

Human Fertilisation and Embryology Authority (HFEA)

The HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. It came into operation on the 1st of August 1991 and sets standards for, and issues licences to, fertility clinics, acting as a regulator in accordance with powers issued through the Human Fertilisation and Embryology Acts 1990 and 2008 and other legislation. Following the public bodies review the Department of Health classified the body in schedules 5 and 7. Their plans, published in the report 'Liberating the NHS: report of the arms-length bodies review' listed an intention to transfer the functions of the (HFEA) and Human Tissue Authority (HTA) to the Care Quality Commission (CQC) and Health Research Authority (HRA) on the basis of aiming to reduce costs and make regulation less burdensome. This decision was seen to be particularly controversial and prompted widespread concern in Parliament.

In the House of Commons members voiced concerns. For example, Valerie Vaz, a member of the commons health select committee, asserted that 'other countries look to the HFEA as a model of good governance and good practice. Losing this accountability, expertise and brand name threatens the future of groundbreaking and ethically responsible research, policy-making and regulation in the UK' (4th November 2011). An EDM was also tabled by Kevin Barron on the future of the HFEA which gained 39 signatures (1290 Session 2010-2012). Opposition was also prevalent within the Lords where Baroness Warwick of Undercliffe, Lord Harries of Pentregarth, Lord Warner, Baroness Warnock, Lord Crickhowell, Baroness Thornton and Baroness Deech amongst many others voiced their opposition.

In the passage of the Bill through the Lords Baroness Thornton tabled an amendment to leave out the HFEA from schedule 5, arguing that the HFEA and the HTA should not be in the Bill (9th March 2011, Column 1689). This proposal gained widespread support but was ultimately withdrawn. It was laid again on the 28th of March at report stage but again withdrawn in the hope of clarifying information ahead of the third reading. On the 9th of May, at third reading, Baroness Deech called for the HFEA and HTA to 'remain untouched until a new research regulatory body is in place with its own statute to receive those functions' (9th May 2011, Column 681). This amendment was moved but defeated by a vote of 199 to 209.

The effect of this opposition from the House of Lords was felt in the media where Lord Warner and Baroness Deech both made pledges to fight the plans. Writing in *The Times* Baroness Deech argued that the government should not 'endanger the rapid progress in embryo research that has been to the advantage of the UK', asserting that 'Lord Patel, Lord Walton, Baroness Warnock, Lord Harries, Lord Mackay, Baron Willis and (modestly) myself, among others' would oppose the plans (Times, 16th August 2010). Opposition was also apparent in statements by other notable health figures with Lord Rees of Ludlow (who had recently stepped down as head of the royal society) raising concerns. He argued that the abolition, particularly of the Human Fertilisation and Embryology Authority could 'prevent ministers from receiving independent scientific advice that was critical to good policymaking', and argued that the proposal seemed to have 'been decided upon without tremendous forethought or consideration' (The Times, 1st December 2010). However, the abolition did not gain significant media coverage compared with other cases (such the forestry commission) and some support for the Government's proposals was voiced. For example, *The Sun* reported the comments of doctor Lord Robert Winston who

argued that the 'fertility watchdog set up to protect IVF patients is "incompetent" and "arrogant" and should be scrapped' (The Sun, 1st December 2010).

The HFEA itself adopted an interesting position. Its chair, Professor Lisa Jardine, is reported in a Guardian article (Gentleman, 10th January 2011) to have 'reined in any personal impulse towards protest or defiance' and to be 'mounting a delicate campaign to ensure that the organisation can be preserved'. The article continued: 'She insists that her job is to comply with what the government has ruled, but makes it clear that she will be working to promote an alternative, which would see the HFEA continue broadly unchanged, swept into the folds of another government-run organisation'. Jardine did assert that 'I feel very passionately that this is a mistake' (ibid.), nevertheless the body's senior management is reported to have 'taken a clear decision not to campaign noisily against closure'. This approach is evident in the body's press releases (for example, HFEA, 28th June 2010) which take a positive approach to the government's announcements.

In terms of a wider campaign The Royal College of Nursing (RCN) argued that the government's plans 'would be detrimental and that the HFEA is the most effective organisation to regulate the infertility sector as well as carry out other functions under the HFE Act' (2nd August 2012). A joint briefing on the issue was also provided to the Lords by the RCN, British Fertility Society (BFS), the Royal College of Obstetricians and Gynaecologists (RCOG), the British Infertility Counselling Association (BICA), Infertility Network UK (INUK) and the Association of Clinical Embryologists (ACE).

Yet, not all organisations opposed the change, the BioIndustry association argued that the merger of the HFEA and the HTA into a single regulator would be 'a step in the right direction towards streamlining the regulatory review processes and creating a more coherent and robust framework with clarity of responsibilities for research regulation and governance' (Mansell, 19th October 2010). The academy of medical sciences had also voiced support in early 2011 for the creation of 'a new Health Research Agency (HRA) to rationalise the regulation and governance of all health research' in their report 'A new pathway for the regulation and governance of health research' (Academy of Medical Sciences, January 2011). In addition the British Medical Journal indicated that it did accept the rationale behind removing bodies, such as the HFEA, which had been established to 'score political points' (Cruse, 4th November 2010, p.8).

