
HFEA Compliance and Enforcement Policy update (including Guidance on Licensing)

Human Fertilisation and Embryology Authority (HFEA)

RPC rating: validated

Description of proposal

The assessment covers an update to existing Compliance and Enforcement Policy and Guidance to Licensing. This is a single policy that sets out how the HFEA deals with non-compliant fertility clinics and research centres. The policy sets out:

- Standard approach to inspections and licensing (licensing guidance)
- Procedures for the management of centres with serious areas of non-compliance (sanctions guidance)

This makes decisions taken by HFEA more transparent and ensures that all centres are treated in the same way. The documents provide clarity for centres and others about licensing decisions, and provide a framework for licensing committees. HFEA notified all licensing centres in advance about the updated policy, through HFEA's e-newsletter.

Impacts of proposal

The UK fertility sector is small (with 132 active clinics and research establishments) and includes both public and private sector organisations. HFEA estimates that 95 clinics and research establishments carry out private work, based on data from its licensing regime. Thus it assumes that 95 businesses are affected.

HFEA argues that the changes clarified existing requirements rather than imposing new ones, and that the only costs to business were therefore familiarisation costs. It assumes that senior consultants would read the revised guidance, as they are typically the persons responsible for ensuring compliance. The total familiarisation cost is estimated at £2646.70. Therefore the EANDCB and BIT score round to zero.

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

Quality of submission

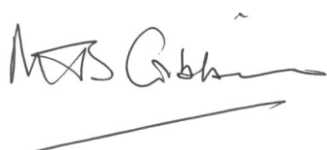
The submission is clear and proportionate, and provides enough information to support its estimate of the cost to business of the measure. A clearer discussion of the assumption that only the senior consultant would read the guidance would have been helpful.

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.