



Annual report and accounts 2016/17



Human Fertilisation and Embryology Authority

Annual report and accounts 2016/17

Presented to Parliament pursuant to sections 6 and 7 of the Human Fertilisation and Embryology Act 1990 as amended by paragraph 3 of schedule 7 of the Human Fertilisation and Embryology Act 2008.

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Chief Executive's foreword

Last September we brought together experts from across the fertility sector to mark the 25th anniversary of the establishment of the HFEA, the first regulator of fertility and human embryo research in the world.

Much has changed over that time. Today, some 60,000 patients a year have fertility treatment in the UK which may lead to a much hoped-for child. Families which carry any of over 400 serious inherited conditions are able to access embryo testing services so that their children will be free from that disease. People born from the result of donated sperm or eggs over 18 years ago, are able to find out about their genetic parent. And cutting-edge research, which is changing our understanding of early stage embryo development, is taking place in UK laboratories.

It is the HFEA's regulatory framework that has allowed such innovation to flourish and public trust to be maintained.

That tradition of innovation continues today. In 2016 we approved the use of mitochondrial donation in clinical treatment, the first such decision in any regulated environment. This provides new treatment options to families affected by serious mitochondrial disease. It is the result of over five years' collaboration with researchers, funders, government and patient groups and demonstrates a better way to make public policy.

Data and information is crucial to providing safe, effective health care. Our Information for Quality (IfQ) programme, which is central to that goal, is nearly finished. We have a new Clinic Portal, a new public website and a new Register and data submission system due in the autumn.

- Our new website will help patients be better prepared for treatment by knowing when to seek help, what treatments are available and what to think about before starting fertility treatment.
- Our new Choose a Fertility Clinic service will give a fuller picture of clinic performance: clear birth and multiple birth statistics will sit alongside inspection ratings and patient feedback so that patients can see the quality of the service in the round.
- Our new Clinic Portal improves behind-the-scenes interaction between us and clinics, and puts in one place all the information needed to run a service – guidance, forms, licence applications, performance information etc. This means less time can be spent submitting or searching for information and more time focusing on services and patients.

IfQ will enable us to be a more intelligence-led organisation. During this reporting year we have begun to reshape the HFEA to meet these new opportunities. Such processes are never easy, but I am confident we have managed it well and will be stronger as a consequence.

This year has not been without its challenges. We have seen continued media and public interest in the area we regulate, with a focus on so-called add on treatments on offer within the sector. We all want innovation in fertility services and treatments. What's crucial is how those innovations are introduced into clinical practice.

Looking ahead, we recently launched our new strategy for 2017 to 2020. High quality treatment and support remains at the heart of what we do. Safe, effective, evidence-based care, excellent emotional support throughout treatment, and high quality research underpinning continued scientific and clinical advances, not just in the best clinics, but in all.



Performance

Overview

The Human Fertilisation and Embryology Authority (HFEA) is the regulator of fertility treatment and human embryo research in the UK. Our role includes licensing and setting standards for clinics and research centres and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

The HFEA has had another highly successful year. We continue to regulate around 140 fertility clinics and embryo research centres and have just under 70 members of staff. Our expenditure is around £5m, around 85% of which is funded by fees from those we regulate. We seek continuously to improve and streamline our processes, reducing the regulatory burden and maintaining efficiency. We manage our finances to ensure fees are set to bring in the income we need to spend on regulating. We keep abreast of scientific developments and adopt a proportionate approach to regulation. We have a strong reputation, both in the UK and internationally, for robust yet proportionate regulation. Our decision-making processes are more robust than ever and have stood the test of forensic examination in the courts.

During the 2016/17 reporting year, we delivered on a number of commitments in our strategy. We neared completion of our Information for Quality programme (IfQ), which has transformed how we collect, analyse and publish information. Patients and clinics will benefit from our improved website (which will go live early in 2017/18), an enhanced Choose a Fertility Clinic service, and a clinic portal.

In December 2016, the Authority approved the use of mitochondrial donation. On the recommendation of the expert panel, who reviewed the development, safety and efficacy of these techniques over five years and four reports, the Authority agreed to introduce this new treatment in the limited circumstances recommended by the panel.

This year our regulatory focus was on:

- shortcomings in the taking and recording of consent;
- medicines management;
- data submission;
- multiple birth rates; and,
- the quality of information published on clinics' websites.

