of the Health Insurance Act 1973

Association of Testing Authorities (NATA). The NATA registration process for pathology laboratories is rigorous and involves continuing surveillance. The process of obtaining and maintaining Commonwealth registration therefore involves a significant financial outlay.

### ***[3.4] The need to regulate the supply of homologous blood and blood products***

There is no doubt that the supply of homologous blood and blood products is essential to public health. However, the activity involves serious risks which must be overcome by the provision of appropriate safeguards to protect the public from the spread of infectious diseases through the blood supply. There are many such diseases which may be spread through a transfusion of blood and blood products, several of which are extremely debilitating and/or fatal, such as HIV and Hepatitis C. It is essential that persons who receive homologous blood and blood products are provided with the best available protection against these diseases in accordance with the highest medical standards. This involves an assessment of donors for their medical suitability and also the carrying out of certain tests upon the donated blood. More effective and efficient tests are constantly being developed, and employing the best screening technology involves a significant investment of resources. Further, where the transmission of an infectious disease does occur, there is often the necessity to trace the source of the infected blood and other recipients of that blood. This is a complex procedure which involves tracing not only the donor, but all persons who may have received blood from that donor. Where there are large numbers of donors and donations involved, the procedure is extremely resource intensive.

Currently in NSW, only “exempt suppliers” may supply homologous blood and blood products, ie the Red Cross, CSL Limited, public and private hospitals. Thus, the supply of homologous blood and blood products in NSW is currently regulated by restricting the persons allowed to supply those products rather than by the setting of standards for the product itself. (Although, as noted above, standards in relation to some blood products are set by the TGA).

Whether this is an appropriate form of regulation requires examination. If the purpose of the Human Tissue Act is to protect the public from contaminated blood and blood products it may only be necessary to regulate the product, rather than to stipulate which persons can supply the product. If standards need to be maintained in relation to blood or blood products, those standards could be set

out in the Act. They could include such matters as the testing of the blood for prescribed contaminants and the screening of donors. Any person could supply homologous blood and blood products provided the standards prescribed for those products are met. Standards for products which are already subject to regulation by the TGA need not be regulated at all under the Human Tissue Act.

However, some may argue that the risks involved in supplying homologous blood and blood products are so great that some restriction on the persons who can engage in the activity is warranted. There could be several rationales for this argument including the following.

- The screening and testing of blood should be carried out in accordance with the latest technology, which can be resource intensive to maintain.
- The centralisation of homologous blood donation records is necessary to ensure that certain blood donations can be traced when necessary. For this reason, the McKay Wells Report notes that there is a need for an efficient vertical integration of blood transfusion services.<sup>7</sup> If several diverse bodies are involved in the supply of homologous blood, this will lead to decentralisation of record keeping and hence, difficulty in carrying out tracing through records.
- The enforcement of standards in relation to blood is difficult and can only be carried out by way of periodic inspections. Therefore, the risks to the public involved in the activity make it unsuitable for the public at large or even the medical profession at large to engage in the activity.

If a restriction on the bodies permitted to supply homologous blood and blood products is justified, the question arises as to which bodies should be granted this permission. CSL Ltd are not involved in the supply of fresh blood products and Commonwealth standards in respect of fractionated plasma products apply to them. The Red Cross is subject to Commonwealth standards in respect of blood products that come within the purview of the Therapeutic Goods Act, and has high standards in respect of fresh blood products. The blood supply activities of these bodies are therefore either wholly or partially under the regulation of the Therapeutic Goods Administration and/or the Department of Health.

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<sup>7</sup> B McKay, R Wells, *op cit*, para 1.3, p 1.

The legislation which governs public and private hospitals does not lay down criteria in respect of the collection or supply of blood and blood products. Generally, it is understood that hospitals are not routinely involved in the collection and supply of homologous blood. However, there may be some circumstances where it is necessary for them to do so.

As noted above, the McKay Wells Report has recommended that standards for fresh blood products be determined at the Commonwealth level under the Therapeutic Goods Act. Clearly, if the role of the Commonwealth TGA were expanded so as to regulate fresh blood products, no further role would exist in this regard for NSW. However, at the time of writing it is understood that no implementation of this recommendation has been progressed.

***Options for discussion***

4. Should there be any regulation by NSW (over and above Commonwealth regulation of pathology laboratories and blood products under the Therapeutic Goods Act 1989 (Cth)) of the supply of homologous blood and blood products?
5. If so, should this regulation be by way of either or both of the following:
  - the setting of standards for homologous blood and blood products (such as testing for certain contaminants, storage, transport etc), allowing any person to supply such products provided that these standards are met; and/or
  - restrictions upon the persons who may supply homologous blood and blood products?
6. If restrictions should be made upon persons who supply homologous blood and blood products, which of the following class of persons should be permitted to engage in this activity:
  - medical practitioners;
  - The Australian Red Cross;
  - CSL Limited;
  - public and private hospitals;
  - persons authorised by the Department of Health?

**[3.5] The need to regulate the supply of autologous blood and blood products**

Generally, the supply of autologous blood and blood products presents less risk factors than the supply of homologous blood and blood products. One class of risk is that to the individual providing the blood in terms of the actual procedure of donation itself. However, these risks are small and do not appear to be unique from risks involved in other medical procedures.

A second class of risk is that posed by “bedside transfusion errors”. This refers to blood taken for autologous donation being erroneously given to a person other than the person from which it was removed. Elimination of this risk provides one rationale for the current regulatory requirements in NSW, which require autologous blood to be treated according to the best practice standards utilised by the Red Cross in relation to homologous blood in terms of storage, transport and testing for prescribed contaminants. Thus, if a bedside transfusion error is made, the recipient will still be receiving blood that has been fully screened.

Certainly, the current regulatory regime governing autologous blood has caused difficulties for some patients. It is understood that no other state apart from NSW has a system of authorising suppliers of autologous blood and blood products. This has led to some difficulties in the provision of medical services across borders. Due to the proximity of health facilities on the Queensland/New South Wales and Victorian/New South Wales borders, it is sometimes the case that a person will have their own blood collected in Queensland or Victoria but undergo the surgical procedure during which the blood will be utilised in New South Wales. However, as suppliers in other states cannot be authorised under the New South Wales legislation, a Queensland or Victorian pathology laboratory or hospital which supplies autologous blood or blood products to a medical institution in NSW will technically be in contravention of the Act. Because there is no comparable authorisation system in adjacent states, there is no ability to make provision for some kind of mutual recognition procedure.

Options which may be considered for the appropriate regulation of autologous blood supplies are similar to those in relation to homologous supplies, although the conclusions drawn may well be different. Standards could be prescribed for autologous blood and blood products allowing any person to provide those products if the standards were met. In addition (or alternatively), a restriction could

be made upon persons able to supply autologous blood and blood products.

Clinical standards have already been set in relation to autologous blood. The Red Cross has issued guidelines for pre-operative autologous blood collections which are followed by the NSW Red Cross collection sites. The Australasian Society of Blood Transfusion Inc has also issued guidelines on pre-operative autologous blood collections. Some may argue that this is sufficient “peer regulation” of this area.

The McKay Wells Report specifically addresses issues in relation to autologous blood, stating that an enquiry into autologous transfusion is necessary and should lead to the promulgation of appropriate national guidelines. Such a report has in fact been commissioned and its terms of reference include:

- consideration of the selection criteria determining eligibility and the safety and testing requirements for autologous blood services;
- comparison of the extent to which aspects of autologous blood services should resemble the homologous blood donation program;
- determination of the most appropriate institutional settings in which autologous blood services should be provided to the Australian community.

At the time of writing, no final report was available. However, clearly if the Commonwealth was to regulate the area of autologous blood supplies, there would be no further role for NSW.

***Options for discussion***

7. Should NSW defer the question of regulating the supply of autologous blood and blood products pending the outcome of the Commonwealth review of autologous blood services?
8. If not, should there be any regulation by NSW (over and above Commonwealth regulation of pathology laboratories and blood products under the Therapeutic Goods Act 1989 (Cth)) of the supply of autologous blood and blood products?
9. If so, should this regulation be by way of either or both of the following:

- the setting of standards for autologous blood and blood products (such as testing for certain contaminants, storage, transport, etc), allowing any person to supply such products provided that these standards are met;
  - restrictions upon the persons who may supply autologous blood and blood products?
10. If restrictions should be made upon persons who supply autologous blood and blood products, which of the following classes of persons should be permitted to engage in this activity:
- medical practitioners;
  - the Australian Red Cross;
  - CSL Ltd;
  - public and private hospitals;
  - persons authorised by the Department of Health.

### ***[3.6] The need to regulate the supply of directed donations***

As noted above, persons undergoing surgery may request that a family member or friend donate blood for transfusion rather than accept blood from the homologous pool. This is usually because the person making the request is of the view that such a directed donation is safer than homologous blood supplied by the Red Cross. In fact, this may not be the case. Individuals may be reluctant to deny a request for blood from a relative, even though they may have some risk factors which would preclude them from being a Red Cross donor. The risk of bedside transfusion errors is also present. In some cases, directed donations may be warranted, for example, if treatment of a particular condition required matched blood from a relative. Presently, only exempt suppliers are legally able to supply blood for directed donations. The issue of whether directed donations should be regulated, and if so, how, must be considered.

#### ***Options for discussion***

11. Should directed donations be regulated?
12. If so, should directed donations be:
- prohibited;
  - allowed only in certain circumstances;



- regulated in the same manner as the supply of homologous blood and blood products;
- regulated in the same manner as the supply of autologous blood and blood products?

