

# Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority

An Independent Report to the Parliamentary  
Under Secretary of State for Public Health and  
the Minister for the Cabinet Office by Justin  
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April 2013



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# Foreword

I have pleasure in presenting the report of my review of the work of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

In undertaking the review I have taken evidence from a wide range of stakeholders of the two bodies. A clear picture has emerged from this work, of two expert bodies each playing an important and distinct role in providing assurance and maintaining public confidence in complex, sensitive, and dynamic areas with important consequences for human dignity and fulfilment.

I have identified opportunities to improve the efficiency, effectiveness, transparency, and accountability of the work of the two bodies, and have made appropriate recommendations. I have also examined the possibility of merging the activities of the two bodies and found that there is relatively little overlap between their respective activities.

The balance of benefit and risk therefore favours a modest step of merging the support functions only. This will allow the Authorities and their staff to focus on their primary task of continuing to develop their regulatory work, including improving their more important interfaces with other bodies. My analysis of the evidence does not support any more radical structural change in the areas I have reviewed.

I have also recommended a review of the legislation governing the use of human tissue and transferring the regulation of tissue intended for applications aimed at Advanced Therapy Medicinal Products (ATMPs) from the HTA to the Medicines and Healthcare products Regulatory Agency (MHRA) to simplify the regulatory pathway in this important area of bioscience.

I believe that the recommendations here provide the basis for updating the approach to regulation of these areas by streamlining it, so that innovation is allowed to flourish and the UK remains fully competitive, while safeguarding public confidence.

# Executive summary

1. Public confidence in the sensitive areas regulated by the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) is high, and the regulatory arrangements play an important role in keeping it so. This is the most consistent message to come from my many discussions with stakeholders. While few believe that the current situation cannot be improved upon, the importance of avoiding making changes that would pose a significant risk to this confidence was stressed by many people. Time and again I heard that specialist expertise and focus in the bodies with regulatory oversight are important factors in maintaining this confidence. Furthermore, these strengths also help the UK's international competitiveness.
2. In terms of potential improvements, stakeholders generally put a higher priority on reducing the burden of regulation (while maintaining its effectiveness), including the associated indirect costs of compliance, than on reducing cost within the regulatory bodies themselves. The review has identified a number of opportunities to reduce this burden, as well as ones to reduce direct costs. In the case of the HFEA, I believe that the changes needed can be achieved without any change to legislation. For the HTA some can be achieved within the current legislative framework but some require changes to the legislation that the HTA enforces. Taken together, these improvements will provide considerably greater benefit than the direct cost savings identified in the impact assessment associated with the proposed transfer of functions to the Care Quality Commission (CQC) in the 2012 consultation<sup>1</sup>.
3. Many of the changes can be achieved by the HFEA or the HTA acting on its own. A significant number, however, involve changing the way in which their interfaces with other bodies operate. For the HFEA the main changes involve the interfaces with the CQC and the Health Research Authority (HRA). For the HTA the main changes involve the interfaces with the Medicines and Healthcare products Regulatory Agency (MHRA) and Clinical Pathology Accreditation (CPA). While there are some issues between the HFEA and the HTA they are relatively minor - and the modest scale of this interface has been a significant factor in developing my recommendations.
4. While most stakeholders feel that the highest priority is to address the indirect costs associated with regulation, there is general support for the need to continue to bear down on the direct costs too. Many recognise that considerable progress has been made in this area by both the HFEA and the HTA in the last 3 years, but would still like to see further savings provided these could be achieved without significant risks to the specialist expertise of the two bodies.
5. I heard widely mixed views on the possibility of merging the two bodies. Some consider that this would be a clear way of reducing cost; others see the possibility of sharing expertise and good practice (e.g. on stakeholder engagement); however, the majority were concerned that significant moves towards formal merger would entail more risks than the relatively modest benefits could justify. The risks identified included both

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<sup>1</sup> Department of Health; June 2012; Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority;  
<http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/health/2012/06/consultation-regulators/>

practical ones of reduction in focus and specialist expertise, and broader ones of potential loss of public confidence. A number of people expressed surprise that a merger was again being considered so soon after the idea had been strongly criticised by a Parliamentary Scrutiny Committee in 2007<sup>2</sup>.

6. After consideration of a number of merger options, and taking into account where the most important interfaces for each body lie, I have concluded that much of the potential benefit can be achieved with minimal risk, by merging the two Finance and Resource groups while retaining the separate statutory Authorities with their respective Chairs, Chief Executives, and Members. I also identified opportunities to improve both transparency in the way the bodies undertake their work and their accountability to those who fund it.
7. The recommendations below will, if implemented, both safeguard the many excellent features of the current regulatory landscape regarding Assisted Reproduction Technology (ART) and use of tissue and will ensure that the main concerns to emerge during my review are addressed effectively and proportionately.

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<sup>2</sup> Joint committee on the Human Tissue and Embryos (Draft) Bill First Report;  
<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/16902.htm>

# Recommendations

## Both Bodies

### Recommendation 1

In order to ensure maintenance of public confidence in the activities they regulate, the HFEA and the HTA should be retained as separate Non-Departmental Public Bodies (NDPBs) with distinct identities.

### Recommendation 2

The support services of the two bodies should be combined and managed by a single Director of Finance and Resources, supporting both Chief Executives. This will facilitate the achievement of significant further efficiency savings, estimated at £2.8M over 10 years.

### Recommendation 3

The Department of Health's future estates strategy should take into account the clear operational benefits in terms of facilitating seamless regulation of co-locating in one building all the bodies engaged in regulation and oversight of health care and related research.

### Recommendation 4

In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings.

### Recommendation 5

Both the HFEA and the HTA should establish and operate a (permanent) fees review group to improve accountability and facilitate dialogue with licence fee payers.

## HFEA

### Recommendation 6

To reduce unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the British Fertility Society (BFS) and Association of Clinical Embryologists' (ACE) paper<sup>3</sup> as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation Document for this work by July

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<sup>3</sup> Jane A Stewart and Alison P Murdoch on behalf of the British Fertility Society (BFS) and the Association of Clinical Embryologists (ACE); 2013; The collection of data on assisted reproduction treatments in the UK: Recommendations by BFS and ACE. Human Fertility (In press) doi:10.3109/14647273.2013.770239

2013 and then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1M.

## Recommendation 7

On completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART.

## Recommendation 8

In order to improve the approval process for research projects involving gametes and embryos, the HFEA should commit to participating fully in the new Integrated Research Application and Approval System (IRAAAS) from its launch in 2014, (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it.

## Recommendation 9

In the legislation establishing the HRA the Department of Health should ensure that it has a duty to provide a “one stop shop” for advice for those intending to undertake health research, and should ensure that the legislation includes a “duty to cooperate” among all regulatory bodies.

## Recommendation 10

The HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different activities that it oversees. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities that it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity.

## Recommendation 11

The HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter’s regulatory oversight but which take place within premises regulated by the HFEA.