We also:

- completed a full inspection programme, approved over 44 new conditions for embryo testing and processed over 558 reported incidents;
- continued to reduce the incidence of multiple births – without impacting on success rates - from 24% in 2008 to 14%, with many clinics well under the 10% target;
- processed almost 300 requests for sensitive personal information from our Register on time and in a way which supported applicants and is compatible with data protection rules; and
- responded to 55 Parliamentary Questions and 82 Freedom of Information requests.

At the end of this reporting year we published our new strategy for 2017-2020, retaining our strong vision for high quality care for everyone affected by fertility treatment. We have the staff and the financial resources in place to complete this varied and challenging programme of work.

How we work

As set out in our strategy, we:

- make the quality of care experienced by patients, donors and donor-conceived people our central priority and the primary consideration in our decision making
- consult and collaborate widely – listening to, and learning from, those with an interest in what we do
- communicate more with stakeholders before making decisions and explain those decisions more clearly
- take the time to implement decisions with appropriate stakeholder involvement, piloting new initiatives when appropriate
- keep abreast of scientific and clinical innovations and actively consider what these might mean for the future quality of care
- are a more agile and flexible organisation, changing course if needed in order to be responsive (both to stakeholders and to new priorities)
- continue to exercise our statutory functions consistently, proportionately, openly and fairly
- observe the highest standards of integrity and professionalism in putting into effect the law as we govern the fertility sector
- continue to treat people and their information with sensitivity, respect and confidentiality.

Our legislation and functions

Our regulatory role and functions are set by two pieces of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – generally referred to as ‘the 1990 Act’; and
- The Human Fertilisation and Embryology Act 2008 (‘the 2008 Act’).

Under this legislation our main statutory functions are:

- to license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment;
- to license and inspect centres undertaking human embryo research;
- to license and inspect the storage of gametes (eggs and sperm) and embryos;
- to publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities;
- to keep a register of information about donors, treatments and children born as a result of those treatments;
- to keep a register of licences granted;
- to keep a register of certain serious adverse events or reactions;
- to investigate serious adverse events and serious adverse reactions and take appropriate control measures.

In addition to these specific statutory functions, the legislation also gives us more general functions, including:

- promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice;
- maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities;
- observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed;
- carrying out our functions effectively, efficiently and economically;
- publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients;
- reviewing information about:
 - human embryos and developments in research involving human embryos
 - the provision of treatment services and activities governed by the 1990 act (as amended)
- advising the Secretary of State for Health on developments in the above fields, upon request.

We also function as one of the two UK competent authorities for the European Union Tissues and Cells Directive (EUTCD). This directive regulates the donation, procurement, testing, processing, preservation and distribution of human tissue and cells for human application.

Activities

Our objectives for 2016/17 were as follows.

Setting standards

Objective 1: Improving the quality and safety of care through our regulatory activities

In 2016/17, we carried out our usual full range of inspection, audit and licensing activities. This ensured that clinics were appropriately inspected and monitored against published performance indicators, and issued with licences for up to four years.

As well as licensing clinics, we also considered a significant number of applications for the authorisation of preimplantation genetic diagnosis (PGD) and human leukocyte antigen (HLA) testing. PGD is a growing area of work, and applications need to be processed effectively and efficiently so that decisions on whether to authorise such treatments are made, and communicated, in a proper and timely manner for the direct benefit of patients awaiting treatment. We also granted the first licence to offer mitochondrial donation treatment; a world-first in a regulated setting.

Our triennial review report was completed in 2016, and was published in April 2017. Our action plan in response to its recommendations has already been completed.

Our multiple births policy, 'One at a Time', has been a real success with many clinics well under the 10% target. In addition, success rates have remained steady and, most importantly, patient understanding of the risks of multiple births and the benefits of single embryo transfer has increased.

We published our latest report on incidents. We encourage our clinics to have a learning culture and we share learning in the sector to maximise safety and minimise errors. We developed a collaborative relationship with NHS Improvement, enabling us to consider wider lessons learned that may have relevance in the fertility sector.

As part of our IfQ programme, we worked with clinics throughout the year to improve the quality of our Register data. Building on that work, we will next improve the data submission systems used by clinics to send us information about treatments.

We have completely redesigned our website and Choose a Fertility Clinic service based on research with patients. The new website contains specific information and journeys for different types of patients. It contains new information about fertility treatment, including video and animation.

The new Choose a Fertility Clinic service will give a fuller picture of clinic performance: clear birth and multiple birth statistics will sit alongside inspection ratings and patient feedback so that patients can see the quality of the service in the round.

