Authority paper

Strategic delivery:	**Setting standards**	☑	**Increasing and informing choice**	☑	**Demonstrating efficiency, economy and value**	☑
Paper title	McCracken review: an update					
Agenda item	7					
Paper number	[HFEA (17/09/2014) 732]					
Meeting date	17 September 2014					
Author	Peter Thompson, Chief Executive					
For information or decision?	Information					
Recommendation	To note the progress made over the past six months: of the ten recommendations in the McCracken review we have completed seven and the remainder are partially complete or well underway. And that this report will be the final standalone update on McCracken.					
Resource Implications	Different recommendations have different resource implications. Recommendation 6 will incur significant capital expenditure.					
Implementation	See Annex 1					
Communication	Different recommendations require different communications mechanisms.					
Organisational Risk	Different recommendations incur different levels of organisational risk. The programme as a whole will require careful oversight alongside the day-to-day business of the HFEA.					
Evaluation	Different recommendations will require different evaluation – to be developed over time.					
Annexes	Annex 1					

1. Introduction

1.1. Justin McCracken's review of the HFEA and the HTA (Human Tissue Authority) was accepted by the Government in July 2013.[1] The Authority agreed its response to the recommendations in the McCracken review at its meeting last September.[2] Part of that response was a commitment to regular updates on progress. The first six monthly update was presented to the Authority in March 2014[3]; this paper provides the second, and final, six month update.

2. The McCracken review

2.1. The McCracken review made 18 recommendations in total, 10 of which required action by the HFEA. The 10 recommendations and the agreed actions are set out in full at Annex 1.

2.2. In summary, we have made good progress: **we have completed seven recommendations and the remainder are partially complete or well underway**.

2.3. As in previous updates, the 10 recommendations can usefully be brigaded into five themes. The remainder of this paper provides an overview of the progress made over the last six months against those themes.

Shared services (Recommendation 2)

2.4. The McCracken review recommended the 'Finance and Resource functions' of the HFEA and the HTA should be merged under a single Director reporting to two Chief Executives.

2.5. We reported this recommendation as being **complete** at the March 2014 update. The new shared Director, Sue Gallone, has been in post for six months now and it is clear that the new arrangements are working well: the NAO approved this year's accounts with no significant issues. We will, of course, look to see what further efficiencies can be found over time and keep staffing levels under review.

Stakeholder engagement (Recommendations 4, 5 and 13)

2.6. The McCracken review recommended we should take action to improve the way in which we engage, listen and feed back to the sector we regulate (Recommendations 4 and 13). At its meeting in September 2013, the Authority agreed a range of actions on stakeholder engagement, including the commissioning of a survey on stakeholder perceptions.[4] Our annual conference in February 2014 (our first for some years) was a great success and indicated a significant improvement in our relations with stakeholders. The conference was part of a consultation on our new strategy for 2014-17 (see also paragraph 2.16 below). And a new stakeholder engagement plan was agreed at the May 2014 Authority

[1] https://www.gov.uk/government/publications/review-of-human-fertilisation-embryology-authority-and-human-tissue-authority
[2] *Authority response to the McCracken review* (11/09/2013) 691
[3] *Progress on the McCracken Review* (05/03/2014) 715
[4] *Stakeholder engagement* (11/09/2013) 692

meeting[5].

2.7. The Authority has recently appointed a Head of Engagement (to start in October 2014), who will lead on implementing our stakeholder engagement plan, as well as our wider work around patient engagement. Our new engagement approach commits us to:

- more face-to-face meetings with stakeholders, including a regular conference;
- making Authority decisions more widely known, with for example audio recordings of meetings on our website (now complete); and
- updated patient information, including new version of the Getting Started booklet.

2.8. A further survey of our stakeholders in spring 2015 will tell us whether such initiatives are having the desired effect. Stakeholder engagement is, by definition, a process, but, taken together, we view the range of actions taken so far as meaning that Recommendations 4 and 13 are now **complete**.

2.9. In addition, the McCracken review suggested the establishment of a separate fees review group to 'improve accountability and facilitate dialogue' with fee payers (Recommendation 5). We have started our preparations to establish such a group with a planned first meeting in October 2014.