## Recommendation 12

The HFEA should implement their agreement with CQC, which was approved by the HFEA during my review, to eliminate duplication of regulatory activity between them.

## Recommendation 13

The HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months’ time the HFEA should undertake a structured

and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan.

## HTA

### Recommendation 14

The HTA should sharpen the risk focus of its regulatory approach, for example by using progressively lighter touch inspections for high performing licence holders as long as risk assessments indicate this is appropriate; reducing the intensity of regulatory scrutiny for lower risk activities such as public displays; and by reviewing the operation of the European Union Organ Donation Directive (EUODD) after the first round of audits.

### Recommendation 15

To further reduce the burden of regulation the Department of Health (DH) should review the legislation governing the use of human tissue and consult on amendments to bring it more into line with the legislation in force in Scotland. Consideration should be given (inter alia) to: reducing the scope so that microscope slide and tissue block samples and bodily products such as saliva, urine, and faeces are excluded; and exempting from the need for a licence the removal of tissue from deceased donors (where appropriate approvals are in place and where this is not part of an anatomical or post mortem examination).

### Recommendation 16

The HTA should continue to pursue closer cooperation with other regulators to eliminate any overlaps or inconsistencies in regulatory activities and to ensure that there are well understood and seamless regulatory pathways for organisations engaged in activities that are regulated by other bodies, notably the MHRA.

### Recommendation 17

The regulation of tissue for applications aimed at developing medicinal products (cell based Advanced Therapy Medicinal Products (ATMPs)) should be transferred from the HTA to the MHRA in order to simplify the regulatory pathway for those involved in such developments.

### Recommendation 18

The HTA should prioritise its collaborative work with CPA to eliminate any duplication in the inspection activities of the two bodies by the end of the current financial year.

# Chapter 1

## Background to the review

1.1 The Coalition Government made a commitment in its programme for Government (May 2010) to cut the number of health arm's-length bodies and to reduce bureaucracy significantly. In *Liberating the NHS: Report of the arm's length bodies review* (July 2010)<sup>4</sup>, DH set out its intention to simplify and reduce radically the number of NHS bodies including the DH's arm's length bodies. It said that the HFEA and the HTA would be retained temporarily as separate arm's length bodies with a view to transferring their functions to other bodies by 2015.

1.2 In June 2012, DH published a consultation document<sup>5</sup> containing detailed options for the future of the HFEA and the HTA, which included the transfer of functions to the CQC and the HRA. The DH response to the consultation, published in January 2013<sup>6</sup>, noted that the majority of respondents did not favour a transfer of functions to the CQC and the HRA and recognised a strong message about the risk of losing specialist expertise if functions were to be transferred. Accordingly it was decided that both bodies should be retained as separate entities, but that an independent review should be set up into the way the HFEA and the HTA operate. The Terms of Reference for the review, which I was invited to undertake, are at Annex 1.

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<sup>4</sup> Department of Health, *Liberating the NHS : Report of the arm's length bodies review*. July 2010  
[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\\_118053.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118053.pdf)

<sup>5</sup> Department of Health; June 2012; Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority;  
<http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/health/2012/06/consultation-regulators/>

<sup>6</sup> Department of Health; January 2013; Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority;  
<http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/health/2013/01/response-hfea-hta/>

# Chapter 2

## Roles of the HFEA and the HTA

### HFEA

2.1 The HFEA regulates treatment using eggs and sperm, and treatment and research involving human embryos. Its role is UK wide. It sets standards for, and issues licences to, fertility clinics. The HFEA's main statutory functions as a regulator under the Human Fertilisation & Embryology Acts 1990 and 2008 and other legislation are to:

- license and monitor clinics carrying out in vitro fertilisation (IVF) and donor insemination;
- license and monitor establishments undertaking human embryo research;
- maintain a register of licences held by clinics, research establishments and storage centres;
- regulate storage of gametes (eggs and sperm) for treatment and embryos;
- as the UK's Competent Authority implement the requirements of the European Union Tissue and Cells Directive (EUTCD) as far as gametes and embryos are concerned;
- license intrauterine insemination (IUI), gamete intrafallopian transfer (GIFT) and other services.

2.2 The HFEA also provides guidance and advice. It has a statutory duty to produce and maintain a Code of Practice setting out quality and safety standards for treatment and research.

2.3 It also has a duty to maintain a formal register of information about donors, licensed treatments and children born as a result of those treatments and has a role in providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients, including servicing the statutory right of access to register information. It also reviews information about human embryos and developments in research involving human embryos.

### HTA

2.4 The HTA ensures that human tissue is used safely and ethically and with proper consent by regulating activities concerning the removal, storage, use and disposal of human tissue for England, Wales and Northern Ireland.

2.5 The HTA licenses and inspects over 800 organisations that store and use human tissue for the purposes listed below:

- teaching about or studying the human body;
- carrying out post-mortem examinations;
- using human tissue to treat patients;
- carrying out research on human tissue;
- organ donation;
- displaying human bodies or tissue in public (e.g. in a museum).

2.6 It also gives approval for donations of organs and, in certain circumstances, bone marrow from living people. A living person who wants to donate their organs or bone marrow has to go

through an independent assessment process to make sure that their interests are looked after and that no payment is made.

2.7 It works under three main pieces of legislation: the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012. It is the UK's Competent Authority for the EU Tissue and Cells Directive (in respect of tissue other than gametes and embryos) and for the EU Organ Donation Directive. The HT Act applies to England, Wales and Northern Ireland. The HTA regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

2.8 To ensure these laws are followed, the HTA sets standards for the regulated sectors against which it carries out inspections. These standards have been developed under the headings of consent; governance and quality; premises, facilities and equipment; and disposal.

# Chapter 3

## The review process

3.1 Work on this review began on 25<sup>th</sup> January 2013 immediately following the announcement of the outcome of the Department of Health's consultation on the transfer of functions from the HFEA and the HTA. In conducting the review I have adopted the principles set out in the Cabinet Office guidelines<sup>7</sup> for the triennial reviews of arm's length bodies and have sought to be as inclusive and transparent as possible, and have challenged extensively – but I hope always in a proportionate way.

3.2 All those who responded to the consultation were informed that an independent review had been commissioned and that my review would take into account comments made in their responses. They were also advised how they could make additional contributions if they so wished.

3.3 I reviewed all 109 consultation responses and subsequently conducted in-depth interviews with around 40 of those respondents.

3.4 The review was made public through a Parliamentary Statement, a press release and on the Department of Health website. In addition I contacted a number of parties (in the UK and internationally) that I thought might offer a valuable perspective on the issues covered by the review and invited them to contribute.

3.5 I have reviewed a range of relevant literature recommended to me by stakeholders and have taken account of proposals from both regulators and from a wide range of stakeholders who identified possible options for improvement.

3.6 I have held discussions with the Chair and Chief Executive of the HFEA and the Chair and Chief Executive of the HTA both separately and together, as well as with a number of their staff.

