SCHEDULE 2

Regulation 16

Directions for securing compliance with the first, second and third Directives

Traceability and coding system

1. Directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive; and

(b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2. Directions given for the purposes of paragraph 1 shall include directions requiring designated individuals to ensure that third parties responsible for human application retain the information listed in Annex VI (information on the minimum donor/recipient data set to be kept) and Annex VII (information contained in the European coding system) to the third Directive.

Reporting obligations

3. Directions under paragraph 2(4)(c) to (e) of Schedule 3 to the 2004 Act (as applied by regulation 8) shall specify the information to be recorded, the form in which it is to be recorded, the period for which such information is to be kept and the persons to whom any specified information is to be provided for the purpose of securing compliance with the requirements of Article 10(1) (register of tissue establishments and reporting obligations) of the first Directive.

Serious adverse events and serious adverse reactions

4. Directions shall require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Third party agreements and termination of licensed activities

5. For the purpose of securing compliance with the requirements of Article 21(5) (tissue and cell storage conditions) and Article 24 (relations between tissue establishments and third parties) of the first Directive, directions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Procurement and use of tissue or cells

6. Directions shall specify the requirements to be met by all licence holders authorised to procure tissue or cells to secure compliance with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid

down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

7. Directions shall be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

8. In giving directions for the purposes of paragraph 7, the Authority shall, in particular, impose a requirement on designated individuals to ensure that records are retained, and the Authority and tissue establishments are notified without delay, of any serious adverse event and any serious adverse reaction.

Selection criteria and laboratory tests required for donors of tissues and cells

9. In relation to donors of tissues or cells who are deceased at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to all such donors, point 1.1 (general criteria for exclusion), and

(b) in relation to such donors who are children, point 1.2 (additional exclusion criteria for deceased child donors),

of Annex I (selection criteria for donors of tissue or cells) to the second Directive.

10. In relation to donors of tissues or cells who are alive at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to autologous donors, point 2.1 (autologous living donor),

(b) in relation to allogeneic donors, point 2.2 (allogeneic living donor),

of Annex I to the second Directive.

11. Directions shall, in respect of all donors of tissues or cells, deal with the biological tests to be performed and carried out, in accordance with the requirements of section 1 (biological tests required for donors) and section 2 (general requirements to be met for determining biological markers) of Annex II (laboratory tests required for donors) to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

12. In respect of—

(a) donation and procurement procedures, and

(b) the reception of tissue and cells at premises specified in a licence under Schedule 1,

directions shall be given for the purpose of securing compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the second Directive
1. **Donation and procurement procedures**	
Consent and donor identification (record of consent, method of identification, donor interview)	Annex IV, point 1.1
Donor evaluation: other than autologous donors (assessment of donor's medical and behavioural information and physical examinations)	Annex IV, point 1.2
Procurement procedures for tissue and cells (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of the procured tissue and cells (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. **Reception of tissue and cells at the tissue establishment**	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, point 2.1 to 2.3
Registration of data	Annex IV, point 2.4

Requirements for holding a licence under Schedule 1

13. Directions shall be given for the purpose of securing compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C
Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence under Schedule 1 for tissue and cell preparation processes

14. In respect of tissue and cell preparation processes, directions shall be given for the purpose of securing compliance with—

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of tissue and cells at the tissue establishment	Annex II, Part A
Processing of tissue and cells (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of tissue and cells (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of tissue and cells (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of tissue and cells containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F