**[3.7] Fees for authorisation applications**

Currently, persons wishing to carry on a business of supplying blood and blood products must make an application for authorisation under the Act. The processing of an application involves the Department in considerable expense, as it requires a premises inspection and various fitness and propriety checks. Ongoing supervision of authorised suppliers is also required.

At present, no application fee is provided for in the legislation. Nor is there any power to charge fees for inspection of authorised suppliers. Should the present system of authorisation continue, a fee may need to be levied upon applications and inspections. It is recognised that this will involve an extra cost for suppliers who already have to bear NATA fees. However, the imposition of a fee may be necessary if the Department is to continue its regulatory role.

**Option for discussion**

13. If the present system of authorising suppliers of blood and blood products continues, should a power to prescribe fees for authorisation applications and inspections be inserted in the Act?

## **PART IV : SPECIAL PROVISIONS CONCERNING THE DONATION OF BLOOD**

### ***[4.1] Background***

The discovery in the 1980s that HIV causing AIDS could be spread through the transfusion of contaminated blood had a significant effect upon blood supplies in NSW. Litigation was instigated against the Red Cross by persons who had become infected with HIV through blood transfusions and Factor VIII. Considerable consternation was felt in the community as to the safety of the State's blood supply and this led to the establishment of a private blood bank, whereby persons could store their own blood for future use rather than rely on the general homologous supply.

Part 3A of the Act ensures a screening process of donors of blood and semen, by requiring that a certificate of medical suitability be obtained in relation to each donor. The Part also provides a defence to suppliers of blood and semen against litigation in relation to the transmission of a contaminant through blood, provided the supplier has taken certain steps outlined in the Act to ensure the safety of the blood or semen. The purpose of the Part is to ensure the continuance of a supply of homologous blood for transfusion and for the manufacture of essential blood products.

### ***[4.2] The present provisions***

#### **Requirement for a medical certificate**

Section 21 of the Act prohibits the removal of blood for homologous transfusion or for other medical, scientific or therapeutic purposes involving a homologous use unless the donor has signed the prescribed certificate of medical suitability.

The certificate to be signed is prescribed in the Human Tissue Regulation and contains various questions designed to expose risk factors in the intending donor for infection with a contaminant transmissible by blood. The current prescribed form was the result of 12 months consultation with interested parties including the Red Cross and has been in effect since 1992.

The penalty for failing to obtain the medical certificate when required by the Act is \$200. There are also penalties for knowingly making a false or misleading statement in a medical certificate (\$5,000 or imprisonment for 1 year or both).

Section 21DA of the Act sets out the statutory defence for suppliers of blood. The defence applies when a person who has become infected with a “prescribed contaminant” or a disease that is attributable to a prescribed contaminant, as a result of the transfusion of blood or blood products or treatment with blood or blood products, or as a result of artificial insemination. The “prescribed contaminants” are listed in the Human Tissue Regulation and are as follows:

- Hepatitis B virus (and Hepatitis B surface antigen);
- Hepatitis C virus (and Hepatitis C antibody);
- Human T-lymphotropic virus Type I (HTLV-I) (and HTLV-I antibody);
- HIV (and HIV antibody); and
- *Treponema pallidum* (syphilis) (and *Treponema pallidum* related antibody).

Any person who has been infected with any of these contaminants in the circumstances noted above who wishes to bring an action against a person in respect of the contamination will be faced with the provisions of subsection (2), (3) or (4) of section 21DA.

Subsection (2) prevents such a person from bringing any action for an offence or for negligence or breach of contract against the donor of the blood unless it is proved that the donor made a statement in the certificate of medical suitability made at the time of donation that was, to their knowledge, false or misleading.

Where the person infected with the contaminant brings proceedings for an offence or in tort or contract against a person other than the donor in respect of the *supply* of blood or blood products, the person against whom the action is brought will have a defence to that action if it can be shown that:

- at the time of supply they were an authorised or exempt supplier;
- if they had removed the blood or blood products from the donor, they had, before the time of supply ensured that:
  - the donor had signed a certificate as to their medical suitability;
  - the blood, or the blood from which the blood product was obtained, had been subjected to tests of a kind approved by the Minister and the test had indicated that no prescribed contaminant was present in the blood;

- if they had obtained the blood or blood products from another person, that other person was an authorised supplier or an exempt supplier; and
- before the time when the blood or blood product was used for transfusion or treatment, they had not become aware that the blood or blood product was, or was likely to have been, contaminated with the prescribed contaminant concerned, or, if before that time, they had become aware of that fact, they had taken all reasonably practicable steps to ensure that the blood or blood product was not used.

Where the person infected with the contaminant brings proceeding against a person in respect of the *transfusion* of, or the *treatment* with, contaminated blood or blood products, that person will have a defence to those proceedings if it can be proved:

- if they had removed the blood or blood products from the donor, they had, before the time of supply ensured that:
  - the donor had signed a certificate as to their medical suitability;
  - the blood, or the blood from which the blood products was obtained, had been subjected to tests of a kind approved by the Minister and the test had indicated that no prescribed contaminant was present in the blood;
- if they had obtained the blood or blood products from another person, that other person was an authorised supplier or an exempt supplier; and
- when the transfusion or treatment was carried out, they were not aware that the blood or blood product was, or was likely to have been, contaminated with the prescribed contaminant concerned.

#### **[4.3] Requirements for the screening of donors**

As stated above, the Act currently requires that all potential donors sign a certificate of medical suitability. However, it does not specifically require that testing be carried out on the donated blood. The fact that testing has been carried out is necessary to claim the benefit of the statutory defence, but the Act itself does not make the testing mandatory. In respect of authorised suppliers of blood and semen, such testing is made mandatory by the terms of their authorisation. However, exempt suppliers are under no statutory obligation to test. This contrasts with the requirements in some other states where testing is mandatory as well as being a prerequisite to claiming the statutory defence.



**Option for discussion**

14. Should the testing of donated blood for prescribed contaminants be mandatory or non-mandatory under the Act in addition to being a prerequisite for claiming the statutory defence?

**[4.4] The statutory defence**

As noted above, the statutory defence offers protection to donors and suppliers of blood and blood products. It is noted that, in this discussion, it is not intended to question the protection the defence offers to individuals who donate blood in good faith. That issue does not impact upon the proper regulatory regime for the supply of blood and blood products. The discussion is concerned only with the protection offered to persons engaged in the businesses of collecting, supplying and/or transfusing blood and blood products.

All the states and territories except Queensland have some “blood shield” legislation in place which protects suppliers of blood from litigation in certain circumstances.<sup>8</sup> The legislation is not uniform, with some applying only to HIV/AIDS and some applying to a range of contaminants.<sup>9</sup> All the legislation requires donors to sign some kind of donor declaration form or medical certificate and for blood to be tested for the contaminant to which the defence relates.

The basis of the defence

The intention of the statutory defence was to codify what would amount to a defence at common law in respect of a negligence action. In other words, the defence applies when the supplier has taken reasonable steps to prevent the transmission of the prescribed contaminant. The statutory defence should, however, operate to limit the number of actions taken against suppliers of blood as it allows prospective plaintiffs to ascertain in advance the factors that will give rise to a successful defence on the part of the defendant and thus the likelihood of success of the plaintiff’s claim.

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<sup>8</sup> Health Act 1958 (Vic); Blood Contaminants Act 1985 (SA); Blood Donation (Limitation of Liability) Act 1985 (WA); Blood Transfusion (Limitation of Liability) Act 1985 (TAS); Notifiable Diseases Act 1985 (NT).

<sup>9</sup> In Victoria, the defence in respect of blood applies to HIV and hepatitis C only (s 132). The SA legislation covers HTLV III (HIV) and any other organism or substance declared by the Commission to be a prescribed contaminant (s 3). The WA, Tas and NT legislation applies only to HIV/AIDS: WA, s 8; Tas, s 5; NT, s 26A.

There are three main factors upon which the statutory defence relies. They are: the exempt or authorised status of the supplier of blood; the obtaining of a signed medical certificate from the donor; and the testing of blood using tests “approved by the Minister”.

#### The exempt or authorised status of the supplier

The statutory defence is available only where the blood has been supplied by an exempt or authorised supplier. Presently, the Regulation prevents authorised suppliers from engaging in the supply of homologous blood. As the defence only applies in respect of homologous blood, the reference to authorised suppliers is, in this provision, otiose.

At paragraph [3.4] and following, the question of abandoning the system of authorising and exempting suppliers of blood is discussed. If such an option is implemented and, instead, standards are prescribed for blood and blood products, the question of who should be given the benefit of the statutory defence will arise. Should the defence be conditional upon meeting standards prescribed in Act? Should the defence be available to private persons who make and distribute blood products, such as pharmaceutical companies, or should it be confined to the Red Cross. Some may question the availability to private persons of a statutory defence to a common law action when the purpose of that defence was to ensure a continued supply of donor blood to the Red Cross.

Related to this is the question of the risk of “moral hazard” posed by the statutory defence. That is, does the existence of the defence provided by the legislation result in the failure to hold entities entirely accountable for the costs of their actions? Further, does this result in entities exercising less care than they otherwise may? It is difficult to come to any conclusions in this regard. It is possible that the mandating of steps which must be taken to claim the benefit of the defence may cause entities to exercise greater care than they otherwise would.

### Subjecting of the blood to approved tests

All the states require blood to be subjected to tests which are approved, or carried out in an approved manner.<sup>10</sup> In NSW, the requirement is that the blood be subjected to “tests of a kind approved by the Minister”. New tests are frequently developed in respect of prescribed contaminants. The Red Cross has utilised at least 5 different tests for detecting HIV infection since testing for that contaminant was introduced in 1984.