3.7 I have liaised with the Devolved Administrations to ensure proper account is taken of the relevant UK-wide perspective in my findings.

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<sup>7</sup> Cabinet Office; June 2011; Guidance on reviews of non-departmental public bodies; [www.civilservice.gov.uk/.../triennial-reviews-guidance-2011\\_tcm6-38900\(4\).pdf](http://www.civilservice.gov.uk/.../triennial-reviews-guidance-2011_tcm6-38900(4).pdf)

# Chapter 4

## Findings of the review

### General

4.1 The most consistent message to come from my discussions with stakeholders is that public confidence in the sensitive areas regulated by the HFEA and the HTA is high, and the importance of not doing anything that would pose a significant risk to this was stressed. Time and again I heard that specialist expertise and focus in the bodies with regulatory oversight are important factors in maintaining this confidence. As one stakeholder put it:

*“what is most important is that regulation is fit for purpose, promotes the interest of patients and inspires confidence in professionals and the wider public. To achieve this, the regulatory pathway requires bodies that are independent, appropriately resourced and financed, and possessed of adequate expertise.”*

4.2 I also heard from industry that the UK regulatory environment, despite its complexity, compares favourably with most others. Again, the specialist expertise in the regulators and their understanding of the science underpinning commercial developments in the field were cited as critical, and important to preserve. Both the HFEA and the HTA have much to be proud of for their role in achieving this degree of public confidence and for the respect in which they are generally held.

4.3 I considered whether or not the work of the HFEA and the HTA meets any of the 3 Cabinet Office tests for arm’s length bodies, and whether or not there is an ongoing need for it. In both cases the work is technical in nature and there is a requirement for impartiality and independent action. The dynamic nature of the fields that each body oversees means that there is an ongoing need for their work. I am therefore satisfied that the tests are met.

4.4 This review also clarified that, while there are similarities between these two bodies and some limited interfaces, by and large their work is separate and each body needs to address different issues if they are to remain effective and efficient as the fields that they regulate continue to develop. It would be a missed opportunity if the recommendations in this report concentrated solely on the areas of common interest, and so I have addressed separately the unique issues for each body as well as the common ones that I believe both should address.

4.5 The most important distinctions to be drawn at a high level are as follows. There is almost universal praise for the Human Fertilisation and Embryology Act, and recognition that it is still fit for purpose. The discretion it gives to HFEA to adjust and adapt the regulatory environment in line with changes in the field of ART has made and continues to make it possible for regulation to keep in step with this developing field. The complex and sensitive nature of the decisions that HFEA takes inevitably means that not everyone agrees with every decision, or indeed even on the scope of what issues it should address, although there is much respect for its work. There is also, however, a fairly widespread sense that the HFEA needs to do more to properly take into account stakeholder views and to be seen to do so. On the other hand, while the HTA is widely seen as a pragmatic and responsive regulator as well as an effective one, there are concerns that some of the provisions of the Human Tissue legislation are overly onerous, adding significantly to regulatory burden without a concomitant increase in public protection.

4.6 In terms of potential improvements, stakeholders generally put a higher priority on reducing the burden of regulation (while maintaining its effectiveness), including streamlining the way different regulators work with each other, and the associated indirect costs of compliance, than on reducing cost within the regulatory bodies themselves. The review has identified a number of opportunities to reduce this burden as well as to reduce direct costs. Taken together, these improvements will save considerably more money for “UK plc” than the direct cost savings identified in the impact assessment associated with the proposed transfer of functions to the CQC in the 2012 consultation. Some of these are already being pursued by the HFEA and the HTA, others need to be addressed by these two organisations (working with others), and some require action by the Department of Health.

4.7 In addressing the specific points in the terms of reference of the Review I will deal first with the issue of merger since the recommendation on this sets the context for the other recommended actions.

## Merger and Cost Saving

4.8 I heard widely mixed views regarding the possibility of merging the two bodies. Some considered that this is a clear way of reducing cost; others see the possibility of sharing expertise and good practice (e.g. on stakeholder engagement); however, the majority were concerned that significant moves towards formal merger would entail more risks than the relatively modest benefits could justify. The risks identified included both practical ones of reduction in focus and specialist expertise, and ones of potential loss of public confidence if the public identity of either body were affected.

4.9 A number of people referred to the consideration in 2007 of establishing a single body to discharge the functions of both HFEA and HTA, and the findings of a joint scrutiny committee of both Houses of Parliament<sup>8</sup>. I was told that the findings, which did not favour such a merger, are as relevant today as then. In essence, the benefits in terms of reduced cost and reduction in number of regulators were not seen to be large enough to offset the associated risks of loss of expertise and focus in each of the distinct areas regulated by these two bodies.

4.10 I have considered these findings. I have also considered that there is now a significantly different environment than that which pertained in 2007, particularly in terms of the pressure on public expenditure and the government’s stated aim of reducing the number of arm’s length bodies.

4.11 While the environment is different from 2007, the basic situation regarding the tasks of the HFEA and the HTA remains unchanged – they regulate distinct and largely separate areas, each of which benefits from the expert focus of a specialist regulator. While it is undoubtedly true that a single larger body could undertake this task, the only potentially significant practical benefit that such an arrangement could bring would be reduced cost (the other potential benefits of sharing good practice in areas of common interest are both modest in scale because the activities regulated are different, and potentially achievable without structural change). I

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<sup>8</sup> Joint committee on the Human Tissue and Embryos (Draft) Bill First Report; <http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/16902.htm>

have therefore looked at the costs of a number of different options to help formulate my view and recommendation.

4.12 The 4 options that I have considered are:

- a) Single body with one Chair, Chief Executive, and one set of Members (this would require amendments to both the HFE Act and the HT Act);
- b) Retention of the present statutory bodies but with a single Chair appointed to both Authorities, a single Chief Executive, and lay Members appointed to both Authorities;
- c) Retention of two Chairs and two Authorities with no systematic sharing of Members, but with a single Chief Executive supporting both;
- d) Retention of two Authorities, two Chairs, two Chief Executives, but a single combined Finance and Resources group (with a single Director) supporting both.

4.13 Estimates have been developed for the likely cost savings in each scenario. No attempt has been made to estimate the costs of the transitions necessary to implement each option, though it is clear that these would be greater (and potentially quite significant) in options (a) to (c). The running cost estimates are set out in Annex 2, together with a short analysis of the issues associated with each option.

4.14 It is important to note that the savings identified in these options are in addition to those that have either already been achieved by the HFEA or the HTA or are already included in their business plans. This baseline against which the savings are measured includes a reduction in the combined cost of the two bodies from £14.4M in 2010/11 to £9.3M in 2014/15.

