Department of Health

Response to the review of the HFEA and HTA

Government response to the report of the independent review of the Human Fertilisation and Embryology Authority and the Human Tissue Authority by Justin McCracken

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Prepared by

Department of Health

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Executive summary

1. The Coalition Government made a commitment in its programme for Government[1] to cut the number of health arm's-length bodies and reduce bureaucracy significantly. In line with this, in *Liberating the NHS: Report of the arm's-length bodies review* (July 2010)[2], the Department of Health (DH) set out its intention to reduce radically the number of NHS bodies and DH arm's-length bodies.

2. As part of the above, DH set out proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) to the Care Quality Commission (CQC) and the Health Research Authority (HRA) and carried out a consultation on those proposals between June and September 2012[3]. The Government response to that consultation, published in January 2013[4], noted that the majority of respondents did not favour a transfer of functions to the CQC and the HRA. The response also took careful note of the strong message about the risks around losing specialist expertise should the functions be transferred.

3. Whilst the consultation showed significant support for retaining the bodies and achieving further efficiencies, there was also a clear message of the need for a review of the way the bodies undertake their functions to enable further efficiencies to be delivered.

4. In the light of the above, the Government decided to retain both the HFEA and the HTA as separate statutory bodies at the present time but also to commission an independent review of the way in which the HFEA and the HTA carry out their functions. The review was undertaken by Justin McCracken (the then Chief Executive of the Health Protection Agency) between January and April 2013 following which he reported to Ministers. The report of the review, which also sets out the Terms of Reference for the review, is published alongside this response[5].

5. Having taken evidence from a wide range of stakeholders, Mr McCracken has concluded that the current regulatory arrangements deliver generally effective

[1] The Coalition : our programme for Government; http://www.direct.gov.uk/prod_consum_dg_digitalassests@dg/@en/documents/digitalasset/dg_187876.pdf

[2] 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

[3] 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/

[4] 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/

[5] Review of the Human Fertilisation & Embryology Authority; An Independent Report to the Parliamentary Under Secretary of State for Public Health and the Minister for the Cabinet Office by Justin McCracken; April 2013

regulation and achieve high levels of public and professional confidence. He carefully considered a merger of the two bodies but found little overlap between the activities of the two. He concludes that greater efficiencies will be obtained by reducing the burden of regulation on industry and others than by structural reform or merger. His report contains a number of recommendations in support of that view.

6. We have carefully considered all of the recommendations in Mr McCracken's report. The majority of the 18 recommendations are addressed to the HFEA and the HTA either jointly or separately. Other recommendations are for Government to retain the organisations as separate bodies, for DH to consider co-location of regulators, to ensure a 'duty to co-operate' in respect of the HRA, to consider a review of human tissue legislation and to propose that the regulation of human tissue for applications aimed at developing cell based Advanced Therapy Medicinal Products (ATMPs) be transferred from the HTA to the Medicines and Healthcare products Regulatory Agency (MHRA).

7. In total, we believe that the recommendations will bring benefits to the regulated sectors through improving the efficiency and effectiveness of the regulators and through elimination of unnecessary costs of regulation and regulatory barriers. Importantly, this will be achieved in a way that does not risk the current high levels of public confidence and protection in sensitive and complex areas.

8. We, therefore, accept all of the recommendations. This means that we will retain the HFEA and HTA as separate statutory bodies (Recommendation 1) and give consideration to their location when appropriate within the estates strategy forward planning process (Recommendation 3).

9. Through the Care Bill, currently before Parliament, establishing the HRA as a N on-Departmental Public Body, provision is made to require the HRA and other bodies and individuals to co-operate with one another in the exercise of their respective functions relating to health or social care research. This is with a view to co-ordinating and standardising practice relating to the regulation of research (Recommendation 9). Those bodies include the HFEA and the HTA.

10. The HRA is committed to working co-operatively and in a manner that will ensure that the appropriate systems are in place to allow researchers to achieve high quality, ethical research in as efficient a manner as possible.

11. We recognise that a review of legislation in the complex area of human tissue (Recommendation 15) will be a significant programme of work for DH and that it will be paramount to maintain public and professional confidence around the sensitive issues on which a review will undoubtedly focus. However, we believe that the evidence from Mr McCracken's review is persuasive and that it is timely to examine the human tissue legislation after nearly a decade since the Human Tissue Act was passed.

12. Additionally, reducing regulation is a key priority for the Coalition Government and a review of human tissue regulation is consistent with the aims of that programme of work which include the elimination of avoidable burdens of regulation and bureaucracy.

