SCHEDULE 2

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

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