We started a review of embryo research, exploring ways that patients can have more opportunity – should they wish – to donate their embryos to research. We are also improving Code of Practice guidance and the application and approval process.

While the UK remains in the EU we will continue to participate in competent authority events and the implementation of associated EU decisions. We participate in two meetings per year.

Objective 2: Improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families

Better information has been central to our IfQ programme. We now have a completely redesigned Choose a Fertility Clinic service, with a new headline measure of births per embryo transferred.

We provide up to date information about donation (via our website) and have improved the information we provide about gamete availability (via CaFC).

We published information about donation so that clinics, donors and patients can understand all the issues and legalities associated with donation. We also emphasised to clinics the importance of their role and performance in relation to donation and the associated information guardianship responsibilities.

In July 2016, we evaluated the first full year of the three-year pilot of counselling support services for applicants to the Register. Feedback so far has been positive. Mediation services are also in place for when donors and donor-conceived people meet.

We were due to complete a set of projects initiated in 2014/15 to implement new EU requirements on the import of donor gametes and new EU coding requirements for human tissue and cells. A Department of Health consultation on the implementation of the directives was delayed until March 2017. Our work on this will be completed after the consultation closes in 2017/18.

Increasing and informing choice

Objective 3: Using the data in the HFEA Register to improve outcomes and research

Throughout the year we continued to ensure that Register data was processed and quality assured, through liaison with clinics on errors and omissions and through validation and verification of Register

entries. We are grateful to clinics for their cooperation and hard work during the latter part of the IfQ programme while we conducted a more extensive data verification exercise than usual to ensure that the new Register structure contains high quality, accurate data when we migrate from the old system.

Our focus for much of the 2016/17 year, through IfQ, was to ensure our published outcome data is more useful and easier to understand, and provides positive incentives for service improvements. Our new Choose a Fertility Clinic service gives a much more rounded picture of quality. For the first time, patients can see at a glance not only the outcome statistics for a particular clinic, but also a rating based on the most recent HFEA inspection report and on patient experience.

One of our most important duties is to facilitate timely access to information from the Register for those who are entitled to it, and we continued to manage requests for donation information on the Register in a sensitive manner and within the required time limits (20 working days, excluding time for counselling).

We provide information for researchers requesting access to Register data, within a required time limit (90 calendar days from approval). Although in 2016/17 we did not receive any requests from researchers, it is important that the information in the Register can be used to best effect, to increase understanding and facilitate good research, and ultimately benefit patients. Engendering more high quality research (data research and also embryo and clinical research) forms part of our new strategy for 2017-2020.

We fulfilled a wide range of access to information requests under various regimes, including regular information publication under various legal and Parliamentary rules.

It is important for us to maintain the good working relationships we have established with the relevant bodies, such as the Government Digital Service (GDS), NHS Digital (formerly the Health and Social Care information Centre) and the National Information Board (NIB). Through collaborative working, we contribute to the objectives of the wider health system, with respect to information management.

Objective 4: Ensuring patients have access to high quality meaningful information

Our new website is aimed primarily at patients and donors. To meet the needs of those users, the information is clear and organised around the patient's treatment journey. It has been designed to be accessed on mobile devices and it presents information in different formats, such as animation and video.

The website provides an expanded range of information about current and future treatment options, the scientific evidence associated with these, and other fertility issues. This includes clearer information for prospective patients, and some useful signposting to external sites and other information resources.

Our information is designed to help patients, donor and donor-conceived people make informed choices. We have involved users in the design of our services and our information and we will continue to do that once the website is launched.

We conducted our annual horizon scanning exercise to ensure we identified possible new scientific developments. Our Scientific and Clinical Advances Advisory Committee (SCAAC) meets regularly to discuss issues identified through this exercise. This helps us to ensure that our future work, our policy developments and our website material for patients are informed by experts and that we maintain an understanding of upcoming scientific developments.

As part of our development work for the website, we have established mechanisms for producing and publishing informative and accurate material when new treatment options emerge, working in collaboration with clinics and experts, including SCAAC.

We receive a significant number of patient and public enquiries each year. These can include complex questions. All enquiries receive a tailored response within five working days.

Efficiency, economy and value

Objective 5: Ensuring the HFEA remains demonstrably good value for the public, the sector and Government

We use our strategy to prioritise our activities and manage our limited resources to best effect. Our IfQ programme will ultimately result in reduced transactional costs for clinics and increased satisfaction for clinic users, whether they are submitting data to us or looking for the latest regulatory guidance.

