Human Tissue Authority (HTA)

The HTA was established by the Human Tissue Act 2004 to regulate organisations that remove, store, use and dispose of tissue for purposes including research, medical treatment, post-mortem examination, teaching and display in public. The HTA also gives approval for organ and bone marrow donations from living people. Following the public bodies review the Department of Health classified the body in schedules 5 (and initially 7 until that was removed from the Bill), giving the Government the power to modify or transfer its functions. These proposals were outlined in greater detail in the report, 'Liberating the NHS: report of the arms-length bodies review', which stated an intention to transfer the functions of the HFEA and HTA to the Care Quality Commission (CQC) and Heath Research Authority (HRA) in an attempt to reduce costs and regulatory burden.

The HTA had no forewarning of the decision. Whilst they welcomed the move towards reform and greater efficiency (because this echoed the changes they themselves had begun to implement), they were not happy with the proposition of a merger (Interview Data). The HTA itself had not been involved with the government's initial review process and did not feel that the decision was well supported. Indeed, one interviewee argued that the 'amount of savings with an organisation as small as ours were going to be very small indeed', raising questions about the motivations for reform. Further concerns were raised about the negative signal sent out to stakeholders and the public by the proposals, a signal which could damage confidence in the handling of human tissue.

In reacting to the decision the HTA board decided to focus on maintaining the provisions in the Human Tissue Act rather than the Authority itself. This was reflected in an open approach to reform symbolised by discussions set up by the HTA between itself, the CQC and the HFEA to consider the reform proposals. The HTA also maintained a dialogue with the department, voicing three key arguments in response to proposals. These focused on:

a) Keeping the HTA's functions together
b) Maintaining public confidence
c) Protecting and ensuring that the principles of the Human Tissue Act were maintained (Interview Data).

These arguments comprised the body's strategic response and were repeatedly made, as apparent in the HTA's press statements which asserted the need 'to retain the HTA as a separate organisation and to make further efficiencies' and to 'continue the effective and efficient regulation of human tissue and organs by the HTA, minimise the risks associated with the use of human tissue, and protect public confidence' (Human Tissue Authority).

In the House of Lords significant opposition was voiced to the Government's proposals with contributions from Lord Crickhowell, Baroness Thornton, Lord Walton of Detchant, Lord Willis of Knaresborough, Baroness Warwick of Undercliffe, Lord Harries of Pentregarth, The Lord Bishop of Guildford, Lord Alderdice and Lord Patel amongst others. A number of amendments were laid on the proposed changes to the HFEA but only one, at third reading, directly related to the HTA. This was tabled by Baroness Deech who '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.

Senior figures within the HTA itself have reported that by the time the Bill was tabled in the Lords there were fewer concerns over the risks of merger, leading them to focus on voicing the case for maintaining the identity of the Human Tissue Act in whatever form reform proposals took. This strategy led the body to provide briefings for experts and professionals associated with the administration and management of Human Tissue, MPs and Peers (via drop in events in Parliament), departmental officials, and select committees (such as the evidence provided to the Health Select Committee). In addition a briefing entitled 'How we make a difference' was published on the body's website on the 26th of November 2012. Information dissemination was therefore a key strand of their strategy but it was not seen by senior HTA members as lobbying (which would have been inappropriate) but rather as information sharing which could inform the proposals as they developed from the initial impetus for merger.

The media coverage of the government's plans for the HTA was limited, yet the *Sunday Times* did note that '[t]he lessons of Alder Hey and Bristol hospitals seem to have been swiftly forgotten' and that the HTA should remain. In addition the decision received attention in local Liverpool press where the local MP, George Howarth's, comment in the House of Commons that 'a lot of people who were affected by [the Alder Hey hospital tragedy] will be aghast that that debt of honour has now been reneged on by this Government?' (Daily Post, 15th October 2010) was reported.

In terms of stakeholder involvement the HTA itself focused on reassuring bodies that they could still have confidence in the system. Initially a number of organisations were in favour of the government's proposals because they were believed to be aimed at the reduction of regulation. However, as the proposals progressed a number of stakeholders came to question the government's rationale and some voiced opposition, particularly given the very different form of regulation that could emerge if another body took over the function. In this sense stakeholders were not actively lobbied by the HTA, rather the HTA maintained clear lines of communication with stakeholders and where concerns had been expressed they directed them (stakeholders) to voice them to the Government (specifically the Home Office). The support for the HTAs retention was mixed as whilst the British Neuroscience Association argued in their consultation response that the HTA 'needs to remain an independent organisation' (British Neuroscience Association, 13 August 2012), 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 consultation on merger proposals was launched on the 28th of June 2012 and ran until the 28th of September 2012. It was established 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 HTA

fed into the process of compiling the consultation document and were consulted over content. 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. In making their own response the HTA argued for option three which pointed towards retaining the HTA and its functions, but delivering further efficiencies. The HTA argued that these efficiencies could be secured through greater collaborative working with other regulators and agencies.

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)

In response to these proposals Baroness Diana Warwick, chair of the HTA, commented:

> "We welcome the decision to retain the HTA and to establish an independent review of regulation in this area. Since we were established, we have become recognised as a highly successful regulator. We see the proposed independent review as an opportunity to build on our positive reputation, and we look forward to having this perspective on our work.
>
> The HTA is an extremely efficient regulator, and has a good track record of saving money, with 27 per cent savings in the last two years. We recently announced a reduction in fees for licensed establishments for the third year running. We have also increased our collaborative work with others, streamlined our regulatory processes and reduced the burden on those we licence.
>
> We remain committed to working with stakeholders and members of the public to ensure that human tissue and organs continue to be used safely and ethically, with proper consent.
>
> I would like to thank our stakeholders and public-facing groups for their support. I would also like to pay tribute to HTA staff and Authority members. The success of the HTA is down to their commitment and hard work" (Warwick, 25th January 2013)

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:

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

Department of Health. (March 2011) Public Bodies Bill: Committee Stage Briefing. London: Human Tissue Authority. London: Department of Health.

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Human Tissue Authority. 'Press Release', http://www.hta.gov.uk/arms-lengthbodiesreview.cfm, accessed 14 January 2013.

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Human Tissue Authority. (27 November 2012) 'Minutes'. Fifty-Eight Meeting of the Human Tissue Authority. London: The Westminster Conference Centre. Available: http://www.hta.gov.uk/_db/_documents/pdf_Authority_papers_27_November.pdf, accessed 14 January 2013.

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.

Warwick, D. (25th January 2013) HTA Responds to the Governments Announcement on its Future. HTA Website. Available here: http://www.hta.gov.uk/newsandevents/htanews.cfm/1116-HTA-responds-to-the-Government-s-announcement-on-its-future.html, accessed 1st February 2013.