13. In producing this response, DH has held preliminary discussions with the HFEA and HTA about the recommendations aimed at the two bodies. The response reflects the positive attitude they have taken towards acceptance of those recommendations, and we will work closely with the HFEA and the HTA to support them in implementing the recommendations. We believe that the work that they have already done to achieve efficiencies and to support this review provides a firm foundation for this.

14. We are grateful to Mr McCracken for carrying out such a comprehensive review supported by a clear evidence base.

Chapter 1

Introduction

1.1 The Government response[6] to the Department of Health's consultation on the transfer of functions from the HFEA and the HTA to the CQC and the HRA[7] set out our intention to commission an independent review of both bodies. This review was conducted by Justin McCracken (the then Chief Executive of the Health Protection Agency) between January and April 2013. The report of Mr McCracken's review is published alongside this response.

1.2 The need for a review of how both bodies undertake their functions was a clear message from respondents to the Department's consultation on the transfer of functions. Even where respondents favoured retaining both the HFEA and the HTA as independent regulators (but also delivering further efficiencies) many did not see this as a reason for maintaining the 'status quo'. The range of strongly expressed views around the need for review was a significant factor in our decision to commission this independent review.

1.3 There is clear consistency between many of the key messages that came from our consultation and those from Mr McCracken's review. For example, this review has reinforced the message that public confidence in the sensitive areas regulated by the HFEA and the HTA is high and that confidence stems from the current regulatory structure. Specialist expertise and focus in independent regulators was again cited in this review as being of key importance in achieving effective regulation in these areas; and most felt that reducing the burden of regulation was more important than reducing the costs of the bodies themselves.

1.4 The review sets out its consideration of a merger of the two bodies and finds that there is little overlap in their activities. It also details the evidence that a merger would present more risks than benefits and proposes action to achieve the same potential benefits with minimal risk.

1.5 Our consideration of the 18 recommendations in the report of the review is set out in Chapter 2. A formal Impact Assessment has not been carried out in respect of this review due to both the low level of potential costs and benefits and to the fact that the review, of itself, does not state an intention to introduce new regulations (any legislative change arising from implementation of recommendations would be consulted on and an Impact Assessment carried out at that time). We do, nevertheless, recognise that there will be clear costs and benefits impacting on the regulators, the regulated sectors and central government. We have, therefore, in the light of the Government's commitment to reducing

[6] 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/

[7] 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/

regulation, carried out a short impact analysis to set out our preliminary view of the benefits and/or burdens arising from this review. Our analysis is at Annex 2.

1.6 We have assessed whether any issues arise under this review in relation to equality and believe there are no significant impacts. Nevertheless, as with the 2012 consultation, we do not underestimate the impact on staff of any change and where this is necessary would seek to minimise the impact of any actions.

Chapter 2

Government response to the McCracken recommendations

Recommendations for Government

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.*

2.1 We have carefully considered the strong message set out in this review of the critical importance of maintaining public confidence in the sensitive areas regulated by each body. We also accept the evidence that there is little overlap in the work of the two bodies and that the specialist expertise that each provides on different issues must be maintained to ensure regulation remains efficient and effective and continues to develop.

2.2 This evidence reinforces the messages we received through our 2012 consultation on the transfer of functions from the HFEA and the HTA. Taking account of all of the evidence we have decided that the HFEA and the HTA should be retained as separate statutory bodies with distinct identities. We believe this is a critical factor in ensuring continuing professional and public confidence in these sensitive and complex areas of regulation.

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.*

2.3 We note the synergies identified in the review that arise from co-location of health regulators. The Department has already demonstrated its intent with the co-location of a number of its arm's length bodies into the same buildings. For example, Public Health England and Monitor are now co-located in Wellington House, London; NHS England and the NHS Trust Development Authority are now located in Quarry House, Leeds alongside DH. We agree that there are further potential operational benefits for regulation in bringing regulators and other organisations more closely together in respect of location. We are committed to ensuring that we critically appraise future location of health regulators and other bodies as part of the future DH estates strategy. Any decisions will be assessed within the overall management of the Government estate as overseen and governed by the Department's Property Asset Management (PAM) Board to ensure best operational practice and value for money with the aim of achieving the best value for money and outcome for patients and professionals alike.

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.*

2.4 We recognise that obtaining the necessary approvals for health research has, previously, been a complex process. One of the primary benefits of the new HRA is that it will help simplify the way regulations governing research are used whilst protecting and promoting the interests of patients and the public.