In January 2017, we released the first phase of the new Clinic Portal, the primary means by which clinics interact with us. The Portal reminds clinics about actions, offers searchable guidance and regulatory information, gives clinics clearer monitoring and performance information and allows them to apply for licence variations, through a simple online system. The second phase of the Clinic Portal, which will follow later in 2017, will involve a new data submission system for clinics to send Register data to us.

We have also continued our engagement arrangements with clinics on fees charged. This provides both accountability and transparency in respect of the fees we charge clinics.

We have started to put in place a new organisational structure to enable us to make full use of our data and improved information channels, following a staff consultation on the changes. It is vital that we maintain the staff capacity and capability to deliver our strategy and our statutory duties. Our staff have the learning and development they need to perform their roles effectively, and have access to Civil Service Learning to build their own development plans and enhance their competencies.

To comply with new better regulation requirements, we published our innovation plan in February 2017. We report annually on compliance with the Regulators' Code, and in time, the new growth duty. In addition, during the year we introduced the new business impact target, which requires regulators to submit a formal business impact assessment for all qualifying activities and projects. Our statutory independent appeals mechanism means that we are exempt from the requirement to have a Small Business Appeals Champion.

Throughout the year, we participated in the collaborative 'one stop shop' for life sciences to provide regulatory advice to those working in the life sciences industry. This is continued joint work between ourselves, the Human Tissue Authority (HTA), the Health Research Authority (HRA) and the Medicines and Healthcare Products Regulatory Authority (MHRA).

This year we worked with the MHRA to provide guidance on CE marking, and on the use of non-CE marked goods for mitochondrial donation techniques. We have attended meetings about their new guidance on medical devices and drug-device combination products. We also continue to work with them on related areas, such as medical devices alerts.

We share services and infrastructure with other organisations, as practicable, sharing a Finance Director and Head of Finance with the HTA, and receiving services through service level agreements (SLAs) with relevant other organisations for some HR services and using Civil Service Learning as our key learning and development provider. We moved to shared premises with NICE in April 2016, helping both organisations to make best use of Crown Estate property, and we receive facilities services from NICE.

We work collaboratively, and have memoranda of understanding with various other ALBs and health regulators UK wide, such as the Care Quality Commission (CQC), the MHRA, the United Kingdom Accreditation Service (UKAS), the HRA, and the General Medical Council (GMC).

We are active members of the National Information Board (NIB) and have good working relationships with regulators in the devolved nations of Scotland, Wales and Northern Ireland.

Risks as at 31 March 2017

Below are the main risks we face that, should they occur, would have the greatest material effect on the functioning of the HFEA as a whole.

By considering such risks, we can assess the continuing viability of our strategy and business plan against changes in circumstance, and make adjustments when necessary. This does not mean we expect the risks to materialise – instead it indicates that these are areas of risk of which we need to be aware and to consider our response to in order to perform our role effectively.

Further information on our approach to managing strategic risks can be found in the governance statement.

| Risk area | Main strategic risks monitored | Related strategic theme |
|----------------------------|-----------------------------------|--|
| Regulatory model | Quality and safety of care | Setting standards: quality and safety |
| | Loss of regulatory authority | |
| IfQ programme | Improved information access | Increasing and informing choice: information |
| | Register data | Increasing and informing choice: Register data |
| | Delivery of promised efficiencies | Efficiency, economy and value |
| Data | Data loss or breach | Efficiency, economy and value |
| | Incorrect data released | |
| Opening the Register (OTR) | OTR service quality | Setting standards: donor conception |
| Financial viability | Income and expenditure | Efficiency, economy and value |
| Capability | Knowledge and capability | Efficiency, economy and value |
| Organisational change | Change-related instability | Efficiency, economy and value |
| Legal challenge | Resource diversion | Efficiency, economy and value |

Going concern

We consider the use of the going concern basis of accounting is appropriate because there are no material uncertainties related to events or conditions that may cast significant doubt about the ability of the organisation to continue as a going concern.

Performance analysis

Measuring performance

Each year, we agree a business plan with our sponsor department, the Department of Health (DH) that includes strategic aims, high level objectives and key performance indicators covering delivery of our strategic plan.

We record performance against key performance indicators monthly and review achievement and action needed at the Corporate Management Group (CMG) meeting. A report is made to the Authority every two months and DH every quarter.

