

Application of Better Regulation Principles

Human Tissue Regulation 2020

Principle 1 - The need for government action should be established

The *Human Tissue Regulation 2015* is due to be repealed on 1 September 2020 in accordance with the provisions of the *Subordinate Legislation Act 1989*. The *Human Tissue Regulation 2020 (Amending Regulation)* remakes the 2015 Regulation to support the operation of the *Human Tissue Act 1983* by providing for:

- the classes of medical practitioners who are eligible to be appointed as *designated specialists*
- the organisms and substances that are prescribed contaminants
- the certificate required to be completed by a person donating blood; and
- the means by which next of kin of a deceased person may give consent to the removal of tissue from the person.

Principle 2 - The objective of government action should be clear

The Amending Regulation seeks to support the operation of the *Human Tissue Act 1983* including by creating a framework to facilitate removal of tissue from a deceased donor. Under the *Human Tissue Act 1983*, a designated officer for a hospital may give an authority to remove tissue from a deceased donor. If the donor's respiration or circulation was being maintained by artificial means prior to death, then the authority cannot be issued unless at least one *designated specialist* has carried out a clinical examination (at the time when the donor's respiration/circulation was still being maintained). The Amending Regulation provides for the persons who can be considered *designated specialists* under the Act.

The Amending Regulation also creates statutory parameters around organisms and substances that are considered *prescribed contaminants* for the purposes of the Act, and the certificate required to be completed by a person donating blood. Section 20D of the *Human Tissue Act 1983* requires that a person must not remove or use a donor's blood if the donor has not signed a donation certificate. Schedule 1 of the Amending Regulation provides the prescribed form of the donor certificate which asks blood donors a range of questions as to a donor's risk factors for blood borne diseases.

Principle 3 - The impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options

There is no non-regulatory option to remake the regulation within the existing legislative framework.

Principle 4 - Government action should be effective and proportional

The Amending Regulation is considered to be effective and proportional.

Principle 5 - Consultation with businesses and the community should inform regulatory development

The Ministry of Health has conducted both public consultation and a targeted written consultation process with key stakeholder in relation to the proposed remake of the regulation.

Principle 6 - The simplification, repeal, reform, consolidation of existing regulation should be considered

The Amending Regulation remakes and replaces the existing *Human Tissue Regulation 2015* with a small change. *Designated specialists* are currently referenced in the 2015 Regulation by way of fellowship of certain colleges (eg Fellows of the Australasian College of Emergency Medicine). The Amending Regulation seeks amends the definition by making use of the fact that specialist registration is now recorded on the Australian Health Practitioner Regulation Agency register. The Amending Regulation therefore refers to the classes of medical practitioner by way of reference to specialist registration under the Health Practitioner Regulation National Law (NSW), rather than being a fellow of a college.

Principle 7 - Regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness

The *Human Tissue Regulation 2020* will be subject to the standard five-yearly staged repeal under the *Subordinate Legislation Act 1989*.