Following the passage of the Public Bodies Bill the Government launched a consultation (on the 28th of June 2012 – running to the 28th of September 2012) to 'consider whether the regulators' responsibilities should move to the Care Quality Commission (CQC) and the Health Research Authority' (Department of health, 28th June 2012). The consultation was framed in terms of the reduction of spending, with the Minister, Lord Howe, arguing that '[s]ervices must be delivered in the most efficient way possible. By making sure that the right functions are being carried out at the appropriate level, we will free up savings to support front-line NHS services' (ibid.). The consultation posed three options:

'Option 1 proposed that all functions of the HFEA and the HTA transfer to the Care Quality Commission (CQC) with the exception of HFEA research-related functions that would transfer to the Health Research

Authority (HRA); and the HFEA and the HTA be abolished. This was the Government's preferred option;

- Option 2 proposed a transfer of functions and abolition as for Option 1 but also proposed that a limited number of functions might transfer elsewhere;

- Option 3 proposed that the HFEA and the HTA retain their functions but deliver further efficiencies' (Department of Health, 2013a, p.6).

The Government widely publicised the consultation and held a workshop for almost 40 stakeholder organisations to discuss the options.

On the 7th of January 2013 the HTA, HFEA and CQC published a Memorandum of Understanding which detailed how the bodies could work together. In a press release the HTA Chief Executive Alan Clamp said: 'Whilst the three organisations regulate different areas, these agreements will help to ensure that the HTA, CQC and HFEA can work together effectively to reduce any regulatory burden for establishments that are jointly regulated and make best use of our resources to regulate even more effectively'. The agreement details how information can be more effectively shared, defines each body's remit to reduce duplication and details functions to offer greater clarity.

On the 25th of January the Government published its response to the consultation. 109 responses were received to the consultation, including from all four main bodies directly affected by the proposals (HFEA, HTA, CQC and the HRA) and key organisations such as the British Medical Association (BMA), the British Fertility Society (BFS), the Academy of Medical Sciences (AMS), the Wellcome Trust and a number of Royal Colleges. The majority of respondents (75%) disagreed with the proposal to transfer functions to the CQC and HRA, citing the considerable expertise of the HTA and concerns over the CQC as a location for functions. Many respondents also felt that 'the anticipated savings [of reform] did not merit the risks associated with the proposed transfers' (Department of Health, 2013a, p.7). On the balance of these responses the government announced that they would 'not pursue a transfer of functions at this time' rather, the HFEA and HTA will 'remain as separate statutory bodies but with the introduction of further efficiencies. To this end, the Department will arrange an immediate review of how the two bodies carry out their regulatory functions, with a view to reducing regulatory burden' (Department of Health, 2013a, p.8).

In outlining the scope of the review the Department of Health committed to assessing and making recommendations on:

- the scope to streamline the way in which the two bodies undertake their regulatory and statutory functions, including through joint working, sharing resources and information and working more closely with other health sector regulators
- the scope to reduce and rationalise the burden of inspection, information collection and process of research approvals that falls on the regulated sector, without compromising the safeguards in the respective Acts;
- the scope for shared Authority membership and leadership, and of a merger of the two bodies (Department of Health, 2013b, p.1)

This review ran between January 2013 and March 2013 and was conducted by Justin McCracken who is currently the Chief Executive of the Health Protection Agency. It was published in April 2013 and concluded that 'the current regulatory arrangements deliver generally effective regulation and achieve high levels of public and professional confidence', hence he did not support merger (Department of Health, July 2013, p.6). Instead a number of recommendations were made which were accepted by the government

Key Documents:

Department of Health. (26th June 2010) Liberating the NHS: Report of the Arm's-Length Bodies Review.

Department of Health. Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Department of Health. (14th June 2012) Impact Assessment.

Department of Health. (June 2012) Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority: Equality Analysis.

Department of Health. (January 2013a) Government Response to the Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority: Equality Analysis. London: Department of Health.

Department of Health. (January 2013b) Department of Health Review of the Way on Which the Human Fertilisation and Embryology Authority and Human Tissue Authority Undertake their Regulatory Functions. London: Department of Health.

Department of Health.(April 2013), *Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority*

Department of Health. (July 2013) *Response to the review of the HFEA and HTA: Government response to the report of the independent review of the Human Fertilisation and Embryology Authority and the Human Tissue Authority by Justin McCracken*, London: Stationary Office.

Gentleman, A. (10 January 2011), 'A quiet battle for life: IVF regulator aims to show its worth', *The Guardian*, <http://www.guardian.co.uk/politics/2011/jan/10/battle-life-ivf-regulator-hfea>, accessed 21 November 2012.

HFEA. (October 2009) About the Human Fertilisation and Embryology Authority.

HFEA (28th June 2010) 'HFEA Press Release Concerning the Arm's Length Bodies (ALB) Review: Proposals to Transfer Functions of HFEA and HTA' <http://www.hfea.gov.uk/7319.html>, accessed 21 November 2012.

Mansell, P. (19th October 2010), 'BIA backs HFEA/HTA consolidation into MHRA, *PharmaTimes Online*, http://www.pharmatimes.com/article/10-10-19/BIA_backs_HFEA_HTA_consolidation_into_MHRA.aspx, accessed 21 November 2012.

Vaz, V. (4th November 2011) 'Valerie calls for expert health and equalities bodies to be saved from quango cull', <http://www.valerievazmp.co.uk/2011/11/valerie-calls-for-expert-health-and-equalities-bodies-to-be-saved-from-quango-cull/>, accessed 21 November 2012.

Royal College of Nursing, (2nd August 2012), <http://tinyurl.com/c75qygm>, accessed 12th October 2012.