Some concern has been raised that the failure to have a test approved by the Minister may result in the loss of the benefit of the statutory defence, even where the test is of the highest quality. Alternatively, the time involved in having a test approved may result in the later implementation of the test than is optimal.

Because the present process of obtaining an approval is necessarily subject to some administrative delays, an alternative requirement in the Act may be to subject the blood to tests which are in accordance with good medical practice. However, while this would remove the administrative requirement of approval, it would also remove that element of certainty in the statutory defence. It may not be possible for a prospective plaintiff to know in advance what tests are in accordance with good medical practice as this would be a matter upon which the court would decide. The deterrent element of certainty of the defence may be diluted.

#### ***Options for discussion***

15. Should the statutory defence in relation to suppliers and transfusers of blood be retained?
16. If so, should it be limited to apply only to the Red Cross and persons transfusing blood supplied by the Red Cross?
17. Should the present requirement that blood be subjected to tests approved by the Minister be amended to a requirement that blood be subjected to tests which are in accordance with good medical practice or some other appropriate standard?

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<sup>10</sup> Health Act 1958 (Vic), s 132; Blood Contaminants Act 1985 (SA), s 4; Blood Donation (Limitation of Liability) Act 1985 (WA), s 9; Blood Transfusion (Limitation of Liability) Act 1985 (Tas), s 4; Notifiable Diseases Act 1985 (NT), s 26C.



#### **[4.5] National blood shield legislation**

One of the recommendations of the McKay Wells Report was that the eight autonomous Red Cross Blood Transfusion Services be subsumed into a single national body, and that national blood shield legislation be enacted in respect of that body.<sup>11</sup> While there have been developments in respect of the nationalisation of the blood transfusion services, the question of national blood shield legislation is still being examined. The status of NSW blood shield legislation will have to be reconsidered if these recommendations of the McKay Wells Report are implemented.

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<sup>11</sup> B McKay, R Wells, *op cit*, paras 1.3 and 1.5, p 2.

## REFERENCES

### Publications

1. B McKay, R Wells, Commonwealth Review of Australian Blood and Blood Product System: Final Report, February 1995.

### Legislation

1. Blood Contaminants Act 1985 (SA)
2. Blood Donation (Limitation of Liability) Act 1985 (WA)
3. Blood Transfusion (Limitation of Liability) Act 1985 (Tas)
4. Notifiable Diseases Act 1985 (NT)
5. Health Act 1958 (VIC)

## APPENDIX 1

### Executive summary of options for discussion

#### BLOOD DONATIONS: PART II

##### *Blood donations by children: para [2.2]*

1. Should the requirement that a medical practitioner advise the parent or guardian of a child from whom blood is to be removed that the removal will not be prejudicial to the health of the child be restricted to children under the age of 16 years?

##### *Removal of blood at certain places: para [2.3]*

2. Should the restriction as to the premises upon which blood may be removed pursuant to a valid consent be repealed?

OR

3. Should the restriction as to the premises on which blood may be removed pursuant to a valid consent be retained, and the premises of authorised suppliers be included in the list of such premises?

#### REGULATING THE SUPPLY OF BLOOD AND BLOOD PRODUCTS: PART III

##### *The need to regulate the supply of homologous blood and blood products: para [3.4]*

4. Should there be any regulation by NSW (over and above Commonwealth regulation of pathology laboratories and blood products under the Therapeutic Goods Act 1989 (Cth)) of the supply of homologous blood and blood products?
5. If so, should this regulation be by way of either or both of the following:
  - the setting of standards for homologous blood and blood products (such as testing for certain contaminants, storage, transport etc), allowing any person to supply such products provided that these standards are met: and/or
  - restrictions upon the persons who may supply homologous blood and blood products?

6. If restrictions should be made upon persons who supply homologous blood and blood products, which of the following class of persons should be permitted to engage in his activity:
- medical practitioners;
  - the Australian Red Cross;
  - CSL Ltd;
  - public and private hospitals;
  - persons authorised by the Department of Health?

***The need to regulate the supply of autologous blood and blood products: para [3.5]***

7. Should NSW defer the question of regulating the supply of autologous blood and blood products pending the outcome of the Commonwealth review of autologous blood services?
8. If not, should there be any regulation by NSW (over and above Commonwealth regulation of pathology laboratories and blood products under the Therapeutic Goods Act 1989 (Cth)) of the supply of autologous blood and blood products?
9. If so, should this regulation be by way of either or both of the following:
- the setting of standards for autologous blood and blood products (such as testing for certain contaminants, storage, transport etc), allowing any person to supply such products provided that these standards are met;
  - restrictions upon the persons who may supply autologous blood and blood products?
10. If restrictions should be made upon persons who supply autologous blood and blood products, which of the following class of persons should be permitted to engage in this activity:
- medical practitioners;
  - the Australian Red Cross;
  - CSL Ltd;
  - public and private hospitals;
  - persons authorised by the Department of Health.

***The need to regulate the supply of directed donations: para [3.6]***

11. Should directed donations be regulated?
12. If so, should directed donations be:

- prohibited;
- allowed only in certain circumstances;
- regulated in the same manner as the supply of homologous blood and blood products;
- regulated in the same manner as the supply of autologous blood and blood products?

***Fees for authorisation applications: para [3.7]***

13. If the present system of authorising suppliers of blood and blood products continues, should a power to prescribe fees for authorisation applications, and inspections be inserted in the Act?

**SPECIAL PROVISIONS CONCERNING THE DONATION OF BLOOD: PART IV**

***Requirements for the screening of donors: para [4.3]***

14. Should the testing of donated blood for prescribed contaminants be mandatory or non-mandatory under the Act in addition to being a prerequisite for claiming the statutory defence?

***The statutory defence: para [4.4]***

15. Should the statutory defence in relation to suppliers and transfusers of blood be retained?
16. If so, should it be limited to apply only to the Red Cross and persons transfusing blood supplied by the Red Cross?
17. Should the requirement that blood be subjected to tests approved by the Minister be altered to a requirement that blood be subjected to tests which are in accordance with good medical practice or some other appropriate standard?

**APPENDIX 2 - HUMAN TISSUE ACT 1983 (EXTRACTS)  
PART 3—BLOOD DONATIONS**

**Part 2 not to apply to removal of blood**

18. Part 2 does not apply to or in respect of the removal of blood from the body of a person in accordance with this Part.

**Consents to removal of blood from adults**

19. A person, other than a child, may consent to the removal of blood from the person's body for the purpose of:
- (a) its transfusion to another person; or
  - (b) its use, or the use of any of its constituents, for other therapeutic purposes or for medical purposes or scientific purposes.

**Consents to removal of blood from children**

20. A parent or guardian of a child may consent to the removal of blood from the child's body for a purpose referred to in section 19 (a) or (b) if:
- (a) a medical practitioner advises the parent or guardian that the removal of blood is not likely to be prejudicial to the health of the child; and
  - (b) the child is in agreement with the proposed removal of blood.

**Effect of consent under section 19 or 20**

21. A consent given under section 19 or 20 is sufficient authority for the removal of blood from the body of the person who has given the consent, or from the body of the child to whom the consent relates, as the case may be:
- (a) at a hospital;
  - (b) at premises, used by the Australian Red Cross Society, or by any other body approved by the Minister for the purposes of this paragraph, in connection with the removal of blood from the bodies of persons; or
  - (c) at prescribed premises or in premises of a prescribed class or description.
  - (d) \* \* \* \* \*

**PART 3A—SPECIAL PROVISIONS CONCERNING  
DONATIONS OF BLOOD OR SEMEN**

- 21A. \* \* \* \* \*

**Application of Part**

- 21B. This Part applies:
- (a) to blood that is removed from a donor:
    - (i) for the purpose of transfusing some or all of the blood to a person other than the donor; or
    - (ii) for the purpose of using some or all of the blood for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of a person other than the donor;
  - (b) to blood products derived or extracted from blood of the kind referred to in paragraph (a); and
  - (c) to semen obtained or received from a donor for the purpose of using some or all of the semen for the artificial insemination of a woman.

## Certificates by donors

**21C. (1)** A person shall not:

- (a) remove any donor's blood intended:
  - (i) for the purpose of its transfusion; or
  - (ii) for the purpose of its use, or the use of any of its constituents, for therapeutic purposes, or for medical purposes or scientific purposes; or
- (b) obtain or receive any donor's semen intended for use for the artificial insemination of a woman,

unless the donor has signed a certificate relating to the medical suitability of the donor, being a certificate in or to the effect of the prescribed form, and had the signature witnessed by a prescribed person or a person of a prescribed class, at the time of the removal of the blood, or the obtaining or receipt of the semen, as the case may be.

Maximum penalty: 2 penalty units.

**(2)** Where:

- (a) blood has been removed solely for a purpose other than a purpose referred to in section 21B (a); or
- (b) semen has been obtained or received solely for a purpose other than the purpose referred to in section 21B (c),

a person shall not subsequently use the blood for any purpose referred to in section 21B (a) or use semen for the purpose referred to in section 21B (c) unless the donor has signed a certificate relating to the medical suitability of the donor, being a certificate in or to the effect of the prescribed form, and had the signature witnessed by a prescribed person or a person of a prescribed class, at the time of, or at any time after, the removal of the blood, or the obtaining or receipt of the semen, as the case may be, and before the use of the blood or semen.

Maximum penalty: 2 penalty units.