Analysis of performance in 2016/17

| Performance indicators | Target 2016/17 | Performance 2016/17 |
|---|--|---|
| A: Compliance | | |
| Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre | 70 working days or less | 65.2 working days |
| Percentage of PGD applications processed within three months (66 working days) | 100% | 77% ¹ |
| B: Communication and information | | |
| Opening the Register requests responded to within 20 working days | 100% | 100% (255 requests) |
| Requests for contributions to Parliamentary questions (PQs) answered within Department of Health deadlines. | 100% | 100% (55/55 PQs within deadline) |
| C: Corporate | | |
| Staff sickness absence rate (%) | No more than 2.5% | 1.6% |
| Cash and bank balance | To continue to move further towards the Department of Health's agreed minimum cash reserve of £1.52m | £2.35m ² (increased from £2.16m at the end of 15/16) |
| Percentage of invoices paid within 10 calendar days | 70% | 94% |
| Debts collected within 60 calendar days | 85% | 90% |

¹ Target missed for the first time due in part to an increasing number of complex applications received throughout the year, which require more processing time, and in part to organisational changes over the last quarter of the financial year

² Due to delays in spend on IfQ and an above forecast increase in income.

Financial review

We are funded from two main sources:

- licence and treatment fees from the establishments we licence (85%), and
- grant-in-aid from the DH (15%).

70% of our expenditure is on staff costs. Our other administrative costs include spend on our IfQ programme (9% of total spend), legal costs (4%) and facilities expenses (5%).

Summary position as at 31 March 2017

| | 2016/17 | 2015/16 |
|---|--------------|--------------|
| | £'000s | £'000s |
| Expenditure | | |
| Staff costs | 3,816 | 3,935 |
| General administrative costs | 1,597 | 1,211 |
| Total expenditure | 5,413 | 5,146 |
| Income | | |
| Licence fees | 5,323 | 4,215 |
| Other income | 26 | 1 |
| Total income³ | 5,349 | 4,216 |
| Net (expenditure)/income before interest and tax | (64) | (930) |

Our financial results are included in the accounts on pages 41 to 44 and show that the deficit before interest and tax was £64,309 (2015/16 a deficit of £929,459). This significant reduction from last year is due to an increase in our treatment fee income (26%). This is an area which we will be focusing on during 2017-18, to identify sources of data that will improve our ability to forecast our future income more accurately and reflect that in the fees we charge going forward.

The DH provided grant-in-aid towards the financing of resource expenditure of £938,000 (2015/16: £1,120,000) and £467,000 cover towards the funding of the IfQ programme (2015/16: £100,000 cash). Taking into account the resource financing, and after interest and tax, we had a surplus of £868,584.

Our total costs are increased from last year due mainly to increased legal fees and a provision for the organisation restructure. The IfQ programme, cost of £553,982 (2015/16 £682,737) has been categorised as development expenditure and has been transferred to our balance sheet under the heading Asset

³ This does not include interest income

under construction. There will be further spend in 2017/18 on our internal systems which may be funded from accumulated reserves subject to DH approval.

Supplier payments

We aim to pay all undisputed invoices in accordance with suppliers' terms of payment, which are usually within 30 days. During the financial year, we settled 99% of all invoices received within 30 days with a value of £1,917,125 in value) (2015/16 £1,814,066 100%).

Our staff

Recruitment

All appointments are made in accordance with our recruitment and selection policy (revised April 2014), so that they are made on the basis of merit and in accordance with equal opportunities.

Learning and development

We actively promote the development of our staff and encourage them to take five days a year learning. We subscribe to Civil Service Learning, a service which provides courses and resources for developing skills to all UK civil servants. This supports a blended approach which is convenient and cost-effective. Individual needs are set out in personal development plans and are met through appropriate means, including e-learning, face-to-face learning and taking part in projects, coaching and job shadowing.

Staff engagement and wellbeing

We promote staff engagement through various channels including staff and team meetings, our annual staff conference, our monthly staff bulletin and ad hoc working groups. Staff surveys provides formal feedback to obtain and respond to staff feedback. In 2016/17 86% (2015/16 75%) of staff responded to the staff survey and 90% (2015/16 98%) reported a clear understanding of the HFEA's purpose.

In December 2016, we formerly announced to staff we were to conduct a consultation on a proposed restructure within the Strategy and Corporate Affairs and Compliance and Information Directorates. That work was completed in March 2017. We have worked with those staff directly impacted by the proposed change and providing support and guidance in relation to their future role within the organisation.

