

Draft Regulations laid before Senedd Cymru under section 20(4) of the Human Transplantation Act 2013, for approval by resolution of Senedd Cymru.

DRAFT WELSH STATUTORY
INSTRUMENTS

2020 No. (W.)

HUMAN TISSUE, WALES

**The Human Transplantation
(Excluded Relevant Material)
(Wales) (Amendment) Regulations
2020**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Human Transplantation (Wales) Act 2013 (“the Act”).

Section 7(4) of the Act provides that express consent must be obtained for the removal of excluded relevant material for the purposes of a transplantation activity.

Regulation 2 of the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 (S.I. 2015/1775 (W.247)) (“the principal Regulations”) makes provision as to the definition of excluded relevant material for the purposes of section 7 of the Act.

These Regulations amend regulation 2 of the principal Regulations.

Regulation 2(2) and (3) of these Regulations expand the list of composite tissues and other types of material specified as excluded relevant material in regulation 2(2) and (3) of the principal Regulations.

‘Trachea’ is added to the list of excluded composite tissues contained within regulation 2(2) of the principal Regulations by regulation 2(2) of these Regulations. However, regulation 2(4) of these Regulations inserts a new regulation 2(5) into the principal Regulations, which provides that the whole or part of the trachea is not specified as excluded relevant material in so far as it is attached to a lung.

Regulation 2(5) of these Regulations inserts regulation 2(6) and (7) into the principal Regulations, to specify certain types of cells as excluded relevant material, in so far as all or part of the cells are for use for the purpose of transplantation in the form of an advanced therapy medicinal product, and to insert a definition of advanced therapy medicinal product.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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Made ***

Coming into force ***

The Welsh Ministers make these Regulations in exercise of the powers conferred by sections 7(2) and 20(1) of the Human Transplantation (Wales) Act 2013(1), and having carried out such public consultation as they consider appropriate in accordance with section 20(3) of that Act.

In accordance with section 20(4) of that Act, a draft of these Regulations has been laid before and approved by a resolution of Senedd Cymru(2).

Title and commencement

1.—(1) The title of these Regulations is the Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations 2020.

(2) These Regulations come into force on XXX.

(1) 2013 anaw 5.
(2) The reference in s. 20(4) to the National Assembly for Wales now has effect as a reference to Senedd Cymru by virtue of s.150A(2) of the Government of Wales Act 2006 (c. 32).

Amendment of regulation 2 of the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015

2.—(1) Regulation 2 of the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015(1) (excluded relevant material) is amended as follows.

- (2) In paragraph (2), after sub-paragraph (e) insert—
“(ea) trachea (but see paragraph (5));”.
- (3) In paragraph (3)—
 - (a) after sub-paragraph (b) insert—
 - “(ba) fallopian tube;
 - (bb) cervix;
 - (bc) vagina;
 - (bd) clitoris;
 - (be) labia;
 - (bf) vulva;”;
 - (b) after sub-paragraph (d) insert—
“(da) prostate;”;
 - (c) at the end of sub-paragraph (g) omit “or”;
 - (d) at the end of sub-paragraph (h) for “.” substitute—
“; or
(i) perineum.”
- (4) After paragraph (4) insert—
“(5) The whole or part of the trachea is not specified as excluded relevant material in so far as it is attached to a lung.”
- (5) After paragraph (5) insert—
“(6) For the purposes of section 7(2) of the Act the following types of cells are specified as excluded relevant material in so far as all or part of the cells are for use in, or as, an advanced therapy medicinal product—
 - (a) limbal stem cells;
 - (b) lung epithelial cells;
 - (c) liver cells;
 - (d) pancreatic cells;
 - (e) renal epithelial cells.
- (7) In this regulation, “advanced therapy medicinal product” has the same meaning as in the Human Medicines Regulations 2012(2).”

(1) S.I. 2015/1775 (W. 247).
(2) S.I. 2012/1916, as prospectively amended by S.I. 2019/775 from implementation period completion day.

Name

Minister for Health and Social Services, one of the
Welsh Ministers

Date