4.15 A number of points emerge from this analysis. First, the total potential savings are smaller than those estimated from just one of the proposed actions to reduce regulatory burden – the revision of the HFEA’s information collection arrangements (see below). This underlines the importance of achieving reductions in indirect costs of regulation, and indicates that the pursuit of merger should not be allowed to distract from that end. Secondly, the difference between the running costs of the most radical option of statutory merger and the merger involving only the Finance and Resources groups is only £0.4M per year (and the net benefit would be reduced by the higher transition costs). Finally, the savings identified in this analysis of the merger of the two Finance and Resources teams (£2.8M over 10 years) can be achieved at very low risk to the specialist regulatory activities of the two bodies and are worthwhile in the context of the total costs of the two bodies. (It is worth noting that these savings are also similar in scale to those identified in the impact assessment of the transfer of functions to the CQC.)

4.16 One important aspect of the governance of each body is the number of Members on each Authority and their make up in terms of expertise. The Authorities have considerably wider roles laid down in statute than those of a typical organisation’s Board, and each has restrictions placed on the balance between professional and lay members. There has been extensive consideration in the past between each Authority and the Department of Health on the most appropriate size and make up of each Authority. This has led to significant reductions in size, from 19 to 12 in the case of the HFEA<sup>9</sup> and from 17 to 12 in the case of the HTA<sup>10</sup>. I am satisfied that this matter has been carefully considered and an appropriate balance struck between streamlining the work of each body and maintaining the expertise and resource necessary for it to continue to discharge its specialist work effectively and so to command public and professional respect.

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<sup>9</sup> Correspondence from Chair, HFEA to Director General Public Health, Department of Health; 15<sup>th</sup> October 2012

<sup>10</sup> Correspondence from Chair, HTA to Director General Public Health, Department of Health; 29<sup>th</sup> January 2013

4.17 In parallel with my review the Department of Health has conducted a review of the back office functions of the two bodies. The report of that review<sup>11</sup> concluded that both bodies already use shared service principles, and did not identify any significant savings in the short term by pursuing this approach further. While the HFEA and the HTA will be expected to take part in the cross government shared service initiative, it noted that small bodies such as these might actually be required to join more expensive services in future in order to support the wider collective benefits. I have therefore taken the view that “self help” between the two organisations is the approach most likely to deliver benefit in the foreseeable future.

4.18 After careful consideration of these options, I do not believe that the risks to regulatory focus and effectiveness associated with the more radical merger options are justified by the relatively modest additional cost savings associated with them. Much of the potential benefit of merger can be achieved by merging the two Finance and Resource groups while retaining the separate statutory entities with their respective Chairs, Chief Executives, and Boards. This approach has the major benefit of posing least risk to public confidence in the sensitive areas regulated by the HFEA and the HTA.

#### *Recommendation 1*

*In order to ensure maintenance of public confidence in the activities they regulate, the HFEA and the HTA should be retained as separate Non-Departmental Public Bodies with distinct identities.*

#### *Recommendation 2*

*The support services of the two bodies should be combined and managed by a single Director of Finance and Resources supporting both Chief Executives. This will facilitate the achievement of significant further efficiency savings, estimated at £2.8M over 10 years.*

4.19 In examining the merger option I also considered location, since evidence shows that proximity promotes improved cooperation. At present the HFEA and the HTA are located in different parts of London, but each shares a building with other health bodies. The HFEA is located in the same building as the CQC and the HTA is in the same building as the MHRA. While it would help the merging of the Finance and Resource function I do not recommend that either the HFEA or the HTA should relocate. For each of them the relationship with the body with which they already share a building is more important in terms of delivering seamless regulation than the relationship between the HFEA and the HTA themselves.

4.20 However, it is clear that overall seamless regulation of the health sector would be facilitated if all health regulatory bodies were located as close together as possible. While I do not believe that the benefits of co-location would justify the costs and disruption of relocating organisations where this is not otherwise necessary, it should be a factor taken into consideration in developing a future estates strategy for the Department of Health’s arm’s length bodies.

#### *Recommendation 3*

*The Department of Health’s future estates strategy should take into account the clear operational benefits in terms of facilitating seamless regulation of co-locating in one building all the bodies engaged in regulation and oversight of health care and related research.*

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<sup>11</sup> Department of Health; February 2013; Review of the HFEA/HTA : Efficiency Savings from Shared Services

## Burden of Regulation and Streamlining

### Both Bodies

4.21 Effective engagement between regulatory bodies and their stakeholders is of great importance because of the contribution it can make to improving mutual understanding, so promoting willing compliance with regulatory standards. It is also potentially of substantial value in helping the regulators identify new issues as they emerge and so enabling them to take early and effective action to adapt to changing circumstances (such as the emergence of new techniques).

4.22 Both the HFEA and the HTA already have arrangements in place to engage and consult with the organisations that they regulate and with their other stakeholders. There are differing views about the effectiveness of these arrangements, and the engagement with some sectors appears to be working more effectively than with others. I found that there was a pattern among stakeholders of less than complete knowledge and understanding about the approach to regulation that each body adopts and about changes that each is planning.

4.23 Such engagement is extremely difficult to perfect, but I believe there is scope for both bodies usefully to establish more comprehensive arrangements for consulting on a routine basis with their stakeholders about their regulatory approach, and proposed changes to it. Such arrangements need to provide meaningful opportunities for stakeholders views to be heard and their issues to be addressed in a transparent fashion.

#### *Recommendation 4*

*In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings.*

4.24 The HFEA and the HTA both cover the majority of their costs by levying charges on the organisations that they regulate. Unsurprisingly some feel that the charges are either too high, linked to the wrong indicators of activity, or insufficiently predictable. I am surprised that neither body has a standing charging review group to provide a forum for discussion of and consultation on such issues on an ongoing basis. Such a group could receive and comment on information concerning the general level of charges that have been applied, and those being proposed for the future; contribute to any review of charging; help devise and consider the merits of alternative charging schemes if appropriate; and report annually to the Authority on the effectiveness, efficiency and operation of the charging regime.

#### *Recommendation 5*

*Both the HFEA and the HTA should establish and operate a (permanent) fees review group to improve accountability and facilitate dialogue with licence fee payers.*

## HFEA

### Information

4.25 The HFEA has an important statutory role in ensuring that adequate records are kept of gamete and embryo donation, assisted conception and their outcomes including, critically, of any offspring resulting from them. They oversee a process of recording and reporting of this information and manage a national register that provides a comprehensive and permanent record. This is a major undertaking and entails significant cost for both the HFEA and the clinics that collect and provide the data.

4.26 There is widespread agreement that this register is valuable and necessary, and needs to continue to be updated. All agree too that a review is needed of what information should be recorded, and the process by which it is collected in order to reduce the costs associated with this work. The HFEA already has a plan to overhaul its work in this area, and agreement in principle with the Department of Health to use part of its existing cash surplus to fund the project. It is essential that this work proceeds without delay. It is equally important that it is conducted in an inclusive manner so that all relevant stakeholders have confidence in the resulting requirements (both in terms of the information that will in future be collected and recorded – and its suitability as a research resource - and in the process by which this happens).

