Regulatory Policy Committee	**Validation of the One-in, Two-out Status and the Net Direct Impact on Business**
Validation Impact Assessment (IA)	Human Fertilisation and Embryology (Quality and Safety) Regulations 2014
Lead Department/Agency	Department of Health
IA Number	3134
Origin	European
Expected date of implementation	April 2014 (SNR 7)
Date of Regulatory Triage Confirmation	20 May 2014
Date submitted to RPC	14 July 2014
Date of RPC Validation	08 August 2014
RPC reference	RPC14-FT-DH-2091(2)
Departmental Assessment	
One-in, Two-out status	Out of scope (EU)
Estimate of the Equivalent Annual Net Cost to Business (EANCB)	-£3.61 million
RPC assessment	**VALIDATED**

Summary RPC comments

The validation IA is fit for purpose. Under the proposals, if partners were to donate reproductive cells multiple times within a 24 month period, only a single blood screening test per partner would be required. This will affect business by lowering their operating costs as a result of conducting fewer blood tests.

On the basis of the evidence presented, we are able to validate the estimated EANCB.

Background (extracts from IA)

What is the problem under consideration? Why is government intervention necessary?

"The *proposed regulation transposes European Union (EU) directive 2012/39/EU into UK law*".

What are the policy objectives and the intended effects?

"Using field experience and scientific evidence, it has been shown that the blood

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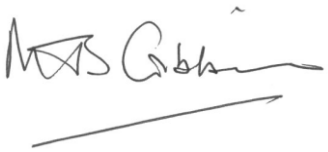
testing requirements for partners providing reproductive donations can be reduced without significantly reducing the level of safety of cells. The suggested reduction involves moving from testing at the point of each donation to testing at fixed time intervals, to a maximum of 24 months.

The current requirement to test at the point of each donation is seen as both costly and cumbersome to both patients and healthcare systems, and there are no additional health benefits for patients. This proposal has created an opportunity to reduce the financial impact to business of the regulation".

RPC comments

The proposal is to transpose the EU Directive into UK law and to change the current domestic policy of testing to align with the Directive. Under the proposals, if partners were to donate multiple times within a 24 month period, only a single blood screening test per partner would be required. This will affect business by lowering their operating costs as a result of conducting fewer blood tests. Under current rules for instance, if partners were to donate reproductive cells three times within a 24 month period, three blood screening tests would be required for each partner totalling six tests. The proposal would mean only two blood screening tests per partner would be required.

The Human Fertilisation and Embryology Authority (HFEA) estimates the average cost of a blood screening test at £150. Based on this and the assumption (from a HFEA sampling exercise) that an estimated 25,000 blood tests would no longer be mandated, the Department has estimated a total direct saving to business of £3.61 million. The IA also explains that If businesses choose to compete with each other on price and use this cost saving as an opportunity to lower prices, consumers will indirectly benefit from the proposal as the overall price of IVF will fall. We note that the Department has provided additional information on the calculation of the EANCB.
On this basis, we are able to validate the estimated EANCB.

Signed		**Michael Gibbons,** Chairman

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