SCHEDULE 1 Regulation 5

Licences for the purposes of regulation 5

1. The Authority may on application grant a licence for the purposes of regulation 5.

Licensing conditions

2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder—

(a) to have in place operating procedures for the management of a serious adverse event or a serious adverse reaction;

(b) to rapidly report to the Authority—

(i) relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities, and

(ii) the management measures taken with regard to such a serious adverse event or reaction;

(c) to ensure that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are—

(i) competent,

(ii) suitably qualified or trained, and

(iii) provided with the training necessary,

to perform their tasks;

(d) to ensure that the data required to ensure the traceability of organs is kept for 30 years from the date of the retrieval of the organ;

(e) to keep information on organ and donor characterisation for a period specified by the Authority in directions given under regulation 11;

(f) to ensure that medical activities are performed under the advice and guidance of a registered medical practitioner; and

(g) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (b) and (d) to (f) shall be complied with.

3. It shall be a condition of a licence for a procurement activity for the licence holder—

(a) to ensure that procurement material and equipment which could affect the quality and safety of an organ are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices; and

(b) to have in place operating procedures demonstrating how the requirements in sub-paragraph (a) shall be complied with.

4. It shall be a condition of a licence for the procurement activity of retrieval of an organ for a licence holder to ensure that—

(a) the procurement is carried out only after all of the requirements relating to consent and authorisation have been met; and

(b) endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and

any serious adverse reaction in the living donor that may result from the donation, and to identify, report to the Authority, and manage any event or reaction.

5. It shall be a condition of a licence for the procurement activity of donor characterisation, and the procurement or transplantation activity of organ characterisation, for the licence holder to ensure—

(a) that where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from relatives of the deceased donor or other persons about the donor and has explained to such persons the importance of swift transmission of that information; and

(b) subject to paragraph 7, that donors and organs are characterised before implantation by—

(i) the collection of information specified in part A of the Annex to the Directive, and

(ii) where considered appropriate by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, the collection of the information specified in part B of the Annex to the Directive, as amended by amendments that have been adopted and have come into force.

6. It shall be a condition of a licence for the transplantation activity of implantation for the licence holder—

(a) to ensure that, subject to paragraph 7, the following have been verified before proceeding to implant an organ in a recipient—

(i) identification of the donor,

(ii) the collection of information prescribed in paragraph 5(b), and

(iii) compliance with the conditions in paragraph 8 about the preservation and transportation of shipped organs; and

(b) to have in place operating procedures demonstrating how the requirements in sub-paragraph (a) (i) and (ii) shall be complied with.

7. Where any of the information specified in part A of the Annex to the Directive is not available, it shall be a licensing condition for the transplantation activity of implantation for the licence holder to conduct a risk-benefit analysis to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.

8. It shall be a condition of a licence for a procurement activity or a transplantation activity that arrangements to transport an organ are made by the licence holder—

(a) to maintain the integrity of the organ during transport and that the transport time is suitable to optimise the quality and safety of the organ;

(b) to ensure that, subject to paragraph 9, the shipping containers used for transporting organs are labelled with the following information—

(i) identification of the licence holder responsible for the retrieval of the organ and the place where the retrieval took place, including an address and telephone number for that place,

(ii) identification of the place that an organ will be implanted in a recipient, including its address and telephone number,

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE", and

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

(c) to ensure that the organs transported are accompanied by a report on the organ and donor characterisation; and

(d) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (a) to (c) shall be complied with.

9. The conditions in paragraph 8(b) do not apply where transportation is carried out in the same establishment.

Fees

10. In determining the amounts of any fees to be charged under paragraph 13 (applications under Schedule 3 to the 2004 Act and accompanying fees) of Schedule 3 to the 2004 Act, as applied by regulation 6, the Authority shall have regard to its costs in connection with the consideration of applications for licences under this Schedule.

SCHEDULE 2

Regulation 11

Directions of the Authority

1. For the purposes of ensuring consistent compliance with the licensing conditions prescribed in Schedule 1 , the Authority shall give directions under section 23(1) (conduct of licensed activities) of the 2004 Act, as applied by regulation 6, specifying—

(a) the serious adverse events or serious adverse reactions that must be notified to the Authority, including the time period for such notification;

(b) the data, or type of data, that must be kept to ensure the traceability of organs;

(c) how long information on organ and donor characterisation must be kept for;

(d) the medical activities, or the types of medical activities, that must be performed under the advice and guidance of a registered medical practitioner;

(e) the European Union, international and national legislation and standards on the sterilisation of medical devices which shall be complied with (and the guidelines on the sterilisation of medical devices which shall be taken into account) in respect of procurement material and equipment which could affect the quality and safety of an organ, or the health of the donor or recipient; and

(f) the adequate facilities and equipment that should be used for organ and donor characterisation.

2. For the purpose of ensuring consistent standards in relation to the procurement activity of donor characterisation and the procurement or transplantation activity of organ characterisation, the Authority shall specify in directions given under section 23(1) of the 2004 Act—

(a) the requirements that apply to laboratories carrying out tests for donor and organ characterisation, to ensure that those tests are carried out by laboratories with suitably qualified, trained and competent personnel and with adequate facilities and equipment; and

(b) the appropriate operating procedures that are to be in place to ensure that information on organ and donor characterisation reaches the person who will implant the organ in a recipient before the quality and safety of the organ is compromised.