More widely we have been engaging with all staff to ensure they understand the drivers for change and how this will help us deliver our strategy 2017-20.

Disabled employees

In 2007-08 we achieved ✓✓ 'positive about disabled people' disability symbol status. We have a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making any reasonable adjustments to the workplace or work processes and having advice available through the occupational health service.

Equality Act 2010 – equality and diversity on pay

We remain compliant with the requirements of the Equality Act 2010 and there is an equality champion on the Authority (our board of directors and appointed members). We continue collectively to ensure,

throughout the year, that we fulfil our obligations under the Equality Act. All posts are systematically evaluated, against a formal job evaluation scheme 'Paypoints II', aiming to ensure that salaries are internally consistent, fair and equitable.

Our gender breakdown at 31 March 2017, of Authority members, permanent and seconded staff, is as follows:

| | Male | Female | Total |
|--|------|--------|-------|
| Authority members | 4 | 7 | 11 |
| Senior Management Team ¹ (SMT) | 3 | 1 | 4 |
| All staff (including SMT, excluding Authority) | 22 | 42 | 64 |

¹SMT membership changed when the Director of Finance and Facilities resigned in September and her replacement commenced in November 2016.

Social, community, sustainability, human rights and environmental issues

We moved office at the start of the 2016/17 financial year after being sub-tenants of the Care Quality Commission (CQC), in Finsbury Tower to Spring Gardens, now we are sub-tenants of the National Institute for Health and Care Excellence (NICE).

We collaborate with NICE on a number of issues, including health and safety services - we follow their lead on fire evacuation procedures and fire warden liaison.

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges. There are two multi-function devices (for secure printing, scanning and photocopying) that are pre-set to print on both sides of the paper and in black and white. IT equipment is re-used and working lives extended where possible, and is switched off when not in use. Surplus equipment is either sold or donated. Many staff are enabled to work from home, reducing the impact on the environment through less travelling.

We are aware of the green agenda in relation to procurement and we use the Crown Commercial Service and other frameworks which have sustainability factored in.



Peter Thompson
Chief Executive
Accounting Officer

5 July 2017

Accountability

Corporate governance report

Directors' report

Our board (the Authority)

Our board is normally made up of 12 members appointed through an open public process. At the end of the year there were 11 members. Below are details of the current and out-going Authority members during the 2016/17 financial year. Biographies for each can be found on our website.

| Authority member | Appointment start date | Appointment end date |
|--|------------------------|--|
| Sally Cheshire (Chair) | 7 November 2006 | 31 March 2020 (re-appointed 13 September 2016) |
| David Archard (Deputy Chair) | 1 November 2005 | 31 October 2016 |
| Rebekah Dundas (Chair of AGC ⁴) | 1 January 2007 | 31 December 2016 |
| Andy Greenfield | 9 November 2009 | 31 December 2018 |
| Lee Rayfield | 23 April 2012 | 22 March 2018 |
| Kate Brian | 12 November 2014 | 11 November 2017 |
| Anthony Rutherford | 12 November 2014 | 11 November 2017 |
| Yacoub Khalaf | 30 April 2015 | 31 March 2018 |
| Margaret Gilmore (Deputy Chair from 1 November 2016) | 30 April 2015 | 31 March 2018 |
| Anita Bharucha (Chair of AGC from 1 January 2017) | 30 April 2015 | 31 March 2018 |
| Anne Lampe | 1 February 2016 | 31 January 2019 |
| Ruth Wilde | 1 January 2016 | 31 December 2018 |
| Bobbie Farsides | 1 February 2017 | 31 January 2020 |

⁴ Audit and Governance Committee (AGC)

Senior Management Team

Our Chief Executive and directors, and their responsibilities, during 2016/17 are set out below.

| | | |
|--|--|--|
| Peter Thompson, Chief Executive | | |
| HR | | |
| Legal | | |
| Richard Sydee ⁵ , Director of Finance and Resources | Juliet Tizzard, Director of Strategy and Corporate Affairs | Nick Jones, Director of Compliance and Information |
| Budgeting | Governance and licensing | Inspection and clinical governance |
| Accounting | Regulatory policy | Business support |
| Financial control | Engagement and communications | Information and the Register |
| Audit and risk assurance | Business planning | Development |
| Facilities | Programme management | Network support |

Interests of Authority members and senior staff

We maintain a register of interests which is available on our website at www.hfea.gov.uk.