2.5 We have made statutory provision in the Care Bill, which is currently before Parliament, which would require the HRA and other bodies and individuals to co-operate with one another in the exercise of their respective functions relating to health or social care research, with a view to co-ordinating and standardising practice relating to the regulation of research. Those bodies include the HFEA and the HTA.

2.6 We have also made statutory provision that the HRA must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and in doing so, seek to ensure that such regulation is proportionate. This gives the HRA a unique, free-standing duty which would require it to take the lead in actively identifying ways to remove duplication, streamline regulation of health and social care research and seek to ensure that regulation is proportionate. The HRA is already working with others to create a unified approval process and to promote proportionate standards for compliance and inspection within a consistent national system of research governance. For example, the National Research Ethics Service (NRES) has transferred to the HRA providing NRES with a firm foundation to develop new systems such as the Integrated Research Application and Approvals System (IRAaS)) referred to in the review. As a non-departmental public body, the HRA will also be responsible for producing guidance on good practice in the management and conduct of health and social care research and any statutory requirements that people conducting research must comply with.

2.7 We believe that, when enacted, the duties and functions above will meet the intention set out in Recommendation 9; and that currently the HRA is committed to working co-operatively and in a manner that will ensure that the appropriate systems are in place to allow researchers to achieve high quality, ethical research in as efficient a manner as possible.

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).*

2.8 We have carefully considered the findings of the review in relation to the burden of legislation. The introduction of the Human Tissue Act 2004 (HT Act) was an important milestone in updating the law on human tissue and has been instrumental in re-building both public and professional confidence in a complex and sensitive area. We are committed to safeguarding the principles of the HT Act and will also take account of the provisions of the EU Directives relating to the quality and safety of tissue for human application and organs for transplantation. However, in the light of the evidence from this review, our own experience of working with the HTA and stakeholders and the fact that the

legislation is now nearly a decade old, we believe that the time is right to undertake a review of the legislation.

2.9 The Department of Health will initiate a project with a view to a public consultation in 2013/14 on streamlining regulation. We will work closely with the HTA and wider stakeholders in developing proposals that build on the evidence gained through this review.

2.10 We will ensure that this work is considered within the overall context of the Government's priority initiative to reduce the burden of regulation.

Recommendations for the HFEA and the HTA

2.11 As noted in his report, Mr McCracken conducted an inclusive and transparent review in line with Cabinet Office guidelines. Both the HFEA and the HTA contributed extensive evidence to the review at a number of levels, from the Chairs and Chief Executives of the Authorities through to key members of staff, and their invaluable contribution to the review is acknowledged by Mr McCracken.

2.12 We believe that both bodies recognise the benefits to be achieved through implementation of the recommendations and that they are well placed to move forward quickly to effect the recommendations relevant to them. Many actions are already in train.

Recommendation for HFEA and HTA jointly

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.*

2.13 We have listened carefully to the evidence from both our consultation and from this review, of the risks to public and professional confidence in merging the bodies. However, as Mr McCracken's analysis (informed by the bodies themselves) shows, there is further potential for cost savings – but without significant risk – in merging the Director of Finance and Resources and we support this recommendation.

2.14 In view of the discussions that have already taken place between the bodies to inform the review on the cost savings possible from a shared Director of Finance and Resources, we believe this could be rapidly developed and implemented. Those discussions are continuing and a detailed analysis of the scope and operation of the shared functions, costs and savings will be undertaken by October 2013 with the aim of having a shared Director in place by April 2014. The speed at which the support services could be shared will depend on compatibility of finance and IT systems.

Recommendations applicable to both the HFEA and HTA independently

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.*

2.15 We believe that openness and transparency are essential elements in good regulation and recognise the efforts that both regulators have made to date in engaging and consulting those they regulate and other stakeholders. Mr McCracken also recognises the current arrangements that both bodies have put in place but identifies scope to make arrangements more comprehensive and we support this view.

2.16 We acknowledge that the HTA has a number of effective working relationships in place both with those they regulate and with other regulators and commend the HTA's intention to strengthen these relationships to achieve even greater transparency. We look forward to seeing the outcome of that work.

2.17 HFEA action to address this recommendation is dealt with under Recommendation 13.

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.*

2.18 Achieving best value for money through a robust fee setting process is essential to ensure the costs of regulation are both proportionate and fair and that the regulated sector can operate efficiently and competitively.

2.19 We welcome the fact that the HFEA accepts this recommendation and plans to establish such a group within the business year; and that the HTA will implement this recommendation by September 2013, to involve fee payers in fee setting for 2014/15. The HTA action will build on the extensive consultation and workshops held before the present fee model was introduced.