4.27 There are clear indicators of how this project should be taken forward, from feedback on a previous HFEA success and from work already undertaken in this area on behalf of the BFS and ACE. The HFEA's work on reducing multiple births, the "One at a Time" project, was well received and recognised as an excellent piece of stakeholder involvement. It should be used as a model for the approach to this project. A clear and detailed report<sup>12</sup> on the information requirements themselves has been prepared on behalf of the BFS and ACE by J Stewart and A Murdoch. The report estimates that adoption of its recommendations would save approximately £1M per annum among the approximately 100 clinics that provide the information to the HFEA. The HFEA itself also expects to make some savings as a result of this work. This report should be used as the basis for discussion of future information requirements.

#### *Recommendation 6*

*To reduce unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the BFS/ACE paper as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation Document for this work by July 2013 and then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1M.*

4.28 A related issue of significant importance is the use of the information contained in the register. This falls into two broad categories, with quite different issues attaching to each. There is the aggregated data, stripped of any personal identifiable information, that is of great value to researchers and is of significant public interest. There is also the detailed personal information of direct relevance to some individuals, particularly to those conceived as a result of ART.

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<sup>12</sup> Jane A Stewart and Alison P Murdoch on behalf of the British Fertility Society (BFS) and the Association of Clinical Embryologists (ACE); 2013; The collection of data on assisted reproduction treatments in the UK: Recommendations by BFS and ACE. Human Fertility (In press) doi:10.3109/14647273.2013.770239

4.29 There is a clear public interest in the aggregated data being made available in easily accessible format. While the HFEA does this to some extent already, I heard a number of comments to the effect that the register still represents an underexploited resource in this regard.

4.30 Access to personal information, especially for donor conceived individuals, is very important. The HFEA already has arrangements in place to facilitate this, and to signpost counselling services to those who may find them helpful. The number of people requesting such information is set to increase significantly in the next few years as greater numbers of donor conceived individuals reach 18 years of age. But this will always remain a relatively minor activity for the HFEA and it will consequently be difficult for it to keep up to date with good practice in the area of support for such people. It may well be that there are other organisations for whom this type of work is more mainstream (such as post adoption services) that would be better placed to do this for the HFEA. This point is also discussed in a recent report by the Nuffield Council on Bioethics.<sup>13</sup>

4.31 Once the information collection project has been completed the HFEA should establish projects to review both of these areas of provision of information from the register, using a similarly inclusive approach as for the information collection project.

#### *Recommendation 7*

*On completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART.*

#### **Research**

4.32 There is considerable concern about the current situation regarding the approval of research projects involving embryos and gametes. The current system exposes the applicants for approval for such research to multiple jeopardy from the different organisations involved in the approvals process and typically takes many months to complete. There are two main consequences of this. There are cost inefficiencies as research teams are prevented from progressing their work and cannot simply be “stood down” pending approval for their new work. Secondly, the difficulties in obtaining research licences inhibit people from applying for them. This can mean that some developments are delayed in the UK, and it provides an incentive for people not to classify activities as research if there is any way of avoiding this. This could potentially lead to important learning, for example from developments in in vitro fertilisation (IVF) techniques, not being captured and shared because they are not properly evaluated and reported. In addition, an increase in the research carried out in this area will enhance the UK’s international competitiveness.

4.33 All concerned, including the HFEA, now agree that the way to resolve the current concerns is for the HFEA to participate in the research application scheme run by the HRA. The HRA told me that they are currently developing a new system that will include coordination not just of the application but also of the approvals, and that this new Integrated Research Application and

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<sup>13</sup> Nuffield Council on Bioethics; April 2013; Donor conception: ethical aspects of information sharing; <http://www.nuffieldbioethics.org/donor-conception>

Approval System (IRAaS) will be introduced in 2014. If the HFEA commits resource now to work with the HRA it could be part of this new system from its launch.

4.34 The IRAaS will be a system platform but greater coordination is also required to ensure that the different partners also work effectively together through the system platform. Currently there are Memoranda of Understanding (MoUs) in place to underpin the coordination of activity between the HRA and the HTA, and the HRA and the MHRA. To ensure full benefit of coordination of activity similar arrangements should be put in place between the HFEA and other bodies with linked activities.

#### *Recommendation 8*

*In order to improve the approval process for research projects involving gametes and embryos the HFEA should commit to participating fully in the new IRAaS system from its launch in 2014 (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it.*

4.35 In view of the complexity of the wider research approvals process (ie not just that relating to the HFEA) stakeholders are keen that there should be a duty for all regulatory bodies to cooperate with the HRA, and for the HRA to act as a “one stop shop” for advice for applicants. I support these proposals and understand that both are currently included in the draft legislation.

#### *Recommendation 9*

*In the legislation establishing the HRA the Department of Health should ensure that it has a duty to provide a “one stop shop” for advice for those intending to undertake health research, and should ensure that the legislation includes a “duty to cooperate” among all regulatory bodies.*

### **Balance of Regulatory Activity**

4.36 The HFE Act requires the HFEA to promote compliance with all requirements of the Act and with its Code of Practice. Its regulatory role in relation to ART is thus broad and includes the welfare of any child who may be born as a result of the treatment.

4.37 I heard widely varying views about the approach taken to regulation of ART by the HFEA. Some believe that ART that does not involve a donor is now routine and does not require any special regulatory oversight beyond that afforded to other medical procedures. Some find the current approach to inspections to be too focussed on process and not enough on the quality of the work in the clinic. Others point out the vulnerable situation of prospective parents considering ART, the potential long time period between interventions and the recognition of their consequences, the ongoing innovations in the techniques involved in ART, and the commercial factors relating to many of the treatments.

4.38 The HFEA is regulating a sensitive, complex, and rapidly changing field. It is beyond the scope of this review to set out in detail what the HFEA should and should not regulate, but it is appropriate to reinforce the role set out for the HFEA in the HFE Act. It should continue to oversee all ART and not, for instance, confine its attention only to those techniques in ART relevant to donor conceived children. In doing this, however, it should ensure that it carefully assesses developing evidence of risk and takes due account of this in determining its priorities for action.

4.39 Innovations in techniques of ART inevitably carry risk and so should receive correspondingly close regulatory scrutiny. The reported wide variation in practice in the use of techniques such as intra-cytoplasmic sperm injection (ICSI) and preimplantation genetic

screening (PGS) between different clinics for instance ought to be subjected to regulatory oversight to ensure that differences are the result of legitimate clinical need and not other factors.

4.40 Similarly where there are well known side effects of ART techniques, such as ovarian hyperstimulation syndrome (OHSS), the HFEA should make sure that appropriate standards in managing them are being adopted across the sector.

4.41 The HFEA should also ensure that relevant information about clinic performance in these areas is available alongside success rates to enable prospective patients to take balanced decisions on their treatment options.

4.42 It is worth noting here that the work that the HFEA led in reducing multiple births, the “One at a Time” project, is universally praised and may provide a model for addressing some of these other topics.

4.43 In dealing with such clinical issues the HFEA must work closely with the relevant professional bodies such as the Royal College of Obstetricians and Gynaecologists (RCOG), the British Fertility Society (BFS), the British Andrology Society (BAS), etc and of course take account of relevant National Institute for Health and Care Excellence (NICE) guidance.