Pensions

Pension benefits are mainly provided by the Principal Civil Service Pension Scheme (PCSPS). We recognise the contributions payable for the year. Full details of the pension scheme are included in the Remuneration report.

Data incidents

Arrangements for data security and any personal data-related incidents are set out in the annual governance statement.

Our auditors

The Comptroller and Auditor General is appointed by statute to audit our financial statements. The fees of the National Audit Office are set out in note three to the accounts. No fees were incurred for non-audit work.

Disclosure of information to our auditors

I have taken all the necessary steps to make myself aware of any relevant audit information, and to establish that our auditors, the National Audit Office (NAO), are aware of that information. So far as I and the other directors are aware, there is no relevant audit information of which the NAO is unaware.

⁵ Richard Sydee is employed by the HFEA and is seconded to the Human Tissue Authority for 2.5 days per week.

Statement of Accounting Officer's responsibilities

Under Section 6(1) of the Human Fertilisation and Embryology Act 1990 (as amended), we are required to prepare a statement of accounts for each financial year in the form, and on the basis determined by, the Secretary of State, advised by HM Treasury.

The accounts are prepared on an accruals basis, and must show a true and fair view of our state of affairs at the year-end, our net expenditure, changes in taxpayers' equity and cash flow for the financial year.

In preparing the accounts, the Accounting Officer is required to comply with the requirements of the Government financial reporting manual, and in particular to:

- observe the accounts directions issued by the Secretary of State, including the relevant accounting and disclosure requirements and apply suitable accounting policies on a consistent basis
- make judgements and estimates on a reasonable basis
- state whether applicable accounting standards, as set out in the Government financial reporting manual, have been followed and disclose and explain any material departures in the financial statements, and
- prepare the financial statements on a going concern basis as there are now no formal grounds to consider this inappropriate.

The Accounting Officer of the Department of Health (DH) has designated our Chief Executive as the Accounting Officer for the organisation. His responsibilities include responsibility for the propriety and regularity of the public finances for which he is answerable, for keeping proper records and for safeguarding our assets, as set out in 'Managing public money' published by the HM Treasury.

The Accounting Officer confirms that the annual report and accounts as a whole is fair, balanced and understandable and takes personal responsibility for the annual report and accounts and the judgements required for determining that it is fair, balanced and understandable.

The Accounting Officer confirms that, as far as he is aware, there is no relevant audit information of which the entity's auditors are unaware, and the Accounting Officer has taken all the steps that he ought to have taken to make himself aware of any relevant audit information and to establish that the entity's auditors are aware of that information.

Accounts direction

The statement of accounts is prepared in a form directed by the Secretary of State for Health dated 18 June 2007, in accordance with section six of the 1990 Act (as amended).

Authority statement

Our Senior Management Team (SMT), the Audit and Governance Committee and the Authority have reviewed the annual report and accounts. I confirm that the annual report and accounts are fair, complete and understandable and provide the information necessary for stakeholders to assess our performance.

Governance statement

This statement sets out our governance and control framework during 2016/17 and the risks to HFEA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HFEA's resources in 2016/17.

The picture is good, with strong performance from the Authority, committees and the executive, and a clean bill of health from internal audit. There have been changes in Authority membership, with continuing members and the executive have provided continuity. IfQ has continued throughout 2016/17 with significant progress made, the programme will conclude in early 2017/18 and provide significant improvements on our existing platforms. There have been no governance issues or incidents in 2016/17.

Governance framework

Our governance framework is set out in the HFE Act 1990 (as amended) and its approved standing orders.

Our board (the Authority)

The Authority has 12 members (including one vacancy at present). During this year two members (Rebekah Dundas and David Archard) reached the end of their term and one member (Bobbie Farsides) joined the Authority in November 2016.

There have been seven Authority meetings in 2016/17, all of which were quorate. The Authority's meetings are open to the public and an audio recording of the meeting is on our website. The Authority has also held a number of workshops before its public meetings, which are used to discuss future strategy and other policy matters. In March 2017, we held our annual conference for fertility professionals.

The papers on which the Authority (and its committees) rely are subject to a rigorous internal assurance process, overseen by the relevant member of the SMT. Feedback from members of the Authority, and the annual review of committees, suggests that the papers are of high quality and accuracy.

