# Audit and Governance Committee Paper

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| **Paper Title** | McCracken update |
| **Agenda Item** | 8 |
| **Paper Number** | [AGC (01/10/2014) 425] |
| **Meeting Date** | 1 October 2014 |
| **Author** | Sue Gallone, Director of Finance and Resources |
| **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.<br>That this is the last discrete report on McCracken as the work is now business as usual. |
| **Resource Implications** | None |
| **Implementation** | None |
| **Communication** | As necessary |
| **Organisational Risk** | Competing priorities on shared finance resources. The programme as a whole will require careful oversight alongside the day-to-day business of the HFEA. |
| **Evaluation** | By the Executive |
| **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. The Authority agreed its response to the recommendations in the McCracken review at its meeting last September. Part of that response was a commitment to regular updates on progress.

**1.2.** The first six monthly update was presented to the Authority in March 2014; the second, and final, six month update, was provided in September.

**1.3.** Updates have also been provided to the Audit and Governance Committee at each meeting, following the updates to the Authority.

**1.4.** As the Authority agreed that there would be no further discrete reports on the McCracken review actions (they are now business as usual), it is recommended that this is also the last regular report to AGC.

## 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**.

## Annex 1

## McCracken Review Action Plan

| Recommendation | Response | Lead Officer |
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| **Theme: Shared services** | | |
| **Recommendation 2**<br>**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**<br>CEO |
| **Theme: Stakeholder engagement** | | |
| **Recommendation 4**<br>**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**<br>Director of Strategy and Corporate Affairs |

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| **Recommendation 13**<br>**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**<br>**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**<br>Director Finance and Resources |
| **Theme: Better use of Information** | | |
| **Recommendation 6**<br>**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**<br>Director Compliance and Information |

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| **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**<br>**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 DATE. | Tba (a)<br><br>**Juliet Tizzard**<br>Director of Strategy and Corporate Affairs (b) |
| **Theme: Working with other regulators** | | |
| **Recommendation 8**<br>**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 in early 2015. | **Name**<br>Job title |

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| **Recommendation 11**<br>**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:<br>• The exchange of information on medical devices used in ART<br>• MHRA Field Safety Notices and other information sent to users by the manufacturer<br>• HFEA Grade A incidents which involve medical devices<br><br>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**<br>Chief Inspector |
| **Recommendation 12**<br>**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. | **Debra Bloor**<br>Chief Inspector |
| **Theme: Regulatory focus** | | |
| **Recommendation 10**<br>**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**<br>CEO, |

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| **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 . Finalised Strategy agreed by Authority in July 2014. New Business Plan underway. | **Paula Robinson** Head of Business Planning |