

## Authority Paper



Committee:	Authority
Meeting Date:	9 May 2007
Agenda Item:	2
Paper Number:	HFEA (28/03/07) 369
Paper Title:	Minutes of the non-confidential Authority meeting held on 28 March 2007
Author:	Committee Secretary
For Information or Decision?	Decision
Resource Implications:	None
Recommendation to the Committee:	The Authority is asked to confirm the minutes as a true and accurate record of the meeting

### **HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY MINUTES OF THE NON-CONFIDENTIAL AUTHORITY MEETING (NON-CONFIDENTIAL - PART 2)**

The meeting was quorate with 11 lay members and 6 professional members attending.

#### **PRESENT**

Shirley Harrison	Jennie Hunt
Sam Abdalla	Emily Jackson
David Archard	Maybeth Jamieson
Chris Barratt	Bill Ledger
Clare Brown	Walter Merricks
Anna Carragher	Sharmila Nebhrajani
Sally Cheshire	Roger Neuberg
Rebekah Dundas	
Ruth Fasht	
Lord Harries	

#### **APOLOGIES**

Neva Haites  
Sue Price

#### **IN ATTENDANCE**

Angela McNab	David Tellis	Paula Robinson
Trish Davies	Sarah Marsh	
Tim Whitaker	John-Paul Maytum	
Sally Townsend	Charles Lister	
Fran Clift	Juliet Tizzard	

#### **OBSERVERS**

Ros Gardner - HGC  
Ted Webb - Department of Health  
Gareth Jones - Department of Health

<b>Item 1.</b>	<b>Apologies, Welcome &amp; Conflicts of Interest</b>	<b>Action</b>
1.0	Apologies were received from:  Neva Haites Sue Price	
1.1	There were no conflicts of interest declared.	
<b>Item 2.</b>	<b>Minutes of the meeting held on 21 February HFEA (21/02/07) 362</b>	
2.0	The minutes were approved as an accurate record of the 21 <sup>st</sup> February meeting with the following amendments:	
2.1	<b>7.4</b> – substitute the word ‘reasoning’ with ‘reasons’	
2.2	<b>7.9</b> – delete ‘by the clinician’ in the last sentence	
2.3	<b>8.3</b> – bullet point 4 should read ‘Consideration of the Helsinki Declaration’	
2.4	<b>8.5</b> – delete ‘and how multiple birth had been reported in the press.’	
2.5	<b>8.8</b> - the second sentence should read ‘The member was informed that women should be under 36 to donate eggs for treatment but potentially donors can be over 35 years of age when donating for research’	
2.6	<b>8.8</b> – delete the last sentence	
<b>Item 3</b>	<b>Matters Arising &amp; Previous Actions HFEA (21/02/07) 363</b>	
3.0	The Authority noted the matters arising.	
3.1	<b>10/01/07 6:6.7</b>  Trish Davies explained that the HFEA does not hold waiting list information. To obtain this information would involve writing to all clinics.	<b>TD</b>
3.2	This will be discussed further at a later date.	
<b>Item 4.</b>	<b>Chair’s Report (verbal) Laboratory Visit</b>	
4.0	The Chair informed the Authority that she had visited Stephen Minger’s laboratory at King’s College with another member of the Authority. They were impressed	

with what they saw in the laboratory and overall found the visit very informative.

4.1 **Moscow – Stem Cell Research and Regulation Speech**

The Chair informed the Authority that she had been invited to Moscow to give a speech on stem cell research at the invitation of the British Council.

4.2 There were participants from the UK and from the EC in attendance and funding for research was high on the agenda for discussion. Russian scientists are keen to become properly regulated so that they may undertake collaborative work with other member states.

4.3 **HTA Open Meeting**

The Authority heard that 2 members had attended the HTA's Open Meeting in Birmingham in line with bringing the two organisations closer together. Similarly, HTA members will be asked to attend the HFEA Annual Conference in June and join members and staff for a meal the night before.

4.4 **HFEA Open Meeting – May**

The Open Meeting will be held in a central Manchester location on 9<sup>th</sup> May 2007.

**Item 5. Chief Executive's Report (verbal)**

5.0 **San Fransisco Stem Cell Conference**

The Chief Executive informed the Authority that she had attended the San Fransisco Stem Cell Conference where she spoke about hybrids and the UK egg donation policy.

5.2 Members heard that this meeting was followed by a meeting with the National Institute of Health, the California regulators and the Australian Federal regulator that had been organised by the British consulate and discussions were had about how to begin developing minimum standards. A discussion paper identifying key issues may be jointly written for the ISSCR Conference in June.

5.3 A follow-up meeting will be held in Washington later in the year.

5.4 **Competent Authorities Meeting**

The Chief Executive informed the Authority that the first EU Commission meeting of the Competent Authorities had been held and one of the issues it had looked at was compensatory payment. The members felt that compensation was an issue which needed transparency and guidance should be written for other member states.

5.5 The first meeting of the Working Group has been arranged for May to discuss these issues and the Chief Executive will keep the Authority informed.

