 Regulatory Policy Committee	Validation of the One-in, Two-out Status and the Net Direct Impact on Business
Validation Impact Assessment (IA)	The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2014
Lead Department/Agency	Department of Health
IA Number	3124
Origin	Domestic
Expected date of implementation	October 2014 (SNR 8)
Date of Regulatory Triage Confirmation	24 October 2013
Date submitted to RPC	17 September 2014
Date of RPC Validation	24 October 2014
RPC reference	RPC14-FT- DH-1926(2)
Departmental Assessment	
One-in, Two-out status	Zero Net Cost
Estimate of the Equivalent Annual Net Cost to Business (EANCB)	N/A
RPC assessment	VALIDATED
Summary RPC comments	
<p>The Validation IA is fit for purpose. The IA addresses the issues raised in the Committee’s opinion of 21 July 2014. The IA now explains that it is likely there will be only one provider for the first few years, which will be publicly funded. The IA correctly assesses any benefits to new entrants as indirect. The Department has reclassified the measure from an OUT to a regulatory proposal that is net beneficial to business (an IN with ‘Zero Net Cost’).</p>	
Background (extracts from IA)	
What is the problem under consideration? Why is government intervention necessary?	
<p><i>“Serious mitochondrial DNA disease results from mutated mitochondrial DNA being passed from mother to child and affects the ability of cells to function, causing life-limiting diseases, such as heart and kidney failure. There are few effective treatments for mitochondrial DNA disease and no cure. Scientists in the UK have pioneered techniques by which faulty mitochondria of the mother is replaced by healthy mitochondria from a donor. However, it is illegal under current regulations to provide treatment of mitochondrial DNA disease based on these techniques. The Department of Health has been asked by researchers to introduce regulations under the section 3ZA of the Human Fertilisation and</i></p>	

Embryology Act 1990 (amended through HFE Act 2008) to allow mitochondrial donation in treatment.”

What are the policy objectives and the intended effects?

“The intended effect of the proposal is to prevent serious mitochondrial DNA disease being passed from mother to child.”

RPC comments

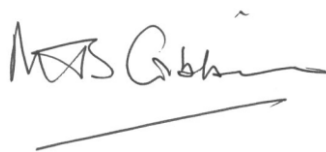
The IA explains how Government regulation will remove the current ban on mitochondria donation treatment and establish a new regulatory framework to allow business to engage in providing such treatment.

The IA addresses the issues raised within the Committee’s opinion of 21 July 2014. The IA explains that there will be a benefit to business as the proposals would present clinics with new opportunities to provide mitochondrial donation treatment on receipt of a licence from the sector regulator, the Human Fertilisation and Embryology Authority (HFEA). Currently, and for the first few years of the policy, it is likely that there will be only one provider of mitochondrial donation treatment, and that provider is publicly funded. The Department has also provided details of the potential costs to new entrant businesses of providing the course of treatment (per case) of £120,000 and the administrative costs of £16,000 associated with applying for a licence (table 8).

Consequently, the majority of the benefits to business of the proposal would accrue to new entrants to this particular market. The IA therefore explains that *“as there are no other providers currently ready to carry out these treatments and it is not expected that these new providers will surface until after the first years of the scenario, the costs and benefits of these potential new providers are considered indirect”* (paragraph 91).

Based on the information provided in the IA, this is a regulatory proposal that is net beneficial to business (an IN with ‘Zero Net Cost’). This is consistent with the current Better Regulation Framework Manual (paragraph 1.9.12) and, based on the evidence presented, appears to provide a reasonable assessment of the likely impacts.

Signed



Michael Gibbons, Chairman