#### *Recommendation 10*

*The HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different activities that it oversees. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities that it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity.*

4.44 A number of items used in IVF clinics fall under the MHRA’s regulatory oversight. This includes items such as the medium in which embryos are grown, incubators etc. In practice the HFEA, because of its close contact with clinics and their labs, will usually learn of any issues involving such items before the MHRA does. The HFEA will therefore effectively provide “eyes and ears” for the MHRA on matters in IVF clinics, involving them as and when appropriate. Adverse incidents will continue to be reported to the MHRA.

#### *Recommendation 11*

*The HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter’s regulatory oversight but which take place within premises regulated by the HFEA.*

### **Cooperation with CQC**

4.45 At present both the HFEA and the CQC regulate IVF clinics. In practice a number of the CQC’s requirements for registration have already been relaxed, so the CQC’s involvement in IVF clinics is now confined to operating theatres. In most IVF clinics this limited involvement of the CQC is inefficient and unnecessary. The HFEA and the CQC have now reached agreement on how the HFEA will take over responsibility for this work, and plan to do this from 1<sup>st</sup> October 2013. In doing so it must be careful to apply the same standards as previously applied by the CQC so that hospitals with multiple operating theatres (most of which will continue to be inspected by the CQC) do not experience different standards applied to different theatres. Its

approach should also take due account of the assurance given by CQC's oversight of hospital systems for managing operating theatres.

4.46 There is not yet widespread understanding of the relaxations in registration requirements introduced by the CQC. The new arrangements whereby the HFEA assumes responsibility for all the CQC's regulatory work in IVF clinics should be introduced as soon as possible and the changes communicated carefully.

*Recommendation 12*

*The HFEA should implement their agreement with the CQC, which was approved by the HFEA during my review, to eliminate duplication of regulatory activity between them.*

## Stakeholder Engagement

4.47 Regulators, particularly ones with sensitive and complex roles such as the HFEA has, will always experience challenges in their relationships with stakeholders – both the organisations that they regulate and those with a particular interest in the degree of protection achieved by their regulatory activities. It was not a surprise to me to receive a number of comments about the HFEA's engagement with its stakeholders. But a pattern emerged from my discussions with stakeholders that needs to be addressed in order to facilitate more efficient and effective regulation, and compliance with the requirements of the HFE Act.

4.48 Many recognise HFEA's expertise in handling large, set piece consultations. It is also recognised that the HFEA puts much resource into communication about its more routine work, and this is appreciated. But this communication is seen as a predominantly one way process. There is not a general confidence that the organisation is really open to suggestions and ideas from outside, or that decision making processes are really influenced by stakeholders' contributions. This leads to a situation where relationships are sometimes unnecessarily confrontational, and decision making sub-optimal.

4.49 The situation is certainly not all bad. Many referred to an excellent example of engagement in the "One at a Time" project and would very much like the HFEA to use the approach adopted for it (with systematic engagement of stakeholders from an early stage in the process) as a template for future engagement. Others commented that there have been some recent signs of a more two way approach to communication.

*Recommendation 13*

*The HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months' time the HFEA should undertake a structured and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan.*

## HTA

4.50 The HTA, since its establishment, has overseen a major improvement in public confidence in the handling of human tissue. This sentiment was expressed by a wide range of stakeholders, and its importance for such practical matters as facilitating organ donation and reducing the stress for recently bereaved families is clear. The HTA has also developed a good reputation among its stakeholders for being prepared to listen to feedback and consider it carefully.

4.51 Despite these very positive aspects of its work, there are still some concerns that the regulatory environment is unnecessarily burdensome at present, and the review has identified some opportunities to reduce this burden without reducing in any significant way the level of public assurance.

### Focus on Risk

4.52 The HTA already adopts a risk based approach to its work, but the sharpness of its focus on risk could usefully be increased. Specific examples include increasing the differentiation in its inspection activities between sites with different risk profiles; taking a more proportionate approach to the regulation of what is clearly a lower risk sector, that of public display; and reviewing the operation of the EUODD after the first round of audits is complete.

4.53 In terms of its inspection activities the HTA should make more extensive use of risk indicators and assessments to differentiate more sharply between sites/organisations with different risk profiles. Now that most of the legislation that it is enforcing is well established, and the requirements better known by operators, there is a clear opportunity to reduce further the routine aspects of inspection and to focus more sharply on specific topics (as already happens to some extent in themed inspections) and on areas where risk assessment indicates that this may be appropriate.

4.54 The HTA should also work with the main organisations involved in public displays to develop a more proportionate approach to the sector, and has already indicated its willingness to do so.

4.55 A new set of regulations<sup>14</sup> to enact the EUODD in the UK was introduced last year and the HTA is engaged in the first round of audits to enforce them. I heard concerns that the enforcement approach may be more rigorous than is needed to achieve good compliance with the regime. It is clearly appropriate to wait until this first round of audits is complete, but then for there to be an open and transparent review of the approach. I understand that the HTA is already planning such a review, but those organisations affected by the regulations to whom I spoke seemed unaware of this intention.

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<sup>14</sup> The Quality and Safety of Organs Intended for Transplantation Regulations 2012 2012 No. 1501; <http://www.legislation.gov.uk/uksi/2012/1501/contents/made>

*Recommendation 14*

*The HTA should sharpen the risk focus of its regulatory approach, for example by using progressively lighter touch inspections for high performing licence holders as long as risk assessments indicate this is appropriate; reducing the intensity of regulatory scrutiny for lower risk activities such as public displays; and by reviewing the operation of EUODD after the first round of audits.*

**Review of Legislation**

4.56 While these refinements of approach by the HTA will achieve significant reductions in the costs associated with regulation, they will not address all the unnecessary burden. This can only be done if the legislation governing the use of human tissue is reviewed and amended. The main provisions of this legislation have introduced substantial and important safeguards in the handling of human tissue and most importantly have ensured that consent is sought and received before potentially sensitive samples are taken, stored, and used. But experience has shown that some of the provisions are less useful and in some cases, as I heard from patients' organisations, can actually increase stress for families after the death of a relative. Useful experience has been gained in Scotland where the legislative provisions are slightly different from those in England. The areas proposed for review are all ones that are already treated differently in Scotland without any apparent reduction in assurance or public confidence.

4.57 Areas that would benefit from review include the scope of the legislation, which currently includes bodily fluids such as saliva, urine and faeces; whether microscope slides and tissue block samples should be regarded as part of the medical record and so be able to be retained without permission (but consent would still be required for use of such samples for research, education, or training purposes); and whether the taking of tissue from deceased donors (where permission is already in place) needs to be done in licensed premises. The legislation should now be reviewed and possible amendments consulted on with a view to reducing the regulatory burden it imposes while maintaining the degree of public protection and assurance it provides. It will need to be established how much can be achieved by Regulations rather than the more complex process of amending the Human Tissue Act itself.