Better use of Information (Recommendations 6 and 7)

2.10. McCracken recommended that we review the information we collect and how we validate and verify that information and that this work should proceed with stakeholder involvement (Recommendation 6). To that end we have established a significant programme of work which we have titled: 'Information for Quality' (IfQ). The Authority agreed this approach at its September 2013 meeting.[6]

2.11. Since then, we have reported progress on IfQ to every Authority meeting. Engagement with stakeholders has been extensive with the establishment of an Advisory Group and several Expert Groups. A paper to this meeting will seek approval for a consultation exercise, commencing on 1 October 2014, on the main areas where we are proposing change and invite further comment: from the information we collect and the frequency of collection; the systems in place to send it to the HFEA; and the means by which we make that information public, notably our websites including changes to 'choose a fertility clinic'.

2.12. The McCracken report also proposed (Recommendation 7) that we develop in time two additional information projects: one on making available better aggregated data for research and another on identifying the best means of providing support to donor conceived individuals when they access information from our Register. At its meeting in March 2014 the Authority agreed to set up three-year pilot which will provide

[5] *Stakeholder engagement* (14/05/2014) 721
[6] *Information for quality* (11/09/2013) 693

counselling and intermediary support for Opening the Register applicants.[7] The proposal envisages entering into a contract with an external provider (likely a post-adoption agency) to supply this service and a formal procurement exercise will begin shortly. We are of the view that Recommendation 7 is now **partially complete**.

Working with other regulators (Recommendations 8, 11 and 12)

2.13. The McCracken review made three related recommendations in this area: that the Authority eliminates any regulatory overlap with the CQC (recommendation 12); that the HFEA and the HRA work more closely together to ensure a single, seamless application process for research applicants (Recommendation 8); and that the HFEA and the MHRA clarify their roles to achieve effective joint working (Recommendation 11).

2.14. Like all relationships between organisations, these three recommendations can be viewed as work in progress. That said, in March 2014 we reported that the formal aspects of these recommendations should be regarded as **complete**. Since then, we have maintained good working relations with all three organisations.

Regulatory focus (Recommendation 10)

2.15. Arguably the most challenging recommendation in the McCracken review concerned the recommendation to conduct a review of the balance of our regulatory activity 'to ensure that it reflects the relative risks of the different activities that it oversees.' The Authority agreed in September 2013 that our new Strategy was the most appropriate vehicle to locate such a review.

2.16. Following an extensive public consultation in the first few months of 2014,[8] the Authority agreed at its July meeting a new strategy for 2014-17 which puts quality of care and outcomes at the centre of what we do[9]. As we set out in the strategy consultation document, we believe that, as the regulator, we can improve the quality of care in three different, but linked ways:

- Setting standards in clinics and checking compliance with them through inspection
- Providing patients information about treatments and services, so that they are able to choose better quality care
- Reducing costs for clinics so that they can focus more of their time on providing care.

2.17. The next stage is ensure that the new Strategy drives our priorities and business planning processes and a paper to this meeting will set out how we plan to do this.[10] We will deliver the strategy through various activities – and through our ways of working – across the next three business years.

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[7] *Improving the sharing, quality and disclosure of donor information* (05/03/2014) 714
[8] *Our future strategy* http://www.hfea.gov.uk/8572.html
[9] *HFEA Strategy 2014-2017* (09/07/2014) 725
[10] Strategy Implementation (17/09/2014) 733

2.18. The Authority has already incorporated more input from patients into inspections, successfully introducing unannounced inspections, where there is greater focus on speaking to the patients who are present in the clinic, rather than only (or mainly) to clinic staff. Much of the work described in our Strategy is about providing better information and support, in various ways, for patients, donors and donor-conceived people. We will also explicitly be focusing on the quality and safety of care, through the way in which we conduct our regulatory activities. Throughout the Strategy the change in stance is evident – we have moved from simply considering patients' (and others') views, to consciously positioning their perspective so it is at the absolute front and centre of our decision-making and our purpose. We have also signalled a move towards even greater collaborative working with professional stakeholders and other regulators, for the benefit of patients and others affected by assisted reproduction.