**(3)** Where a donor is required by subsection (1) or (2) to sign a certificate and have the signature witnessed and the donor is, by reason of illiteracy or physical incapacity, incapable of signing the certificate, the donor shall be deemed to have signed the certificate and had the signature witnessed in accordance with that requirement if:

- (a) in the case of a donor who is illiterate but not physically incapable of signing—the donor makes his or her mark on the certificate and a prescribed person or a person of a prescribed class witnesses the making of the mark and certifies on the certificate that, before the mark was made, the nature and effect of the certificate were explained to the donor; or
- (b) in the case of a donor who is physically incapable of signing—a person authorised to do so by the donor has signed the certificate on the donor's behalf and a prescribed person or a person of a prescribed class witnesses that signature.

(4) This section does not apply in respect of semen obtained or received from a donor solely for the purpose of its use for the artificial insemination of the donor's spouse.

## False or misleading statements

**21D.** A person shall not, for the purposes of this Part, sign a certificate which contains any statement which, to that person's knowledge, is false or misleading in a material particular.  
Maximum penalty: 50 penalty units or imprisonment for one year, or both.

**Restrictions as to legal proceedings involving infection by a prescribed contaminant etc.**

**21DA. (1) If:**

- (a) a person has become infected with a prescribed contaminant, or a disease that is attributable to a prescribed contaminant; and
- (b) the contaminant was or may have been transmitted to that person:
  - (i) as a result of a transfusion of blood or a blood product or of any other treatment involving the use of blood or a blood product; or
  - (ii) in the case of a woman who has been artificially inseminated—as a result of the artificial insemination,

the provisions of subsection (2), (3) or (4) apply according to the circumstances of the case.

**(2)** Proceedings for an offence (except an offence against section 21D) or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) may not be brought against the donor of the blood or semen concerned in the infection, unless it is proved in the proceedings:

- (a) that the donor has previously been found guilty of an offence against section 21D or of an offence against a law of another State or a Territory that corresponds to that section; or
- (b) that the donor would have been found guilty of such an offence had the donor been charged with such an offence.

**(3)** If proceedings for an offence or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) are brought against a person (other than the donor) in respect of a supply by that person, or an employee of that person, of blood, a blood product or semen, it is a defence in those proceedings for the defendant to prove that:

- (a) at the time of supply, the defendant was an authorised supplier or an exempt supplier;
- (b) if the defendant or an employee of the defendant removed the blood or the blood from which the blood product was derived or extracted, or had obtained or received the semen, from the donor—the defendant or that employee had, before supply, ensured that:
  - (i) the donor had signed either a certificate of the kind referred to in section 21C or a similar document as to the medical suitability of the donor to provide blood for a purpose referred to in section 21B (a) or to provide semen for the purpose referred to in section 21B (c); and
  - (ii) the blood, the blood from which the blood product was derived or extracted or, as the case may be, the blood of the donor of the semen had been subjected to tests of a kind approved by the Minister for the purposes of this section and those tests had indicated that no prescribed contaminant was present in that blood;



- (c) if the defendant or an employee of the defendant obtained the blood, blood product or semen from another person—that other person was an authorised supplier or an exempt supplier; and
- (d) before the time when the blood or blood product used for transfusion to, or for otherwise treating, the infected person, or the time when the semen was used for the artificial insemination of the infected woman, the defendant had not become aware that the blood, blood product or semen was or was likely to have been contaminated with the prescribed contaminant concerned or, if, before that time, the defendant had become aware of that fact, the defendant had taken all reasonably practicable steps to ensure that the blood, blood product or semen was not so used.

**(4)** If proceedings for an offence or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) are brought against the person who carried out the transfusion, treatment or artificial insemination or the employer or any supervisor of that person, it is a defence in those proceedings for the defendant to prove that:

- (a) if the defendant or an employee of the defendant removed the blood or the blood from which the blood product was derived or extracted, or obtained or received the semen, from the donor directly, the defendant or that employee had ensured that:
  - (i) the donor had signed either a certificate of the kind referred to in section 21C or a similar document as to the medical suitability of the donor to provide blood for a purpose referred to in section 21B (a) or to provide semen for the purpose referred to in section 21B (c); and
  - (ii) the blood, the blood from which the blood product was derived or extracted or, as the case may be, the blood of the donor of the semen had been subjected to tests of a kind approved by the Minister for the purposes of this section and those tests had indicated that no prescribed contaminant was present in that blood;
- (b) if the defendant or an employee of the defendant obtained the blood, blood product or semen from another person—that other person was an authorised supplier or an exempt supplier; and
- (c) when the transfusion, treatment or artificial insemination was carried out, the defendant was not aware that the blood, blood product or semen was or was likely to have been contaminated with the prescribed contaminant concerned.

### **Records**

**21E.** The regulations may provide for the keeping of certificates given for the purposes of this Part and for the making and keeping of records in respect of those certificates.

## **PART 3B—REGULATION OF BUSINESSES SUPPLYING BLOOD, BLOOD PRODUCTS OR SEMEN**

### **Definitions**

**21F. (1)** In this Part:

- (a) a reference to carrying on a business of supplying blood or blood products is a reference to carrying on a business or undertaking of supplying blood or blood products to medical institutions and other persons:

- (i) with a view to transfusing some or all of the blood or blood products to persons; or
  - (ii) with a view to using some or all of the blood or blood products for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons; and
- (b) a reference to carrying on a business of supplying semen is a reference to carrying on a business or undertaking of supplying semen to medical institutions and other persons for the purpose of using some or all of the semen for the artificial insemination of women.

**(2)** In this Part:

“authorisation” means an authorisation issued by the Secretary under section 21I;

“inspector” means a person holding office as an inspector under section 21P;

“Secretary” means the Secretary of the Department of Health or a person acting in that position.

**Unauthorised persons prohibited from carrying on a business of supplying blood, blood products or semen**

**21G. (1)** A person shall not:

- (a) carry on a business of supplying blood, blood products or semen; or
- (b) participate in the management of such a business, unless there is in force in respect of that business an authorisation in writing issued under section 21I.

**(2)** Subsection (1) does not apply to an exempt supplier.

**Applications for authorisations**

**21H. (1)** Any person who wishes to carry on a business of supplying blood, blood products or semen may make an application in writing to the Secretary for an authorisation.

**(2)** An application under subsection (1) must contain or be accompanied by such particulars as may be prescribed with respect to:

- (a) the applicant;
- (b) the business of supplying blood, blood products or semen proposed to be carried on by the applicant;
- (c) the persons who are to be employed in that business; and
- (d) the premises at which it is proposed to carry on the business.

**(3)** As soon as practicable after receiving an application made under subsection (1), the Secretary shall proceed to consider and dispose of the application.

**Issue of authorisations etc.**

**21I. (1)** The Secretary may refuse to issue an authorisation applied for under section 21H on the ground that:

- (a) the application does not contain or is not accompanied by the prescribed particulars;
- (b) the applicant, or any person who is to be concerned in the management of the business proposed to be carried on by the applicant, is not a fit and proper person to carry on or be concerned in the management of the business of supplying blood, blood products or semen;
- (c) the persons or any of the persons proposed to be employed in the business proposed to be carried on by the applicant do not hold

- the prescribed qualifications in relation to particular functions to be performed in connection with that business;
- (d) the premises at which it is proposed to carry on the business do not satisfy the prescribed requirements or will contravene prescribed restrictions;
  - (e) the Secretary is of the opinion that the health of the community would be jeopardised; or
  - (f) the Secretary is of the opinion that the applicant would, if issued with an authorisation, be unable to comply with the prescribed conditions applicable to the authorisation,
- but otherwise the Secretary must issue an authorisation.
- (2)** If the Secretary refuses to issue an authorisation applied for under section 21H, the Secretary must notify the applicant in writing of the refusal and the grounds on which it is based.
- (3)** An authorisation is subject to such conditions and restrictions as are prescribed or as are imposed under subsection (4).
- (4)** In issuing an authorisation, the Secretary may impose such conditions and restrictions, not inconsistent with this Part or the regulations, as appear to be necessary to maintain the health of the community.
- (5)** An authorisation shall remain in force on and from the date of its issue until revoked by the Secretary.
- (6)** The Secretary shall not refuse to issue an authorisation without giving the applicant for the authorisation an opportunity to be heard.

#### **Variation and revocation of conditions and restrictions of authorisation**

**21J.** The Secretary may from time to time, by notice in writing served on the holder of an authorisation:

- (a) vary a condition or restriction imposed in respect of the authorisation under section 21I (4) or paragraph (b);
- (b) impose in respect of the authorisation such additional conditions and restrictions on that holder as appear to the Secretary necessary to preserve the health of the community; or
- (c) revoke a condition or restriction imposed in respect of the authorisation under section 21I (4) or paragraph (b).

#### **Revocation or suspension of authorisations**

**21K. (1)** If the Secretary is satisfied that the holder of an authorisation is failing or has failed to comply with or is contravening or has contravened a condition or restriction to which the authorisation is subject, the Secretary may, by notice in writing served on the holder of the authorisation, either revoke the authorisation or suspend its operation for a period not exceeding 90 days.

**(2)** An authorisation may be revoked under subsection (1) even though its operation is suspended at the relevant time.

**(3)** If the operation of an authorisation is suspended under subsection (1), the authorisation shall, for the purposes of section 21G, be deemed to have been revoked.

**(4)** The Secretary shall not revoke an authorisation without giving the holder of the authorisation an opportunity to be heard.

**(5)** If the holder of an authorisation surrenders the authorisation to the Secretary with a request for revocation, the Secretary must immediately revoke the authorisation.

#### **Offences under Part 3B**

**21L.** A person who:

- (a) contravenes section 21G; or

- (b) fails to comply with or contravenes a condition or restriction to which an authorisation is subject, is guilty of an offence and liable to a penalty not exceeding 100 penalty units.