*Recommendation 15*

*To further reduce the burden of regulation the Department of Health should review the legislation governing the use of human tissue and consult on amendments to bring it more into line with the legislation in force in Scotland. Consideration should be given (inter alia) to: reducing the scope so that microscope slide and tissue block samples and bodily products such as saliva, urine, and faeces are excluded; and exempting from the need for a licence the removal of tissue from deceased donors (where appropriate approvals are in place and where this is not part of an anatomical or post mortem examination).*

**Cooperation with Others**

4.58 The HTA has already made significant progress in cooperating with other regulators with the aim of reducing overlap between regulatory requirements and addressing any inconsistencies that may exist between its approach and that of other bodies regulating the same organisations. It also adopts a proactive approach to helping its stakeholders navigate their way through the various regulatory pathways. Even though the HTA does not have a direct role in the approval of individual research proposals it has engaged proactively with the newly formed HRA, and this approach was widely praised. It is close to agreement with the HFEA on eliminating the need for dual licensing of facilities used for the storage of ovarian tissue (this affects 5 establishments, and the intention is that such storage will be regulated by only one

body by the end of this financial year). It has introduced joint inspections with the MHRA for the premises that they both authorise.

*Recommendation 16*

*The HTA should continue to pursue closer cooperation with other regulators to eliminate any overlaps or inconsistencies in regulatory activities and to ensure that there are well understood and seamless regulatory pathways for organisations engaged in activities that are regulated by other bodies, notably the MHRA.*

4.59 Particular concerns were expressed to me about the regulation of activities aimed at developing cell based therapies. The range of activities undertaken in moving from early research to the marketing of a product involves a complex regulatory pathway, engaging a number of pieces of legislation and several regulators. While established large companies are able to negotiate this pathway without undue difficulty, and all responsible stakeholders recognise the need for close and effective regulatory scrutiny of this pioneering field, there are concerns that the complexity of the current arrangements may be deterring inward investment and is hindering the progress of some small organisations working in this field. The amount of activity in this field is modest at present but it is predicted to grow, so it is important that the regulatory pathway is seamless and as streamlined as is consistent with appropriate public protection. The MHRA needs to be engaged when these developments reach the cell banking stage in preparation for medicinal product clinical development, and has much relevant experience. It therefore seems logical that it should regulate all activities of organisations engaged in this work, so that organisations developing therapies just have to deal with the requirements of one regulator. This will require the MHRA to carry out the licensing and inspecting of the use of tissue and cells (including donation, procurement and testing) when this is aimed specifically at the development of cell based therapy medicinal products. To work as efficiently and effectively as possible this will require close cooperation between the HTA and the MHRA and a degree of flexibility in its application. This may best be achieved by delegation of the functions concerned from the HTA to the MHRA, as is allowed under the Human Tissue Act, rather than by a statutory transfer of functions. The two bodies, with support from the Department of Health, should agree and implement the best means of achieving this change. However, the HFEA should continue to regulate the use of embryos in the small number of instances where these are involved in the early stages of such work.

*Recommendation 17*

*The regulation of tissue for applications aimed at developing medicinal products (cell based ATMPs) should be transferred from the HTA to the MHRA in order to simplify the regulatory pathway for those involved in such developments.*

4.60 Many of the facilities regulated by the HTA are also accredited by CPA, thereby demonstrating compliance with a wide range of laboratory standards and practices. At present the HTA's inspections cover much of the same ground as CPA ones. The HTA has been in discussion with CPA for some time to assure itself that the standards required by CPA are appropriate to its regulatory needs. Having satisfied itself on this point the HTA is now planning to recognise CPA assessment in its own inspection programme, and so cease inspecting those aspects of a facility that have already been assessed by CPA. This change is scheduled to be introduced during the current financial year (2013/2014).

*Recommendation 18*

*The HTA should prioritise its collaborative work with CPA to eliminate any duplication in the inspection activities of the two bodies by the end of the current financial year.*

# Chapter 5

## Conclusions

5.1 The regulatory regimes operated by the HFEA and the HTA are achieving their primary purposes of providing effective public protection and commanding public confidence in sensitive, complex, and dynamic areas. There are thus no public protection or public confidence drivers for changes in the regulatory landscape.

5.2 There are both direct and indirect costs associated with this protection and assurance. Many of these costs are unavoidable, but some costs associated with the current arrangements could be further reduced without any significant reduction in or risks to the fundamental protection that is currently in place.

5.3 Similarly, the existence of a clear and expert regulatory framework facilitates much innovation in these fields in the UK, but the overall complexity of the system is off-putting to some and risks inhibiting growth in an important area of bioscience.

5.4 The recommendations in this report propose a way forward that safeguards the current levels of public protection and confidence while reducing significantly the unnecessary costs of regulation and the regulatory barriers to growth in the bioscience sector.

# Acknowledgements

I am very grateful to all the stakeholders of the HFEA and the HTA who, in contributing their time, insights and ideas, played an essential and invaluable role in my review. I am also grateful to the Chairs, CEOs, Members and staff of the HFEA and the HTA who have been consistently helpful, constructive and courteous in all my dealings with them. Finally I would like to thank the staff in the Department of Health, particularly the Health Science and Bioethics Division, who have supported me most ably and efficiently throughout the review.

# Glossary of Acronyms

ACE:	Association of Clinical Embryologists
ART:	Assisted Reproduction Technology
ATMP:	Advanced Therapy Medicinal Products
BAS:	British Andrology Society
BFS:	British Fertility Society
CEO:	Chief Executive Officer
CPA:	Clinical Pathology Accreditation
CQC:	Care Quality Commission
DH:	Department of Health
EUODD:	European Union Organ Donation Directive
EUTCD:	European Union Tissue and Cells Directive
HFEA:	Human Fertilisation & Embryology Authority
HRA:	Health Research Authority
HTA:	Human Tissue Authority
ICSI:	Intra-cytoplasmic sperm injection
IRAaS:	Integrated Research Application & Approval System
IVF:	In vitro fertilisation
MHRA:	Medicines and Healthcare products Regulatory Agency
MoU:	Memorandum of Understanding
NDPB:	Non-Departmental Public Body
NICE:	National Institute for Health and Care Excellence
OHSS:	Ovarian hyperstimulation syndrome
PGS:	Preimplantation genetic screening
RCOG:	Royal College of Obstetricians and Gynaecologists

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2012 No. 1501; <http://www.legislation.gov.uk/uksi/2012/1501/contents/made>

# ANNEX 1

## Terms of Reference

### Key Activities of the Review

With the intention that the Human Fertilisation & Embryology (HFEA) and the Human Tissue Authority (HTA) introduce further efficiencies in the way in which they both undertake functions and operations, the review will assess and make 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.

### Key Outcomes

A report to be made available by April 2013 for the Public Health Minister and Minister for the Cabinet Office, featuring recommendations in each key activity area about the further efficiencies that could be achieved.

### Timeframe

The project to run from January 2013 to end March 2013.