2.19. The true test of the effectiveness of the Authority's new regulatory focus will only be seen in the decisions it takes over the coming months and years, but we are of the view our new Strategy meets the formal requirements set out in the McCracken review and that recommendation 10 should therefore be regarded as **complete**.

3. Recommendations

3.1. The Authority is invited to note the progress made over the past six months in meeting the McCracken recommendations in section 2 above and at Annex 1. In summary: **we have completed seven recommendations and the remainder are partially complete or well underway**. In view of the progress made the Authority is also invited to agree that progress on the remaining outstanding recommendations (5, 6 and 7 – in part) should be undertaken in other formats. If accepted, this progress report on McCracken will be the last.

Agenda item 7 **Paper number [HFEA (17/09/2014) 732]**

Annex 1

McCracken Review Action Plan

Recommendation	Response	Lead Officer
Theme: Shared services		
Recommendation 2 **The support services of the two bodies [the HFEA and HTA] 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.**	**Complete:** the new shared Director of Finance and Resources started in March 2014.	**Peter Thompson** CEO
Theme: Stakeholder engagement		
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.**	**Complete:** stakeholder survey commissioned in January 2014 to understand better perceptions of the HFEA, its work, and to gather views about possible improvements. The findings of the survey informed a stakeholder engagement plan which was agreed by the Authority in May 2014. Stakeholder survey will be rerun in Spring 2015 to assess progress.	**Juliet Tizzard** Director of Strategy and Corporate Affairs

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 recommendation 4.	
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.**	**In progress:** fees review group expected to be in place in October 2014.	**Sue Gallone** Director Finance and Resources
Theme: Better use of Information		
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**	**In progress:** work programme entitled 'Information for Quality: modernising how we collect, use and publish information' set out in scoping paper August 2013. Programme overseen by an Advisory Group established in October 2013 and progress reported to each Authority meeting. The group has established four expert sub-groups to advise on: the data dictionary; data submission; data reporting; and website/public information. Options appraisal and user research review completed in May 2014. It is expected that the Programme will be completed in the 2015-16 business	**Nick Jones** Director Compliance and Information

then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1M.	year.	
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.**	**Partially complete:** on (a), the McCracken recommendation assumes completion of Recommendation 6 before beginning work. On (b), HFEA staff met a range of external stakeholders in June 2013 to discuss information and support for people seeking information from the Register. Options presented to the Authority in March 2014 and agreement reached on three year pilot project to provide counselling and intermediary services for Opening the Register applicants. Formal procurement exercise to begin in Autumn 2014.	Tba (a) **Juliet Tizzard** Director of Strategy and Corporate Affairs (b)
Theme: Working with other regulators		
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.**	**Complete:** agreement reached in November 2013 with the HRA that HFEA will participate in the new IRAaS system when it launches (tbc 2015).	**Debra Bloor** Chief Inspector

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.**	**Complete:** an information sharing agreement between the HFEA and the MHRA was agreed. It covers: • The exchange of information on medical devices used in ART • MHRA Field Safety Notices and other information sent to users by the manufacturer • HFEA Grade A incidents which involve medical devices MHRA / HFEA collaboration has already resulted in CE Marking Guidance being issues to licensed clinics. The work has established effective lines of communication between HFEA and MHRA and liaison where there are areas of common concerns is now embedded.	**Debra Bloor** Chief Inspector
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.**	**Complete:** HFEA / CQC agreement effective from 1 April 2013. Feedback on additional inspection activities undertaken by HFEA as a result of this work has been very positive.	**Debra Bloor** Chief Inspector
Theme: Regulatory focus		
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**	**Complete:** New Strategy 2014-17 will address directly the issues of regulatory focus. Consultation on aspects of the strategy issued online on 10 February 2014 and	**Peter Thompson** CEO

activities that it overseas. 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.	closed on 28 March 2014. Finalised Strategy agreed by Authority and subsequently published in July 2014. New Business Plan underway.	**Paula Robinson** Head of Business Planning