HFEA Mitochondrial Donation Regulations regulatory system and Code of Practice Update October 2015

Human Fertilisation and Embryology Authority (HFEA)

RPC rating: validated

Description of proposal

The HFEA has a statutory duty to produce a Code of Practice, which sets out how fertility clinics and human embryo research centres should comply with the Human Fertilisation and Embryology Act, Directions under that Act and any other legislation relevant to the fertility sector.

This measure revises the existing code of practice, launches a new guidance note, and makes some minor changes to other guidance notes regarding mitochondrial donation. It also introduces consent forms, a licence variation form, and patient application forms for clinics to offer the treatment options.

The Department of Health (DH) submitted a Regulatory Impact Assessment (RIA) in 2014 for the Act and in this the regulations scored as zero net cost to business, on the grounds that no more than one business was expected to be in a position to provide mitochondrial donation. The HFEA implementation of the regulations has not gone beyond that which was set out in the DH RIA.

Since the initial DH assessment no additional businesses have been impacted by this regulatory provision and the single clinic currently affected has almost exclusively focused on NHS work. Research conducted by DH also suggests that the assumption that there will be no further entrants to the market over the next ten years remains plausible. In the long term DH predicts that mitochondrial donation will have a market profile which is broadly similar to other fertility treatments – with around 40% public and 60% private sector funding.

Impacts of proposal

HFEA argues that it has not undertaken any activity that was not set out and costed in DH's original IA, which was validated by the RPC. It has notified clinics about the change, using a brief article in its monthly e-newsletter, so that familiarisation costs were minimal.

Overall, therefore, there is a negligible impact on business at this stage, though HFEA notes, correctly, that this position is expected to change as the market develops in the long term.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of £0.0 million. This is a qualifying regulatory provision.

Quality of submission

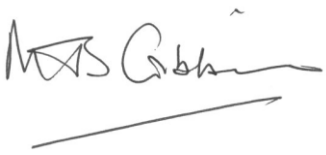
The submission is clear and provides sufficient evidence to support the estimate of the cost to business. HFEA gives sufficient explanation of the regulatory provisions it is implementing based on a submission by its home department, DH.

Departmental assessment

Classification	Qualifying regulatory provision
Equivalent annual net cost to business (EANDCB)	£0.0 million
Business net present value	£0.0 million
Societal net present value	£0.0 million

RPC assessment

Classification	Qualifying regulatory provision
EANDCB – RPC validated[1]	£0.0 million
Business Impact Target (BIT) Score[1]	£0.0 million
Small and micro business assessment	Not required



Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.