Transposition Note for Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation ("the Implementing Directive").

This Transposition Note outlines how the Implementing Directive is transposed by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (Amending Regulations).

The Implementing Directive is made under Article 29 of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation ("Principal Directive"). The Principal Directive was transposed by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 ("Principal Regulations"). The Amending Regulations amend the Principal Regulations.

The Human Tissue Authority (HTA) is the UK's competent authority under the Principal Directive and Implementing Directive. The approach taken in the Amending Regulations has not been to copy-out the relevant provisions of the Implementing Directive, but to impose obligations on the HTA by reference to such provisions. This is considered appropriate in this case given the clarity of the relevant provisions and given that the relevant obligations are imposed on only one body. The Regulations only do what is necessary to implement the Directive

Article	Objective	Implementation	Responsibility
Article 1: Scope			
1	Scope of Directive	Not necessary.	n/a
Article 2: Subject matter			
2	Subject matter of Directive	Not necessary.	n/a
Article 3: Definitions			
3	Sets out definitions of Directive.	Not necessary.	n/a
Article 4: Common Procedural Rules			
4(1)	Requires member states to ensure that information transmitted pursuant to the Directive between competent authorities, delegated bodies, procurement organisations and transplantation centres is in a certain format.	Regulation 8 amends regulations 18(1) and 18(2) of the Principal Regulations, and inserts regulation 18(1A) into those Regulations, to impose obligations on the HTA to comply with this provision. Regulation 10 amends Schedule 2 to the Principal Regulations to require the HTA to issue directions to licensing bodies to ensure compliance this provision. Regulations 4 and 5 supplement these provisions by amending regulations 6 and 12 of the Principal Regulations to enable the HTA to issue guidance	Human Tissue Authority

		and directions to ensure compliance with the Directive. Regulation 6 also supplements these provisions by amending regulation 13 of the Principal Regulation so that the HTA's duty to establish a framework under that provision includes specifying how their requirements for the quality and safety of organs for transplantation shall be met in compliance with the Implementing Directive.	
4(2)	Enables in cases of urgency information to be exchanged verbally but followed up in writing.	As above.	Human Tissue Authority
4(3)	Requires member states to ensure that receipt of information is transmitted to the sender in accordance with the requirements of Article 4(1).	As above.	Human Tissue Authority
4(4)	Requires member states to ensure that competent authorities are available to receive and	Regulation 8 amends regulations 18(1) and 18(2) of the Principal Regulations, and	Human Tissue Authority

	transmit information without delay.	inserts regulation 18(1A) into those Regulations, to impose obligations on the HTA to comply with this provision.	
Article 5: Information on organ and donor characterisation			
5(1)	Requires member states to ensure that prior to organs being provided to another member state, competent authorities or delegated bodies have to provide certain information to that other member state.	Regulation 8 amends regulation 18(1) of the Principal Regulations to impose obligations on the HTA to comply with this provision.	Human Tissue Authority
5(2)	Requires member states to ensure that where required information is not available at the time of initial transmission, it must be transmitted later by the competent authority, delegated body or procurement organisation.	Regulation 8 amends regulation 18(1) of the Principal Regulations to impose obligations on the HTA to comply with this provision. Regulation 10 amends Schedule 2 to the Principal Regulations to require the HTA to issue directions to licensing bodies to ensure compliance this provision.	Human Tissue Authority
5(3)	Requires member states to ensure	Regulation 8 amends	Human Tissue Authority

	that procurement organisations and transplantation centres transmit to competent authorities or delegated bodies copies of information provided under Article 5.	regulation 18(1) of the Principal Regulations to impose obligations on the HTA to comply with this provision. Regulation 10 amends Schedule 2 to the Principal Regulations to require the HTA to issue directions to licensing bodies to ensure compliance this provision.	
Article 6: Information to ensure the traceability of organs			
6(1)	Requires member states to ensure that competent authorities or delegated bodies provide certain information relating to an organ to another member state when an organ is sent to that member state.	Regulation 8 amends regulation 18(1) of the Principal Regulations to impose obligations on the HTA to comply with this provision	Human Tissue Authority
6(2)	Requires member states to ensure that competent authorities or delegated bodies provide certain information relating to an organ to another member state when organ is received from that member state.	Regulation 8 inserts regulation 18(1A) into the Principal Regulations to impose obligations on the HTA to comply with this provision.	Human Tissue Authority
Article 7: Reporting of serious adverse events and reactions			

7	Requires member states to ensure that competent authorities or delegated bodies follow certain procedures when reporting adverse events in relation to organs sent to or received from another member state.	Regulation 8 amends regulation 18(2) of the Principal Regulations to impose obligations on the HTA to comply with this provision	Human Tissue Authority
Article 8: Interconnection between member states			
8(1)	Imposes obligation on member states to inform Commission of certain information.	Not necessary.	Secretary of State
8(2)	If a member state has several competent authorities then member states must make sure information received by one is forwarded to appropriate body at national level.	Not necessary (as only one competent authority).	Secretary of State
8(3)	Commission must make available to member states certain information and member states must keep that information up to date	Not necessary.	Secretary of State
Article 9: Transposition			
9(1)	Requires member states to bring into force the laws, regulations and provisions to comply with Directive by 10 April 2014.	Not necessary.	Secretary of State

9(2)	Member states to communicate to the Commission the text which they adopt in the field cover by Directive.	Not necessary	Secretary of State
Article 10: Entry into force			
10	Date of entry into force.	Not necessary	n/a