EXPLANATORY MEMORANDUM TO

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) REGULATIONS 2014

2014 No. 1459

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The purpose of these Regulations is to amend the Quality and Safety of Organs Intended for Transplantation Regulations 2012 ("Principal Regulations"). This is primarily to transpose 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"). The United Kingdom (UK) was required to transpose the Directive by 10 April 2014. These regulations also rectify errors made by the Principal Regulations.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Regulations also amend a number of drafting errors made by the Principal Regulations. The Joint Committee did not report the Principal Regulations .

4. Legislative Context

4.1 The Implementing Directive is transposed under section 2(2) of the European Communities Act 1972. The Secretary of State has been designated for the purpose of that provision in relation to health protection measures regulating the use of material of human origin.

5. Territorial Extent and Application

5.1 Most of the provisions in these Regulations extend to England and Wales, Northern Ireland and Scotland. However, the amendments made to the Human Tissue Act 2004 extend to England and Wales and Northern Ireland only. Gibraltar will transpose the Implementing Directive separately. The Implementing Directive does not apply to the Channel Islands or the Isle of Man.

6. European Convention on Human Rights

6.1 Public Health Minister Jane Ellison has made the following statement regarding Human Rights:

In my view the provisions of *The Quality And Safety Of Organs intended for Transplantation (Amendment) Regulations 2014* are compatible with the European Convention on Human Rights

7. Policy background

7.1 Despite rapid advances in transplantation medicine and increased use of human organs for transplantation, there is a shortage of organs available for transplantation across the European Union (EU).

7.2 Consequently, EU Member States decided in July 2010 to adopt 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 ("the Principal Directive") to try and improve the quality and safety of organs for transplantation; enhance the efficiency and accessibility of transplantation systems; and increase organ availability across the EU. The Principal Directive was transposed into UK law by the Principal Regulations in 2012.

7.3 Article 29 of the Principal Directive required the European Commission to draw up detailed rules for the procedures for the transmission of information where organs are exchanged between Member States, procedures to ensure their traceability, and the reporting of any severe events or reactions during or after transplantation. The Implementing Directive 2012/25/EU sets out such rules. These Regulations amend the Principal Regulations to transpose the requirements of the Implementing Directive.

7.4 In addition these Regulations correct a number of drafting errors in the Principal Regulations and also amend other legislation to rectify errors made by amendments made by the Principal Regulations. This includes substituting section 32(3A) of the Human Tissue Act 2004. This provision was inserted by the Principal Regulations in order to ensure compliance with Article 13 of the Principal Directive. Article 13 essentially requires Member States to ensure that the donation of organs is voluntary and unpaid. However, the way that section 32(3A) is currently worded

means that it goes further than intended by Article 13 and runs the risk of unintentionally capturing, for example, Government funding to support organ donation. Given this, these regulations substitute section 32(3A) so that it more specifically ensures compliance with Article 13, as well as compliance with Article 12 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Article 12 of that Directive requires Member States to ensure that the donation of tissues and cells is voluntary and unpaid.

8. Consultation outcome

8.1 These Regulations transpose procedural requirements that were largely already in place. The main burden of compliance will fall on NHS Blood and Transplant (NHSBT), the organisation responsible in the UK for the allocation of organs, and on the Human Tissue Authority as the UK regulator. Therefore no formal public consultation has been undertaken. Rather, the Department of Health has worked closely with both organisations to agree implementation that builds on current arrangements for organ characterisation, traceability and severe event and reaction reporting. The view of both organisations is that compliance will entail minimal changes to current arrangements.

9. Guidance

9.1 The Human Tissue Authority will issue a communication to the 40 or so organisations licensed under the 2012 Principal Regulations setting out what the changes will mean in practice, although for most there will be little to no change as it will be largely NHS Blood and Transplant that will have to make any changes or standardise procedures in relation to information about organs exchanged with other Member States. .

10. Impact

10.1 The threshold for an Impact Assessment is a £1 million impact upon the public sector. Within the UK around 130 organs cross borders (most with the Republic of Ireland) – some 65 imported and 65 exported. Therefore an Impact Assessment would be required if the cost of changing the characteristics recorded of donated organs exceeded £7700 per organ, based upon the current cost of a kidney transplant (£50,000 in 2011/12 prices). The impact of implementing this Directive is minimal and

certainly below £7700 per donation, and therefore an Impact Assessment is not required.

10.2 In developing these Regulations, we have also had regard to their impact on equality in accordance with section 149 of the Equality Act 2010. A full equality assessment was undertaken when transposing and implementing the Principal Directive 2010/53/EU. This did not identify any inequities. These Regulations provide further information on one aspect of that Principal Directive – cross border exchanges. Again we do not believe that implementation will have disadvantageous effect on any section of the population. Nor do we have evidence that it would impede the advancement of equality of opportunity or good relations between persons who share a 'relevant protected characteristic' and those who do not.

11. Regulating small business

11.1 The legislation does not have an impact on small business as none of the ten private hospitals undertaking procurement and transplantation activity come within the micro or small business categories.

12. Monitoring & review

12.1 These Regulations will be reviewed in August 2019, when we will examine whether the UK's procedures for traceability and the reporting of severe adverse events and reactions have improved over the 5-year period.

13. Contact

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