**Item 6. Regulation, Finance and HR Report  
HFEA (28/03/07) 364**

6.0 **Regulation**

Trish Davies, Deputy Chief Executive & Director of Regulation, introduced this report.

6.1 Ms Davies informed the Authority that the activity report for January shows that the HFEA is on schedule to complete statutory inspections by the end of the year. The high level of activity associated with enforcement action in respect of two centres has had a noticeable impact on the workload of the team and this will be apparent in subsequent months. Inspectors are working hard to keep report production on time. Alert 22 has now been sent out to all clinics and members.

6.2 The Authority heard that complaints about clinics had been unusually high due to the recent regulatory action.

6.3 It was pointed out that the graph 4a needs to be updated to reflect the new category 'C' incidents. **TD**

6.4 A member asked for a copy of the most recent Complaints Report. **TD**

6.5 Members also asked for information on those who made an initial complaint and then went on to make it formal. **TD**

**Finance**

6.6 Sally Townsend, Director of Resources and Corporate Development, introduced this paper.

6.7 The Authority was informed that the report represents the January 2007 Management Accounts. The report was reviewed by the Organisation & Finance Committee on

14 March 2007.

- 6.8 Ms Townsend continued that the latest figure for the year end would generate a small surplus as the delay in implementation of EDI had meant that full information on income for the financial year was not available until shortly before the year end. The Department has confirmed that the HFEA can retain the surplus as long as it can provide evidence of committed costs.
- 6.9 A member of both OFC and the Authority raised the point that the HFEA should apply to the Department for funding to assist with current regulatory action.
- 6.10 Ms Townsend explained that when unforeseen costs arise, the Department have advised the HFEA that, in the first instance, the HFEA must first look to accommodate these additional costs within our own budget. Due to the low level of legal expenditure in the early part of 2007/08, the additional cost of regulatory action has been covered in the main by existing budget. However, the Department is kept abreast of the cost of action and the Department confirmed this approach as appropriate.

## HR

- 6.11 Sally Townsend, Director of Resources and Corporate Development, introduced this paper.
- 6.12 The Authority was informed that the establishment is currently one person over ALB requirements but this is a temporary appointment, necessary to assist the Legal Adviser with the current regulatory action. As a number of some fixed-term contracts end on 31 March the HFEA will be on-target for the year end. Sickness levels continue to remain low.
- 6.13 Ms Townsend continued that the first phase of the Diversity training had been completed. The two working groups on staff safety and PDP's have concluded their preparatory work on both these topics and recommendations from these groups will be sent out to staff for consultation.
- 6.14 The HFEA is also supporting a 6 month HR development programme for an HTA staff member to help improve HR understanding and links between the two organisations.

**Item 7. Final Business Plan  
HFEA (28/03/07) 365**

- 7.0 Paula Robinson, Head of Business Planning, introduced this report.
- 7.1 The Authority was informed that the Business Plan presented had been revised in line with the Authority's comments from the January 10 Meeting, comments made by the ALB Business Support Unit and DH sponsors.
- 7.2 Ms Robinson continued that the plan was approved by the OFC on 14 March and since that time, DH have approved the 2007/08 budget.
- 7.3 The Authority heard that due to the current workload and financial constraints, the HFEA may need to make some prioritisation decisions over the course of the year and extra resources may need to be negotiated from DH and this is identified as a key risk. It will continue to be monitored closely.
- 7.4 The Authority was informed that the main amendments since the January meeting are:
- More detail in forthcoming hybrids work
  - Added and enhanced wording throughout relating to stakeholder satisfaction
  - Addition to the risk page of information about business continuity planning
  - The addition of an organisation chart
  - Inclusion of performance indicator targets for 2007/08, and updated information about progress on current performance indicators (these will be finalised completely on 1 April when the final year-end figures are available)
  - Page 9, bullet point 6, under the heading 'Selected Activities' has been removed at the request of the DH

**Discussion**

- 7.5 A member raised the issue of 'major incident' mentioned in the report on page 17 and whether the Authority carried out disaster management exercises.
- 7.6 The Chief Executive responded that the Authority has a Business Continuity Plan in place and disaster recovery has been tested in terms of IT systems. However, in the business plan 'major incident' referred to an incident in a

clinic and there are clear protocols in this instance.

- 7.7 A member requested the following amendments to the Plan:
- 7.8 Page 4, 2nd paragraph, remove 'and in' from the 3<sup>rd</sup> sentence
- 7.9 Page 5, 5<sup>th</sup> bullet point, replace 'InVitro' with 'in vitro'
- 7.10 Page 6, add bullet point to 'Patient and Public Involvement' highlighting meetings with patient organisations
- 7.11 The Authority approved the Business Plan with the amendments stated.