#### **Presumptions in certain legal proceedings**

**21M.** If in any legal proceedings relating to an alleged contravention of section 21G it is proved that:

- (a) a person, other than the donor:
  - (i) has supplied blood or blood products on at least 2 occasions to one or more persons for the purpose of transfusion to other persons or for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons; or
  - (ii) has supplied semen on at least 2 occasions to one or more persons for the purpose of artificially inseminating women; or
- (b) a person, other than the donor, has kept on premises occupied by that person blood or blood products or, as the case may be, semen in excess of the prescribed quantity,

it shall, until the contrary is proved, be presumed for the purposes of those proceedings that the person was carrying on a business of supplying blood or blood products or of supplying semen.

#### **Offences by directors of corporations etc.**

**21N. (1)** If a corporation contravenes, whether by act or omission, any provision of this Part or a regulation made for the purposes of this Part, each person who is a director of the corporation or who is concerned in the management of the corporation shall be deemed to have contravened the same provision if the person knowingly authorised or permitted the contravention.

**(2)** A person may be proceeded against under a provision pursuant to subsection (1) whether or not the corporation has been proceeded against under that provision.

**(3)** Nothing in this section affects any liability imposed on a corporation for an offence committed by the corporation against this Part or a regulation made for the purposes of this Part.

#### **Time at which decision of the Secretary under section 21J or 21K is to have effect**

**21O.** A decision of the Secretary under section 21J or 21K takes effect on the day after the day on which notice of the decision is served on the authorised supplier concerned or at such later time as may be specified in the notice.

#### **Inspectors**

**21P. (1)** The Secretary may appoint any officer of the Department of Health, or any person whom the Secretary considers to be suitably qualified for the purpose, to be an inspector for the purposes of this Part.

**(2)** On appointing an inspector under subsection (1), the Secretary shall issue to the inspector a certificate of authority authorising the inspector to exercise the powers conferred by section 21Q.

#### **Powers of inspectors**

**21Q. (1)** An inspector may exercise all or any of the following powers for the purposes of this Part:

- (a) the power at all reasonable times to enter and inspect all premises for the purpose of ascertaining whether or not a provision of this Part or a regulation made for the purposes of this Part is not being or has not been complied with or is being or has been contravened;
- (b) the power to inspect:
  - (i) all blood, blood products or semen kept on those premises;
  - (ii) all containers that the inspector reasonably believes to contain or to have contained blood, blood products or semen; and
  - (iii) all equipment kept on the premises that the inspector reasonably believes to be or to have been used for processing, packing or storing blood, blood products or semen;
- (c) the power to take and remove for analysis or testing a sample of any blood, blood product or semen kept on the premises;
- (d) the power to inspect all records kept on those premises and the power to require any person whom the inspector reasonably believes to have custody or control of those records to produce them for inspection;
- (e) without limiting paragraph (d), the power to inspect, and the power to require a person to produce for inspection, any records in the custody or under the control of the person, being records which relate:
  - (i) to the question of whether or not a provision of this Part or a regulation made for the purposes of this Part is not being or has not been complied with or is being or has been contravened; or
  - (ii) to financial transactions relating to a business of supplying blood, blood products or semen;
- (f) if any records inspected, produced or required to be produced in accordance with paragraph (d) or (e):
  - (i) are not in writing;
  - (ii) are not written in the English language; or
  - (iii) are not decipherable on sight,the power to require the person who has custody or control of those records to produce a statement in the English language and decipherable on sight setting out the contents of those records;
- (g) the power to make and take away copies of the whole or any part of a record inspected or produced in accordance with paragraph (d) or (e) or a statement produced in accordance with paragraph (f);
- (h) the power to seize and detain:
  - (i) any blood, blood product or semen in relation to which the inspector reasonably believes an offence against this Part or against a regulation made for the purposes of this Part is being or has been committed;
  - (ii) any container in which any such blood, blood product or semen is kept; and
  - (iii) any equipment which the inspector reasonably believes is being or has been used in connection with any such offence;
- (i) the power:
  - (i) to place any blood, blood product or semen, referred to in paragraph (h), in a container;
  - (ii) where any blood, blood product, semen, container or equipment referred to in that paragraph has been seized

on premises entered in accordance with paragraph (a), to place the blood, blood product, semen, container or equipment in a room, compartment or cabinet located on those premises; and

- (iii) to mark, fasten and seal that container or, as the case may be, the door or opening providing access to that room, compartment or cabinet;
- (j) in order to make copies of records or of parts of records which may be inspected in accordance with paragraph (d) or (e) or of statements produced in accordance with paragraph (f), the power to take away and retain, for such period as may be reasonably necessary, any such records or statements;
- (k) if the inspector concerned reasonably believes that any such records or statements are evidence of an offence against this Part or a regulation made for the purposes of this Part, the power to take away and retain those records or statements until proceedings for the offence have been disposed of.

**(2)** Subsection (1) (a) does not authorise an inspector to effect an entry to premises by the use of force or to enter a part of premises that is used for residential purposes without the consent of the occupier of that part.

**(3)** Before taking away a record or statement under subsection (1), an inspector must tender an appropriate receipt to the person from whom it is taken.

**(4)** Any blood, blood product, semen, container or equipment seized under subsection (1) (h) may, at the option of the inspector who made the seizure or another inspector acting in place of that inspector, be detained on the premises where it was found or be removed to other premises and detained there.

**(5)** If any information whatever is given to an inspector by an officer of a corporation which is carrying on or has carried on a business of supplying blood, blood products or semen, the information is, for the purposes of any proceedings against the corporation for an offence against this Part or a regulation made for the purposes of this Part, binding on and admissible in evidence against the corporation, unless it is proved that the information was given in relation to a matter in respect of which the officer had no authority to bind the corporation.

**(6)** The provisions of subsection (5) are in addition to any enactment or rule of law relating to the binding effect and admissibility in evidence of statements made by an officer of a corporation.

**(7)** In subsections (5) and (6), "officer", in relation to a corporation, has the same meaning as that expression has in the Companies (New South Wales) Code.

### **Obstruction etc. of inspectors**

**21R. (1)** A person who:

- (a) prevents or attempts to prevent an inspector from exercising the power conferred by section 21Q (1) (a);
- (b) hinders or obstructs an inspector in the exercise of any of the other powers conferred by section 21Q; or
- (c) fails or refuses to comply with a requirement made under that section,

is guilty of an offence and liable to a penalty not exceeding 10 penalty units or to imprisonment for a term not exceeding 3 months.

**(2)** A person is not guilty of an offence under subsection (1) unless:

- (a) it is established by the prosecutor that the inspector concerned produced at the relevant time the certificate of authority issued to the inspector under section 21P (2);

- (b) where the offence arises under subsection (1) (a) or (b)—it is established by the prosecutor that the person was informed by the inspector concerned, or otherwise knew, that that inspector was empowered to exercise the power to which the offence relates; or
- (c) where the offence arises under subsection (1) (c)—it is established by the prosecutor that the inspector concerned warned the person that a failure or refusal to comply with the requirement was an offence.

### Disposal of seized articles

#### **21S. (1) If:**

- (a) any blood, blood product, semen, container or equipment seized under section 21Q (1) (h):
  - (i) has not been disposed of as referred to in subsection (2); or
  - (ii) in the case of blood, a blood product or semen, has not been destroyed under subsection (5), and no application for disallowance of the seizure has been made within the period allowed by section 21T (1); or
- (b) any such application has been made within that period and the application has been refused or withdrawn before a decision in respect of the application has been made,

the blood, blood product, semen, container or equipment shall be forfeited to the Crown and may be destroyed or disposed of in such manner as the Secretary directs.

#### **(2) If:**

- (a) any blood, blood product, semen, container or equipment seized under section 21Q (1) (h):
  - (i) has not been forfeited by virtue of subsection (1); or
  - (ii) in the case of blood, a blood product or semen, has not been destroyed under subsection (5); and
- (b) the Secretary is satisfied that no failure to comply with or contravention of any of the provisions of this Part or of the regulations made for the purposes of this Part has been committed in relation to the blood, blood product, semen, container or equipment,

the Secretary shall immediately cause the blood, blood product, semen, container or equipment to be delivered to such person as appears to the Secretary to be entitled to it.

#### **(3) If:**

- (a) any blood, blood product, semen, container or equipment seized under section 21Q (1) (h) is forfeited to the Crown by virtue of subsection (1) because no application for disallowance of the seizure was made within the period allowed by section 21T (1);
- (b) the Secretary is satisfied that no failure to comply with or contravention of any of the provisions of this Part or of any regulations made for the purposes of this Part has been committed in relation to the blood, blood product, semen, container or equipment; and
- (c) the blood, blood product, semen, container or equipment has not been destroyed or disposed of in a manner that would prevent it from being dealt with in accordance with this subsection,

the Secretary shall immediately cause the blood, blood product, semen, container or equipment to be delivered to such person as appears to the Secretary to be the person who would, but for the forfeiture, have been entitled to it.

**(4)** If any blood, blood product, semen, container or equipment is delivered to a person in accordance with subsection (3), such proprietary

and other interests as existed immediately before the forfeiture are revived.

**(5)** If:

- (a) an inspector who has seized any blood, blood product or semen under section 21Q (1) (h) is satisfied on reasonable grounds that the blood, blood product or semen contains a prescribed contaminant; and
- (b) the blood, blood product or semen is not required or is no longer required to be retained for the purposes of any legal proceedings, the inspector shall cause the blood, blood product or semen to be destroyed.

### **Disallowance of seizure**

**21T. (1)** Any person claiming to be entitled to any blood, blood product, semen, container or equipment seized under section 21Q (1) (h) may, within 10 days after the date on which the seizure took place, make an application to the District Court for an order disallowing the seizure of the blood, blood product, semen, container or equipment.