Recommendations for the 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[8] 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.*

2.20 The HFEA Business Plan for 2013/14 commits the organisation to a fundamental review of the information requirements it places on the clinics it regulates. The Department of Health supports this work and has agreed that the HFEA can fund the significant capital expenditure required from its historic cash surplus. The project will cover the scope of the data collected and the method by which it is verified and validated. That work explicitly

[8] 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

builds on the paper referred to in the McCracken Review and the HFEA is putting in place arrangements to ensure that the project is overseen by a wide range of stakeholders, including representatives from the fertility sector.

2.21 We welcome this action.

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 assisted reproduction technology (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.*

2.22 We recognise the importance of this recommendation and support its implementation to maximize the availability and use of information to benefit donor conceived people. We welcome the HFEA's acceptance of this recommendation.

2.23 The HFEA already provides access to its Register for research and is keen to make this vital resource more readily accessible. The HFEA will consider what further support people born as a result of ART may be able to access at its next meeting in July 2013.

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 (IRAaS) 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.*

2.24 We recognise that the HFEA and the HRA have been discussing this issue for some time and both organisations plan to reach a formal agreement at their respective next board meetings. Both organisations support the aim that the HFEA should be a full member of the new IRAaS when it launches.

2.25 We welcome this action towards implementation of this recommendation.

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.*

2.26 The HFEA fully supports this recommendation. It plans to explore these issues through a new Corporate Strategy which will set out the organisation's strategic direction over the next five years. That strategy will be the subject of a public consultation later in this business year (2013/14).

Recommendation 11: *The HFEA should clarify to all concerned how it cooperates with the Medicines and Healthcare products Regulatory Agency (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.*

2.27 The importance of co-operative working to reduce regulatory burden has been a fundamental finding of both this review and the DH consultation itself and we support this - and related – recommendations.

2.28 The HFEA agrees that the regulatory responsibilities of the HFEA and the MHRA should be clarified and it has been working with the MHRA for some months to that end. That work will be completed in the coming months.

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.*

2.29 The HFEA and the CQC reached agreement in March 2013 to eliminate any duplication between their respective regulatory duties in England. That agreement will take effect from 1 October 2013 and communication with the clinics affected will start shortly.

2.30 We welcome the early implementation of this recommendation.

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.*

(see also Recommendation 4)

2.31 The HFEA accepts recommendations 4 and 13. It has already started work on redeveloping its electronic communication tools for clinics and stakeholders. Further work on stakeholder engagement will follow, including the benchmarking of stakeholder views to establish the effectiveness of improvements. This work will build on the HFEA's successful consultations on multiple births, donation and mitochondrial replacement.

Recommendations for the 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.*

2.32 We are aware that the HTA, as a proportionate regulator, welcomes Mr McCracken's support for its work in this area. The HTA has already focussed on areas of greatest risk by;

- introducing themed inspections in its two biggest sectors which reduce the burden on higher performing establishments;
- redefining its risk assessment model so that it is focused on outcomes and will seek up-to-date compliance information from many establishments later this year to inform future inspection schedules;
- reaffirming its commitment to reviewing the audit model for the EUODD sector towards the end of the first round of audits.

2.33 To move further forward with implementation, we understand that the HTA will maintain its track record of risk based regulation and will continue to look for other opportunities to reduce its regulatory burden, including in the public display sector, by the end of the current financial year

2.34 We welcome this approach.

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.*

2.35 As stated previously, for example in Recommendation 11 above, the importance of co-operative working is a key element in reducing regulatory burden which we fully support.

2.36 We welcome the fact that Mr McCracken has recognised in his report the progress the HTA has already made in working with other regulators to reduce overlap but accept the need to strive for continuing closer cooperation. We are encouraged that the HTA has a number of actions in train to achieve the aims of this recommendation.

2.37 The HTA works with closely with other regulators including the HFEA, HRA and the MHRA and is committed to improving the effectiveness of regulation. It has a programme of joint inspection with the MHRA so that inspections go ahead on a joint basis. It also works closely with the MHRA to ensure that those organisations who are jointly regulated have a seamless regulatory pathway. One current initiative is to work with regulated organisations to define and implement a stem cell history file (a standard data set) which will provide the necessary information for all regulators.

2.38 The HTA has worked closely with the HFEA for some time. There is a small number of establishments who store ovarian tissue and are currently required to be regulated by both organisations. The HTA and HFEA expect to publish a joint policy in 2013/14 to minimise the burden of joint regulation and remove the need for HFEA to regulate those which are not fertility centres and so do not otherwise require HFEA regulation.

