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DRAFT STATUTORY INSTRUMENTS

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**2007 No.**

**HUMAN TISSUE**

**The Human Tissue (Quality and Safety  
for Human Application) Regulations 2007**

<i>Made</i>	- - - -	<i>2007</i>
<i>Coming into force</i>		
<i>for the purposes of</i>		
<i>regulation 1(3)</i>		<i>2007</i>
<i>for all other purposes</i>		<i>5th July 2007</i>

**THE HUMAN TISSUE (QUALITY AND SAFETY  
FOR HUMAN APPLICATION) REGULATIONS 2007**

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Signature

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SCHEDULE 1 — Licences for the purposes of regulation 7

*Power to grant licence*

1. The Authority may on application grant a licence for the...

*Characteristics of licences*

2. A licence under this Schedule may authorise the carrying-on of...
3. A licence— (a) shall designate an individual as the designated...
4. A licence — (a) shall specify the premises (other than...
5. It shall be a condition of a licence under this...

*Fees*

6. In determining the amounts of any fees to be charged...

SCHEDULE 2 — 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...
2. Directions given for the purposes of paragraph 1 shall include...

*Reporting obligations*

3. Directions under paragraph 2(4)(c) to (e) of Schedule 3 to...

*Serious adverse events and serious adverse reactions*

4. Directions shall require licence holders to adopt such—

*Third party agreements and termination of licensed activities*

5. For the purpose of securing compliance with the requirements of...

*Procurement and use of tissue or cells*

6. Directions shall specify the requirements to be met by all...
7. Directions shall be given— (a) for the purpose of securing...
8. In giving directions for the purposes of paragraph 7, the...

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

9. In relation to donors of tissues or cells who are...
10. In relation to donors of tissues or cells who are...
11. Directions shall, in respect of all donors of tissues or...

*Donation and procurement procedures and reception at the tissue establishment*

12. In respect of— (a) donation and procurement procedures, and

*Requirements for holding a licence under Schedule 1*

13. Directions shall be given for the purpose of securing compliance...

*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...

SCHEDULE 3 — Appropriate statements

Explanatory Note