**(2)** An application made under subsection (1) shall not be heard unless the applicant has previously served a copy of the application on the Secretary.

**(3)** The Secretary is entitled to appear as respondent at the hearing of an application made under subsection (1).

**(4)** The District Court shall, on the hearing of an application made under subsection (1), make an order disallowing the seizure:

- (a) if it is proved by or on behalf of the applicant that the applicant would, but for the seizure, be entitled to the blood, blood product, semen, container or equipment and if it is not proved by or on behalf of the respondent beyond all reasonable doubt that an offence was being or had been at the time of the seizure, committed in relation to the blood, blood product, semen, container or equipment; or
- (b) if, in the opinion of the Court, there are exceptional circumstances justifying the making of an order disallowing the seizure, but otherwise the Court must refuse the application.

**(5)** If on the hearing of an application made under subsection (1) it appears to the District Court that the blood, blood product, semen, container or equipment that is the subject of the application is required to be produced in evidence in any pending proceedings in connection with an offence against this Part or against any regulation made for the purposes of this Part, the Court may, either on the application of the respondent or on its own motion, adjourn the hearing until the conclusion of those proceedings.

**(6)** If the District Court makes an order under subsection (4) disallowing the seizure of any blood, blood product, semen, container or equipment, the Court must also make one or both of the following orders:

- (a) an order directing the respondent to cause the blood, blood product, semen, container or equipment to be delivered to the applicant or to such other person as appears to the Court to be entitled to it;
- (b) where the blood, blood product, semen, container or equipment cannot for any reason be so delivered or has in consequence of the seizure depreciated in value, an order directing the Secretary to pay to the applicant such amount by way of compensation as the Court considers to be just and reasonable.

**(7)** The award of costs with respect to the hearing of an application made under subsection (1) is in the discretion of the District Court.



(8) If the District Court makes an order for the payment of any amount as compensation under subsection (6) (b) or awards any amount as costs under subsection (7), that order is enforceable as a judgment of the Court.

### **Injunctions**

**21U. (1)** If a person has engaged, is engaging or is proposing to engage in any conduct that constituted, constitutes or would constitute a contravention of section 21G, the Supreme Court may, on the application of the Secretary, grant an injunction restraining the person from engaging in that conduct and, if in the opinion of the Court it is desirable to do so, requiring the person to do any act or thing.

**(2)** If an application is made to the Supreme Court for an injunction under subsection (1), the Court may, if in the opinion of the Court it is desirable to do so, before considering the application, grant an interim injunction restraining a person from engaging in conduct of the kind referred to in subsection (1) pending the determination of the application.

**(3)** The Supreme Court may rescind or vary an injunction granted under subsection (1) or (2).

**(4)** If an application is made to the Supreme Court for the grant of an injunction restraining a person from engaging in conduct of a particular kind, the power of the Court to grant the injunction may be exercised:

- (a) where the Court is satisfied that the person has engaged in conduct of that kind—whether or not it appears to the Court that the person intends to engage again, or to continue to engage, in that conduct; or
- (b) where it appears to the Court that, in the event of the injunction not being granted, it is likely that the person will engage in conduct of that kind—whether or not the person has previously engaged in conduct of that kind.

### **Service of notices**

**21V. (1)** A notice required under this Part to be served on an authorised supplier may be served:

- (a) if the authorised supplier is a person other than a body corporate:
  - (i) by delivering it to that person personally; or
  - (ii) by sending it by post addressed to that person at the supplier's residence or at any place at which the supplier carries on business, whether of supplying blood, blood products or semen or not; or
- (b) if the authorised supplier is a body corporate:
  - (i) by leaving it with a director or the secretary of the body corporate; or
  - (ii) by sending it by post addressed to the body corporate at its registered office or, if its registered office is not located in New South Wales, to the principal place of business of the body corporate in New South Wales.

**(2)** Subsection (1) does not affect the operation of any law authorising a document to be served in a manner not provided for by that subsection.

## **APPENDIX 3 - HUMAN TISSUE REGULATION 1995 UNDER THE HUMAN TISSUE ACT 1983**

2. Commencement
3. Definitions
4. Prescribed definitions: section 4
5. Designated specialists: sec. 5
6. Certificates relating to blood and semen donors: sec. 21C
7. Prescribed witnesses in relation to certificates by donors: sec. 21C
8. Keeping of certificates: sec. 21C
9. Applications for authorisations: secs. 21H and 21I
10. Qualifications for persons performing particular functions: sec. 21I
11. Requirements for premises: sec. 21I
12. Conditions to which authorisations are subject: sec. 21I
13. Prescribed quantities of blood: sec. 21M
14. Repeal

### SCHEDULE 1—FORMS

### SCHEDULE 2—PARTICULARS TO ACCOMPANY APPLICATION FOR AUTHORISATION TO CARRY ON BUSINESS OF SUPPLYING BLOOD, BLOOD PRODUCTS OR SEMEN

### SCHEDULE 3—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF BLOOD OR BLOOD PRODUCTS

### SCHEDULE 4—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF SEMEN

#### Citation

1. This Regulation may be cited as the Human Tissue Regulation 1995.

#### Commencement

2. This Regulation commences on 1 September 1995.

#### Definitions

3. (1) In this Regulation:

(i) "AS 3864" means the Australian Standard Specification entitled "Medical Refrigeration Equipment for the Storage of Blood and Blood Products and Containers for the Transport of Blood and Blood Products" and numbered AS 3864 of the Standards Association of Australia, as in force on 1 September 1995;

(ii) "Director-General" means the Director-General of the Department of Health;

(iii) "the Act" means the Human Tissue Act 1983.

(2) In this Regulation, a reference to a form is a reference to a form set out in Schedule 1.

#### Prescribed definitions: section 4

4. (1) The following organisms and substances are declared to be prescribed contaminants for the purposes of the Act:

Hepatitis B virus

Hepatitis B surface antigen

Hepatitis C virus

Hepatitis C antibody

Human T-lymphotropic virus Type-I (HTLV-I)

Human T-lymphotropic virus Type-I (HTLV-I) antibody

Human immunodeficiency virus  
Human immunodeficiency virus antibody  
Treponema pallidum  
Treponema pallidum related antibody

(2) For the purposes of the Act, a body is an exempt supplier of blood products to the extent that the body supplies blood products that are therapeutic goods within the meaning of the Therapeutic Goods Act 1989 of the Commonwealth and that are:

- (a) registered goods within the meaning of that Commonwealth Act, or
- (b) exempt goods for the purposes of Part 3 of that Act.

(3) Goods are taken not to be exempt goods for the purposes of subclause (2) (b) if the body does not comply with the conditions (if any) of the relevant exemption that apply to the body.

Designated specialists: sec. 5

5. For the purposes of section 5 (2) (b) of the Act, the following classes of medical practitioners are prescribed:

- (a) Fellows of the Australian and New Zealand College of Anaesthetists;
- (b) Fellows of the Royal Australasian College of Physicians;
- (c) Fellows of the Royal Australasian College of Surgeons;
- (d) Fellows of the Royal Australian College of Obstetricians and Gynaecologists.

Certificates relating to blood and semen donors: sec. 21C

6. For the purposes of section 21C (1) and (2) of the Act, the prescribed form is:

- (a) Form 1, except in the case of a form to be completed by a donor referred to in paragraph (b); and
- (b) Form 2, in the case of a form to be completed by a donor who donates blood solely for the purpose of clinical trials approved by the Director-General.

Prescribed witnesses in relation to certificates by donors: sec. 21C

7. (1) For the purposes of section 21C (1) of the Act, a prescribed person is:

- (a) a medical practitioner; or
- (b) a nurse; or
- (c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the blood is to be removed or where the semen is to be obtained or received.

(2) For the purposes of section 21C (2) of the Act, a prescribed person is:

- (a) a medical practitioner; or
- (b) a nurse; or
- (c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the blood is to be removed or used or where the semen is to be obtained, received or used.

(3) For the purposes of section 21C (3) (a) and (b) of the Act, a prescribed person is:

- (a) a medical practitioner; or
- (b) a nurse; or

- (c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the certificate is signed. Keeping of certificates: sec. 21C

8. (1) A certificate signed for the purposes of section 21C (1) of the Act is to be retained, for a period of not less than 10 years from the date on which it was signed, by the person by whom the blood was removed or by whom the semen was obtained or received.

(2) A certificate signed for the purposes of section 21C (2) of the Act is to be retained, for a period of not less than 10 years from the date on which it was signed, by the person by whom the blood or semen was used.

(3) If the person who removed or used the blood, or obtained, received or used the semen, did so in the person's capacity as an employee or agent of some other person or body, that other person or body is to retain the relevant certificate.

Maximum penalty: 2 penalty units.

Applications for authorisations: secs. 21H and 21I

9. For the purposes of sections 21H and 21I of the Act, the prescribed particulars to be contained in or to accompany an application for an authorisation to carry on a business of supplying blood, blood products or semen are those specified in Schedule 2.

Qualifications for persons performing particular functions: sec. 21I

10. (1) The qualifications specified in this clause are prescribed for the purposes of section 21I (1) (c) of the Act.

(2) A person employed to superintend the collection, testing, storage or supply of blood or blood products, or the keeping of records relating to that collection, testing, storage or supply, must be a Fellow of the Royal College of Pathologists of Australasia or a medical practitioner recognised by that College as a specialist pathologist.

(3) A person employed to superintend the collection, testing, storage or supply of semen, or the keeping of records relating to that collection, testing, storage or supply, must be a medical practitioner.

(4) A person employed to collect blood from donors must be:

- (a) a medical practitioner; or
- (b) a registered nurse; or
- (c) an enrolled nurse working under the direct supervision of a registered nurse.