**Item 8. Hybrids Consultation Document  
HFEA (28/03/07) 366**

- 8.0 Juliet Tizzard, Deputy Head of Policy, introduced the paper.
- 8.1 The Hybrids Review was initiated in January, after the HFEA received two research applications to create embryos using animal eggs. A public consultation document was presented to the Authority for approval. The Authority heard that the document is aimed at a lay audience and seeks to explain difficult scientific procedures and ethical issues as simply as possible.
- 8.2 It was explained to the Authority that the text of the document needs to be finalised by 2nd April 2007.
- 8.3 **Discussion**  
  
A member asked about the first 3 questions of the Consultation as they were general questions about embryo research, which is not under review. It was explained that these questions had been written to aid the HFEA to identify people with strong views about embryo research and put the later questions into context. This is explained in the preliminary paragraph but it was agreed to highlight this further.
- 8.4 A member asked whether a paragraph could be added stating the HFEA's support for hybrid research. Ms Tizzard explained that this information is included within the 'Legal' section but this could be added to the Chair's Foreward.

- 8.5 A member asked whether more illustrations could be added to the document, particularly a representation of an embryo with stem cells in-situ. The member also asked whether more clarity could be given as to why there were questions in the Consultation about procedures which are prohibited under current legislation.
- 8.6 Ted Webb, Deputy Director Scientific Development & Bioethics Division at the Department of Health, asked whether the questions had been seen by DTI Sciencewise as they had experience of engaging public scientific interest. He was informed that they had had some input to the Consultation but had not seen the final questions.
- 8.7

The Authority approved the Consultation with the suggested changes. Any typographical or grammatical amendments will be sent to Ms Tizzard electronically with ideas for the title of the Consultation by Friday 30 May 2007.

**Item 9. Terms of Reference  
HFEA (28/03/07) 367**

- 9.0 Sally Townsend, Director of Finance and Corporate Development, introduced this paper.
- 9.1 Ms Townsend explained that the HFEA's Internal Auditors had noted that the Authority had not formally ratified the terms of reference for all committees. The Authority was therefore requested to confirm acceptance of all the extant terms of reference, as included in this paper. From this point, the Terms of Reference will be formally presented to the Authority annually or when significant changes are made.

**Discussion**

A member requested the following amendments:

- 9.2 Page 8, the title should read 'Scientific & Clinical Advances Group'
- 9.3 Page 10, paragraph 5, point 4, the 'Licensing & Regulation Committee' should read 'Regulation Committee'
- 9.4 A member requested the format of the IMPB terms of reference to be changed to match those of the other committees.

- 9.5 A further member stated that, on page 3 under paragraph 5.2, bullet point 4 of the Organisation & Finance Committee terms of reference, the figures seemed quite modest and the limits may need to be revised. It would also be helpful to add an 'Authorisation Hierarchy' to the document.
- 9.6

**Item 10. Royal College of Physicians Report on the Effects of Cancer Treatment  
HFEA (28/03/07) 368**

- 10.0 Charles Lister, Head of Policy, introduced this report.
- 10.1 Mr Lister explained that the Authority had been asked to comment on 'The Effects of Cancer Treatment on Reproductive Functions: Guidance on Management', a draft report of a working group of the Royal College of Physicians and Royal College of Radiologists.
- 10.2 The aim of the report is to educate clinicians, persuade Government, funding bodies and research groups of the importance of techniques to preserve fertility and provide patient information on these techniques.

**Discussion**

- 10.3 A member stated that this report is only updated every 10 years and so very important that anyone with comments pass them on to the Royal College of Physicians.
- 10.4 A member expressed the importance of how much information these patients are given particularly in light of the Natalie Evans case. All the different options must be made clear given that patients are often under pressure. The Chair stated that under the heading 2. Comments, paragraphs 3 could be strengthened to reflect this.
- 10.5 All amendments and comments will be e-mailed to Mr Lister before the 4 April.

Tabled paper  
T1 **Decision Making Process for the Revised Guidance on Imports and Exports**  
Charles Lister, Head of Policy, introduced this paper.

T2 The Authority heard that the paper had been put before them to agree to delegate decision making on new

import rules on the implementation of the EU Tissues and Cells Directive (EUTCD) to the Regulation Committee. This will enable decisions to be made in time for the publication of the 7th edition Code of Practice at the end of April and the EUTD implementation date of 7 June 2007.

T3 Mr Lister continued that the EUTD regulations amending the 1990 Act require significant changes to the current policy on imports and exports, in that movement of gametes and embryos between European Economic Area (EEA) countries will be treated as transfers between premises. The HFEA will no longer be able to issue special directions for the movement of gametes and embryos within the EEA. The responsibility will be placed with Persons Responsible (PR) and new forms and Directions are being developed requiring PRs to declare that they have met requirements.

T4 The Authority was informed that in line with the Directive, the amended 1990 Act will allow the Authority to impose more stringent requirements relating to safety and quality on transfers into the UK than required by the Directive and Regulation Committee is being asked to decide what these requirements should be. The deadline for publication of the new Code of Practice is mid-April and there is no opportunity to bring the decision back to the Authority for approval.

T5 The Authority approved delegating decision making powers on rules for transfers to the Regulation Committee.

**Item 11 Any Other Business**

11.0 There was no other business to discuss.

**Date of Next Meeting**

The next Authority meeting will be held on 9 May 2007

I confirm this to be a true and accurate record of the meeting

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**Chair**

Date .....