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.*

2.39 We have taken careful note of the concerns raised in this review around the regulation of activities aimed at the development of cell-based therapies. We recognise

that there is a complex landscape of regulation covering early research through to the market place. However, the development of cell based Advanced Therapy Medicinal products (ATMPs) is an important future market for the UK and it is crucial that the regulatory landscape does not discourage the bioindustry (particularly small companies) from investing in the UK.

2.40 We agree on the importance of streamlining the regulatory pathway in this field as far as possible. Close co-operation between the HTA and the MHRA is a critical element in enabling this. We note the findings in the review that there should be a degree of flexibility here and we understand that the existing HTA/MHRA initiative to define a stem cell history file may go some way to meeting this recommendation.

2.41 We understand that the HTA and MHRA have already had discussions about how regulation in this area could be streamlined including whether it would be proportionate for the MHRA to carry out some functions on the HTA's behalf. This would apply to around 15 regulated establishments at present, out of the 800 establishments licensed and regulated by the HTA.

2.42 We look forward to seeing the HTA/MHRA analysis of how the regulation of ATMPs could be simplified, with a detailed proposal for implementing those changes, by the end of this business year (2013/14). We will remain closely involved in this area as HTA and MHRA develop the implementation plan and we will provide advice and support where required.

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.*

2.43 We are committed to the principles of collaborative working and recognise the benefits of joint working wherever feasible to those working in the regulated sectors both in terms of fees to the sector and the overall cost of regulation to the tax payer.

2.44 The HTA has been working with the Clinical Pathology Accreditation (CPA) to identify any areas where the HTA can rely on the CPA's inspection results rather than inspecting against similar standards. The HTA expects to reach agreement with CPA very soon and aims to have an agreement in place by the end of the current business year so that any unnecessary duplication is removed for inspections from 2014/15.

Chapter 3

Conclusion

3.1 We are grateful to Justin McCracken for carrying out his review in a thorough, inclusive and transparent manner. We believe that his conclusions and recommendations provide an effective platform for helping to reduce the overall burden of regulation in particularly complex and sensitive areas whilst safeguarding public and professional confidence.

3.2 We believe that the actions and commitments set out in this response provide a sound platform for achieving early, valuable gains from this review. We commend the commitment of the HFEA and the HTA to seeking regulatory efficiency – over and above the cost efficiencies they have already achieved since 2010.

3.3 Implementation of the recommendations in the review does not contribute any additional financial burdens for the regulated sectors. Indeed, the overall impact is one of reducing the costs of regulation. The preliminary Impact Assessment carried out to help inform this response shows that the savings from implementation would be £2.8M over 10 years.

3.4 We will work with all the relevant bodies affected by this review to achieve the benefits identified in the recommendations and monitor progress via the normal accountability processes in place for these arm's length bodies. We believe, in line with the conclusions of the review, that this way forward will not only achieve a reduction in the burdens of regulation but it will do so whilst safeguarding the current levels of public protection and confidence.

Annex 1

Recommendations of the McCracken Review

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[9] 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.

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 (IRAaS) 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

[9] 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

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.

Annex 2

Impact Analysis of the Government response to the McCracken Review

Only those recommendations where regulations are proposed would be subject to a formal Impact Assessment. This annex considers a qualitative impact analysis of the effects falling on the regulatory and private sectors.

The private sector will benefit from the recommendations. They will find two regulators that are more responsive to the changing landscape of the respective medical areas. Using estimates from the British Fertility Society and the Association of Clinical Embryologists it is estimated the industry could save £1m per year from removal of unnecessary burden. The two regulators will be made more transparent with regard to consulting stakeholders and regulated providers on developments in their respective sectors.

The recommendations create financial benefits for central government finances. By consolidating the shared service functions of both organisations, there will be estimated savings to government of £2.8m over 10 years. This is over and above the efficiency gains both organisations have made since the 2010 Election.

We anticipate that all the recommendations in the review can be implemented at reasonably little cost. For instance, action to implement the recommendation on fee review groups will, in respect of the HTA, build on previous engagement by the HTA and thus costs will be contained. There will be some increased costs with conducting surveys and more frequent stakeholder engagement events.

This report and its recommendations sit outside the scope of One In Two Out (OITO). The recommendations do not directly require regulations to be laid in order to implement them. One recommendation places obligations on the Department of Health to review the regulatory framework for human tissue. Any changes to regulation that stem from that review would be assessed separately for impacts on business and its OITO status.