Requirements for premises: sec. 21I

11. (1) The requirements specified in this clause are prescribed for the purposes of section 21I (1) (d) of the Act.

(2) Premises used for carrying on the business of supplying blood or blood products must include the following:

- (a) a reception area;
- (b) an area set aside for the processing of blood for storage;
- (c) an area set aside for the storage of blood and blood products;
- (d) an area set aside for the secure storage of records relating to the collection, identification, testing, storage and supply of blood and blood products;
- (e) if blood is to be collected from donors at the premises:
  - (i) a blood collection room; and
  - (ii) a recovery and refreshment area;
- (f) if testing of blood for prescribed contaminants is to be carried out on the premises, a laboratory set aside for that purpose.

(3) An area set aside for the storage of blood and blood products must be equipped with one or more refrigerators that comply with the relevant provisions of AS 3864.

- (4) Premises used for carrying on the business of supplying semen must include the following:
- (a) a reception area;
  - (b) an area set aside for the processing of semen for storage;
  - (c) an area set aside for the storage of semen;
  - (d) an area set aside for the secure storage of records relating to the collection, identification, testing, storage and supply of semen;
  - (e) if semen is to be provided by donors at the premises, semen collection rooms;
  - (f) if testing of semen for prescribed contaminants is to be carried out on the premises, a laboratory set aside for that purpose.
- (5) An area set aside for the storage of semen must be equipped with one or more cryo-storage vessels for the storage of semen in liquid nitrogen.

Conditions to which authorisations are subject: sec. 211

12. For the purposes of section 211 (3) of the Act:
- (a) the conditions set out in Schedule 3 are prescribed in respect of an authorisation to carry on the business of supplying blood or blood products; and
  - (b) the conditions set out in Schedule 4 are prescribed in respect of an authorisation to carry on the business of supplying semen.

Prescribed quantities of blood: sec. 21M

13. For the purposes of section 21M (b) of the Act:
- (a) the prescribed quantity of blood is 1 litre; and
  - (b) the prescribed quantity of blood products is, in relation to any particular kind of blood product, the quantity of blood products of that kind that is equivalent to the quantity of blood products of that kind that can be derived or extracted from 1 litre of blood; and
  - (c) the prescribed quantity of semen is 1 millilitre.

Repeal

14. (1) The Human Tissue Regulation 1984 is repealed.  
(2) Any act, matter or thing that, immediately before the repeal of the Human Tissue Regulation 1984, had effect under that Regulation is taken to have effect under this Regulation.

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## SCHEDULE 1—FORMS

### Form 1

(Cl. 6 (a))

## HUMAN TISSUE ACT 1983

*(Section 21C)*

### *\*PART A—CERTIFICATE BY PERSON DONATING BLOOD*

#### *BEFORE YOU GIVE BLOOD*

There are some people in the community who **MUST NOT** donate blood because it may transmit infections to patients who receive it.

You must complete this form if you want to donate blood. If you do not know how to answer any of the questions, please check with the interviewing sister. It is against the law to knowingly make a false or misleading statement. If you do, you may receive a \$5,000 fine or 1 year in prison, or both.

TO THE BEST OF MY KNOWLEDGE MY ANSWERS TO THE FOLLOWING  
QUESTIONS ARE TRUE

- |     |   |                                 |                            |
|-----|---|---------------------------------|----------------------------|
| 1.  | Have you any reason to believe that:<br>—you have AIDS (Acquired Immune Deficiency Syndrome)?<br>—you have been infected with the virus that causes AIDS (HIV)? | Yes                             | No                         |
|     |   | Yes                             | No                         |
| 2.  | In the last 6 months have you had:<br>—night sweats?<br>—unexplained weight loss?<br>—persistent fever?<br>—diarrhoea?<br>—swollen glands                       | Yes<br>Yes<br>Yes<br>Yes<br>Yes | No<br>No<br>No<br>No<br>No |
| 3.  | Have you had male to male sexual activity since 1977?   | Yes                             | No                         |
| 4.  | Have you had sexual activity with a bisexual male since 1977?   | Yes                             | No                         |
| 5.  | Have you had sexual activity with any person who may have been exposed to the virus that causes AIDS (HIV)?   | Yes                             | No                         |
| 6.  | Have you EVER injected yourself, or been injected with, any drug not prescribed by a doctor?  | Yes                             | No                         |
| 7.  | Have you EVER shared drug needles?  | Yes                             | No                         |
| 8.  | Have you been accidentally stuck with a used needle in the last 12 months?  | Yes                             | No                         |
| 9.  | Have you EVER been a male or female prostitute?   | Yes                             | No                         |
| 10. | Have you had sexual activity with a male or female prostitute in the last 12 months?  | Yes                             | No                         |
| 11. | Have you been tattooed within the last 12 months?   | Yes                             | No                         |
| 12. | Have you received a blood transfusion or treatment with human blood products in the last 12 months?   | Yes                             | No                         |
| 13. | In the last 2 years have you had jaundice or hepatitis, or been in close contact with any person with either of these illnesses?                                | Yes                             | No                         |
| 14. | Are the answers to questions 1–13 also correct for your present and past spouse(s) and present and past sexual partner(s)?                                      | Yes                             | No                         |

Please do not sign the form yet.

Take it with you to the interviewer.

Signature of Donor .....  
Name (PRINT) .....

Signature of Witness .....  
Name (PRINT) .....  
DATE .....

\*PART B—CERTIFICATE BY PERSON DONATING SEMEN

BEFORE YOU DONATE SEMEN

There are some people in the community who MUST NOT donate semen because it may transmit infections to patients who receive it.

You must complete this form if you want to donate semen. If you do not know how to answer any of the questions, please check with a nurse or medical practitioner. It is against the law to knowingly make a false or misleading statement. If you do, you may receive a \$5,000 fine or 1 year in prison, or both.

TO THE BEST OF MY KNOWLEDGE MY ANSWERS TO THE FOLLOWING QUESTIONS ARE TRUE

- |    |   |                                 |                            |
|----|---|---------------------------------|----------------------------|
| 1. | Have you any reason to believe that:<br>—you have AIDS (Acquired Immune Deficiency Syndrome)?<br>—you have been infected with the virus that causes AIDS (HIV)? | Yes<br>Yes                      | No<br>No                   |
| 2. | In the last 6 months have you had:<br>—night sweats?<br>—unexplained weight loss?<br>—persistent fever?<br>—diarrhoea?<br>—swollen glands                       | Yes<br>Yes<br>Yes<br>Yes<br>Yes | No<br>No<br>No<br>No<br>No |
| 3. | Have you had male to male sexual activity since 1977?   | Yes                             | No                         |
| 4. | Have you had sexual activity with a bisexual male since 1977?   | Yes                             | No                         |
| 5. | Have you had sexual activity with any person who may have been exposed to the virus that causes AIDS (HIV)?   | Yes                             | No                         |
| 6. | Have you EVER injected yourself, or been injected with, any drug not prescribed by a doctor?  | Yes                             | No                         |
| 7. | Have you EVER shared drug needles?  | Yes                             | No                         |
| 8. | Have you been accidentally stuck with a used needle in the last 12 months?  | Yes                             | No                         |
| 9. | Have you EVER been a male or female prostitute?   | Yes                             | No                         |

- |     |  |     |    |
|-----|--|-----|----|
| 10. | Have you had sexual activity with a male or female prostitute in the last 12 months?   | Yes | No |
| 11. | Have you been tattooed within the last 12 months?  | Yes | No |
| 12. | Have you received a blood transfusion or treatment with human blood products in the last 12 months?                              | Yes | No |
| 13. | In the last 2 years have you had jaundice or hepatitis, or been in close contact with any person with either of these illnesses? | Yes | No |
| 14. | Are the answers to questions 1–13 also correct for your present and past spouse(s) and present and past sexual partner(s)?       | Yes | No |

Please do not sign the form yet.

Take it with you to the interviewer.

Signature of Donor .....  
Name (PRINT) .....

Signature of Witness .....  
Name (PRINT) .....  
DATE .....

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\* Delete whichever Part is inapplicable.

Form 2

(Cl. 6 (b))

HUMAN TISSUE ACT 1983  
(Section 21C)

CERTIFICATE BY PERSON DONATING BLOOD FOR USE IN A CLINICAL TRIAL

The following certificate must be completed and signed by any person who wishes to donate blood for the purposes of a clinical trial conducted by ..... at ..... Please read it carefully. It is against the law to knowingly make a statement which is false or misleading. If you do, you may receive a \$5,000 fine or 1 year in prison, or both. If in doubt please consult a medical practitioner or nurse.

CERTIFICATE

I hereby certify that to the best of my knowledge all of the following statements are true:

1. I have reason to believe that I am carrying the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
2. I am donating blood solely for the purposes of its use in a clinical trial which is being conducted by .....



at .....

I am signing this certificate in the presence of a \*medical practitioner/nurse/other person nominated for that purpose who is employed at the place I am attending.

Name: .....  
(Please print)

.....  
Signature of donor

.....  
Signature of witness

Date:.....

\* Delete whichever is inapplicable.