### Background

The Department of Health, as part of its contribution to the Public Bodies Reform (PBR) programme, conducted a consultation on the proposed transfer of functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA), to the Care Quality Commission (CQC) and Health Research Authority (HRA). The consultation was held between 28 June and 28 September 2012.

The majority of respondents (nearly three quarters) including most of the leading bodies, disagreed with the option of transferring the HFEA and HTA functions to the CQC and HRA. Given the strength of responses, DH Ministers have taken the view that they do not believe it would be appropriate at this time to proceed with the transfer of functions.

DH are now proposing to maintain the HFEA and HTA as statutory bodies for the time being, but, in recognition of the broader policy objectives of the PBR programme, are committed to continuing to deliver the statutory duties of the two bodies in a significantly more efficient and lower cost manner. The Department will seek to achieve this by:

- including the HFEA and HTA in the DH Shared Services programme, and;
- commissioning an independent review of the way in which the HFEA and HTA undertake their functions and operations, with a view to delivering greater efficiencies and giving serious consideration to a merger of the two bodies.

The need for a review was a clear message in the consultation responses.

The Review will be undertaken by Justin McCracken.

Justin is currently Chief Executive of the Health Protection Agency. He has substantial experience of regulation, having previously been the Deputy Chief Executive of the Health and Safety Executive and a Regional Director of the Environment Agency. Prior to that Justin, a physicist by background, worked in industry. He started his career as a research scientist and gained experience in operations and marketing before becoming Managing Director of a substantial international technology business.

# ANNEX 2

## HFEA & HTA : Merger Options – Analysis and Assumptions

### The Baseline

The table below sets out the costs of the HFEA and the HTA over the last 3 years and the planned reductions in cost set out in their respective business plans (which cover the period up to 2014/15). They thus represent the baseline against which each of the 4 merger options have been considered.

<b>Base business plans</b>	2010/11	2011/12	2012/13	2013/14	2014/15
HTA £M	6.4	5.0	4.7	4.2	4.0
HFEA £M	8.0	6.5	6.1	5.4	5.3
<b>Total £M</b>	<b>14.4</b>	<b>11.5</b>	<b>10.8</b>	<b>9.6</b>	<b>9.3</b>
HTA People	58	50	46	44	42
HFEA People	79	76	71	69	67
Total People	137	126	117	113	109

Note: The costs in this baseline are lower than those assumed in the Impact Assessment of the proposed transfer of functions to CQC. The Impact Assessment baseline assumed a higher staff number (by 2) in 2014/15 which is equivalent to approximately £100k in cost.

## **Potential for further efficiencies under merger options:**

### **a) Single Body**

#### **Board/ Authority**

It would be important to respect and preserve the balance between expert and lay members and to preserve subject matter expertise on the Board. This implies having between 6 and 8 expert members and at least one lay member more than the number of experts, plus a lay Chair. This gives a Board of 15 +/- 2 plus a Chair.

With fewer members in total there is a risk of greater pressure on their time - particularly that of the Chair and lay members. This could be managed without increasing their time commitment by delegating more of the work associated with individual regulatory decisions to the Executive and giving Members' work a more strategic focus.

The reduction in the number of Members compared with the current situation is therefore expected to be around 7.

Approximate cost saving of £100k

#### **Executive**

The CEO would have a single senior management team of 4 (CEO, Director of Regulation, Director of Policy, Director of Finance and resources), saving 3 posts compared with the current position.

Approximate cost saving of £300k

Staff savings below this level would be concentrated in the support services area to avoid reducing the regulatory capability of the new organisation compared with the current ones. The potential savings have been estimated at between £200 - 400k. Addition significant savings may be possible by moving to a single business support system. This needs further analysis, so no savings are assumed here.

Approximate cost saving below SMT level £300k

Total Approximate cost savings of this option £700k

### **b) Single Chair, Single CEO, Shared Lay Members across 2 Statutory Authorities**

In principle this option should be very similar in cost terms to option 1, but in practice the existence of two separate authorities with their distinct duties and identities would mean that there were some extra costs (for instance preparation of Annual Reports and Accounts, separate committees). This has not been considered in any detail, but a figure of an extra cost of £100k compared with option 1 is considered to be sensible.

Total Approximate cost savings of this option £600k

### **c) Two Chairs and Authorities with single CEO, no system of sharing lay members**

There would be no cost saving in terms of the Boards/Authorities compared with the current situation, and so an increase in cost of £100k compared with option 2.

Total Approximate cost savings of this option £500k

### **d) Two Chairs, Authorities, and CEOs**

In this scenario each CEO will require a senior management team, but the Director of Finance and Resources would be shared between the two bodies, and the savings in support services identified above also achieved.

There would thus be a saving of one post at SMT level and the savings below this level assumed in options (b) and (c).

Total Approximate cost savings of this option £300k

### **Other Points**

There would be transition costs associated with each option, and these are potentially significant in comparison with the expected savings. No accommodation cost savings have been included as potential savings are dependent on headcount, not the structure of the bodies.

### **Appraisal of Options**

#### **Option (a)**

This would require changes to primary legislation and so could not be achieved quickly. It would also entail significant transition costs, and associated expenditure of effort by both bodies and the Department of Health. Loss of the distinct and separate identities of the two bodies would pose a risk to public and professional confidence. There is a risk of significant distraction from the primary work of regulation in the run up to and during the transition. The extended period of uncertainty for staff may lead to loss of some expertise and reduction in morale and so effectiveness. Experience elsewhere has also shown that joining together specialist bodies with distinct functions leads to the establishment of new groups to provide specialist advice in particular areas to the Board/ Executive, so there is a risk that the actual savings achieved would be lower than those estimated here.

#### **Option (b)**

This would be quicker to achieve than option 1 because no change to legislation is required. Risks associated with transition would consequently be reduced, but there would still be significant costs. Assuming the two separate identities were kept the risks to public confidence would be significantly reduced. The new arrangements would be fairly complex to operate (although many many charitable bodies have similar structures) with the potential for effectiveness to be reduced.

### **Option (c)**

This option would be at least as quick to implement as option (b), and the transition costs would be similar. However, consideration of how it might work in practice leads to real concerns about how conflicting priorities between the two separate bodies might be resolved. In order to cope with this, the single Chief Executive reporting to two Chairs and Authorities might in practice end up delegating much of one area to a senior member of staff who may then come to be seen as the “de facto” chief executive for that area. It is not recommended.

### **Option (d)**

This is the most straightforward, least expensive, and least risky option to implement. The potential savings are correspondingly smaller but, as the changes do not involve the regulatory staff in either body, it is the only option that does not present any risks to the programme of work proposed elsewhere in this report to reduce the indirect burden of regulation. It is worth noting that the expected running cost of this option is very similar to the cost estimated in the 2012 Impact Assessment for continuing these functions within CQC – but the costs and risks associated with the transition are much reduced. The total savings from this option over 10 years are £3.3M, which is equivalent to a net present value of £2.8M at a discount rate of 3.5%.