SCHEDULE 2—PARTICULARS TO ACCOMPANY APPLICATION FOR  
AUTHORISATION TO CARRY ON BUSINESS OF SUPPLYING BLOOD, BLOOD  
PRODUCTS OR SEMEN

(Cl. 9)

1. Full name and address of applicant.
2. Type of business to be carried on.
3. Proposed name of business.
4. Proposed location of business (details of which are to include two copies of sketch plans of the premises at which it is proposed to carry on the business, drawn to a scale of at least 1: 100 and showing the dimensions of each part of the premises and the use to which each part is to be put, with any proposed alterations or extensions to the premises shown by distinctive colouring or cross-hatching).
5. Details of the management structure of the business (including the full names of key personnel involved in its administration).
6. In the case of a business to be conducted by a corporation:
  - (a) the registered number of the corporation; and
  - (b) the address of the registered office of the corporation; and
  - (c) the full name, residential address and position of:
    - (i) each current director of the corporation; and
    - (ii) the principal executive officer of the corporation; and
    - (iii) the secretary or, if there is more than one, each secretary of the corporation;
  - (d) in the case of a corporation limited by shares:
    - (i) the types of shares and the number of shares of each type issued; and
    - (ii) in the case of a private corporation—the full name of, and the number of shares held by, each shareholder; and
    - (iii) in the case of a public corporation—a list of the 20 largest shareholdings and of the full names of the holders of each of those shareholdings;
  - (e) if the shares are held by another corporation, the name of the ultimate holding corporation.
7. The full name and qualifications of the person (or each person, if more than one is to be appointed) who will superintend the collection, testing, storage and supply of blood, blood products or semen and the keeping of records relating to that collection, testing, storage and supply.

SCHEDULE 3—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR  
THE SUPPLY OF BLOOD OR BLOOD PRODUCTS

(Cl. 12 (a))

#### General

1. (1) The collection, storage and supply of blood and blood products must be for the following purposes only:

- (a) the transfusion of blood back to the person from whom the blood was removed; or
- (b) the use of blood or blood products for other therapeutic purposes, or for medical purposes or scientific purposes, involving the treatment of the person from whom the blood was removed; or
- (c) the use of blood or blood products for the purpose of cross-matching with other blood or blood products.

(2) Blood for storage or supply may be collected only at the premises specified in the authorisation or at the premises of an exempt supplier.

(3) Blood and blood products may be stored only at:

- (a) the premises specified in the authorisation; or
- (b) a pathology laboratory accredited under section 23DN of the Health Insurance Act 1973 of the Commonwealth; or
- (c) the premises of an exempt supplier.

#### Attendance by medical practitioner

2. A medical practitioner must be in attendance whenever blood is being collected from a donor unless the donor:

- (a) falls within the criteria for acceptability of blood donors prepared by the Australian Red Cross National Blood Transfusion Committee; and
- (b) is not pregnant or, if pregnant, is not expected to give birth within the following 4 weeks.

#### Statement to be signed

3. (1) An intending blood donor must be required to complete and sign a statement in or to the effect of Part A of Form 1.

(2) If the intending donor is unable to complete and sign a statement in accordance with subclause (1), blood must not be collected from the intending donor unless:

- (a) the matter is referred to a medical practitioner; and
- (b) the medical practitioner to whom the matter is referred gives written authority for the collection of the blood; and
- (c) any conditions specified by the medical practitioner to whom the matter is referred are complied with.

#### Testing of blood

4. (1) All donated blood must be tested for ABO and Rh (D) blood groups.

(2) All donated blood must be tested for the prescribed contaminants using the tests approved pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act.

(3) If any blood is found by the tests referred to in subclause (2) to be positive for a prescribed contaminant:

- (a) the donor and the referring medical practitioner must be notified of the result; and
- (b) the blood must not be used for any therapeutic purpose without the approval of the Director-General; and
- (c) the container of the blood must be prominently labelled with the biohazard symbol.

#### Labelling of containers of blood and blood products

5. (1) The container of any donated blood, or of any blood product derived or extracted from donated blood, must be labelled with:

- (a) the name of the business conducted by the authorised supplier; and
- (b) a unique identification number; and

- (c) the product type; and
  - (d) the blood group; and
  - (e) the date of collection; and
  - (f) the expiry date; and
  - (g) the full name and date of birth of the donor; and
  - (h) the signature of the donor.
- (2) Before any donated blood, or any blood product derived or extracted from donated blood, is released for use, its container must be labelled with the name of the medical practitioner requesting the blood or blood product.
- (3) The particulars referred to in subclause (1) (b), (c) and (d) must be printed in both of the following forms:
- (a) machine-readable barcode printed in accordance with specifications prepared by the Committee for Commonality in Blood Banking Automation, as published by the America Blood Commission; and
  - (b) readable alpha-numeric form corresponding with the machine-readable code referred to in paragraph (a).
- (4) The identification number referred to in subclause (1) (b) must be integrated with the numbering system used throughout Australia by the Australian Red Cross Society. Storage and transportation of blood and blood products
6. All blood and blood products must be stored and transported in refrigeration equipment that complies with the relevant provisions of AS 3864.

#### Service and maintenance of equipment

7. All equipment must be properly serviced and maintained in good working order, and a record made of all servicing and maintenance of the equipment for the life of the equipment.

#### Certain blood and blood products to be discarded

8. Any blood or blood products must be discarded if the temperature during storage in the liquid state rises above 10°C for more than 30 minutes at any one time. Emergency resuscitation equipment

9. Emergency resuscitation equipment must be immediately available at all times while blood is being collected from donors, and staff trained to use the equipment must be in attendance throughout the blood collection and recovery period.

#### Quality assurance

10. A quality assurance program, approved by the Director-General, must be established and maintained by the authorised supplier. Records

11. (1) The following records must be maintained by the authorised supplier in respect of each donation:

- (a) the donor's written consent and the statement completed by the donor in accordance with clause 3 (1);
  - (b) if a written authority has been given by a medical practitioner in accordance with clause 3 (2), that authority;
  - (c) the results of all tests performed in accordance with clause 4 (1) and (2);
  - (d) the identification details referred to in clause 5 (1);
  - (e) the name of the requesting practitioner referred to in clause 5 (2);
  - (f) any temperature monitoring records made for the purposes of clause 6;
  - (g) any equipment maintenance records made for the purposes of clause 7;
  - (h) any quality assurance records made for the purposes of clause 10.
- (2) The records required by subclause (1) must be retained at the premises specified in the authority:
- (a) where they relate to donors aged 20 years or over at the date of donation—for a period of not less than 10 years from the date of donation; or

- (b) where they relate to donors aged under 20 years at the date of donation—until the donor to whom the record relates attains, or would have attained, the age of 30 years.
- (3) If the authorisation is revoked or suspended, or the authorised supplier ceases to carry on the business of supplying blood or blood products, the authorised supplier must deal with the records in accordance with the instructions of the Director-General.

SCHEDULE 4—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR  
THE SUPPLY OF SEMEN

(Cl. 12 (b)) General

- 1. Semen may be stored only at:
  - (a) the premises specified in the authorisation; or
  - (b) a pathology laboratory accredited under section 23DN of the Health Insurance Act 1973 of the Commonwealth; or
  - (c) a laboratory accredited for that purpose by an accrediting body of the Fertility Society of Australia; or
  - (d) the premises of an exempt supplier.

Testing of semen and blood

2. (1) All donated semen (other than semen donated solely for the purpose of its use for the artificial insemination of the donor's spouse) must be tested by culture of specimens in aerobic, anaerobic and carbon dioxide enriched environments.

(2) If any semen is found by the tests referred to in subclause (1) to be positive for any pathogenic micro-organism, the semen must not be used for any therapeutic purpose without the approval of the Director-General.

(3) Blood samples must be taken from all donors at the time of donation (or at an earlier time that is as close as practicable to that time) and at the expiry of the quarantine period referred to in clause 5, and must be tested for the prescribed contaminants using the tests approved pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act.

(4) If any blood is found by the tests referred to in subclause (3) to be positive for a prescribed contaminant:

- (a) the donor and the referring medical practitioner must be notified of the result; and
- (b) any stored semen, or semen subsequently obtained, from that donor must not be used for any therapeutic purpose without the approval of the Director-General; and
- (c) the cryo-storage vessel containing the semen must be prominently labelled to indicate the presence of a contaminant. Labelling of straws of semen

3. Each straw containing donated semen must be labelled with a code identified in the records with the donor and the date of the donation. Storage and transportation of semen

4. All semen must be stored and transported in cryo-storage vessels containing liquid nitrogen.

Quarantine period

5. Semen must not be released for use until after the expiry of such quarantine period (if any) as may be recommended by the Fertility Society of Australia.

Quality assurance

6. A quality assurance program, approved by the Fertility Society of Australia, must be established and maintained by the authorised supplier.

Facilities must comply with certain requirements

7. The facilities provided by the authorised supplier must meet the requirements of an accrediting body of the Fertility Society of Australia.

Records

8. (1) The following records must be maintained by the authorised supplier in respect of each donation:

- (a) the full name and date of birth of the donor;
- (b) the donor's written consent;
- (c) the results of all tests performed in accordance with clause 2 (1) and (3);
- (d) the identification details referred to in clause 3;
- (e) the name of the medical practitioner to whom the semen is supplied;
- (f) any quality assurance records made for the purposes of clause 6.

(2) The records required by subclause (1) must be retained at the premises specified in the authority:

- (a) where they relate to donors aged 20 years or over at the date of donation—for a period of not less than 10 years after the date of donation;  
or
- (b) where they relate to donors aged under 20 years at the date of donation—until the donor to whom the record relates attains, or would have attained, the age of 30 years.

(3) If the authorisation is revoked or suspended, or the authorised supplier ceases to carry on the business of supplying semen, the authorised supplier must deal with the records in accordance with the instructions of the Director-General.

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NOTES

Human Tissue Regulation 1995 published in Gazette No. 105 of 1.9.1995, p. 5458 and amended in Gazette No. 20 of 21.2.1997, p. 817.

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Table of Amendments

Cl. 4—Am. 21.2.1997.

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