Statutory and standing committees

The Authority has several committees to which it delegates a number of its functions. The following table sets out each committee alongside their frequency and attendance details.

| Committee | Membership at 31 March 2017 | Number of meetings 2016/17 | Attendance rate |
|--------------------------------|-----------------------------|----------------------------|-----------------|
| Authority | 12 | 7 | 90% |
| Appointments Committee | 3 | 1 | 100% |
| Audit and Governance Committee | 3 | 4 | 92% |
| Executive Licensing Panel | 9 | 25 | 100% |
| Licence Committee | 5 | 7 | 88% |

| Committee | Membership at 31 March 2017 | Number of meetings 2016/17 | Attendance rate |
|--|--|---------------------------------------|------------------------|
| Register Research Panel | 3 | 1 | 100% |
| Remuneration Committee | 3 | 2 | 100% |
| Statutory Approvals Committee | 5 | 12 | 84% |
| Scientific and Clinical Advances Advisory Committee | 5 | 3 | 93% |

The Executive

The Authority and its committees are supported in their work by the Executive, led by the Chief Executive (the Authority's Accounting Officer) and three directors, collectively the Senior Management Team (SMT).

The SMT are:

| | |
|----------------|---|
| Peter Thompson | Chief Executive |
| Nick Jones | Director of Compliance and Information |
| Juliet Tizzard | Director of Strategy and Corporate Affairs |
| Richard Sydee | Director of Finance and Resources (shared with the HTA) |

Richard Sydee joined HFEA in November 2016, replacing Sue Gallone who resigned in September 2016. The Director of Finance and Resources (and the Head of Finance) are shared with the HTA and the shared arrangement does bring unique challenges. Aware of the potential loss of corporate knowledge that a change in the senior team could pose we have ensured a good handover between the outgoing and incoming post holders, aided in no small part by the Head of Finance. As Chief Executive, I am confident that the risks are being handled appropriately and effectively.

The SMT and Corporate Management Group (CMG) oversee the delivery of our business plan. CMG is chaired by the Chief Executive and attended by the directors and heads of department, and meets once a month as a minimum. It also considers strategic risks before the Audit and Governance Committee (see below).

The Executive's Programme Board oversees individual projects and ensures that suitable controls are in place. Risk assessment and management are substantial aspects of this oversight arrangement, with the project manager and sometimes also the project sponsor (usually a director) reporting to the Programme Board at regular intervals. In turn, the Programme Board reports to CMG every month, with a highlight report covering each live project.

IfQ has its own separate governance and reporting arrangements, including a separate Programme Board, owing to its large size and separate DH-approved funding stream.

Corporate governance

Like other ALBs in the health and care sector, we have a framework agreement with the DH which defines the critical elements of our relationship with them. The way in which we work with the DH, and how we both discharge our accountability responsibilities effectively, is outlined in the agreement. The Chair and Chief Executive meet the Senior Departmental Sponsor (SDS) at the DH for a formal annual accountability review and informally throughout the year. In addition, the SMT meets other DH officials at quarterly intervals, and has regular contact as issues require. Representatives from the DH are also present as observers at Board meetings of the Authority and at the Audit and Governance Committee.

The operational objectives that help us deliver our corporate strategy are set out in the annual business plan. Drafts of this document are shared with the DH in advance and quarterly monitoring information is also submitted to them. Along with meetings with the SDS and other officials at the DH, this provides assurance that the delivery of objectives is on track.

Our system of corporate governance complies with the requirements of the 'Corporate governance in central Government departments: code of good practice', in so far as they relate to ALBs. It is designed to ensure that sufficient oversight of operational matters is held by our Authority and Audit and Governance Committee, while allowing for clear accountability and internal control systems at Executive level.

Effectiveness and performance

We have achieved our core statutory functions of licensing and regulating fertility clinics, maintaining a register of treatments and a Code of Practice, and increasing and informing choice for patients. In common with all public sector organisations, we have done so under continued pressure on our staff.

We look to improve and make more efficient the way in which we engage with significant matters of policy and operational delivery. One of the ways in which the Authority makes better use of its time is through 'workshop' sessions before full Authority meetings, at which the Authority has discussed issues such as mitochondrial donation, information for patients on the website and IfQ. This way of working makes more efficient and productive use of member and executive time and allows better informed decision-making.

This, along with the annual review of committee effectiveness and consequent changes to governance and standing orders, gives assurance that the exercise of our statutory functions is delegated appropriately and legally, adhering to the recommendations outlined in the Harris review.

Members of the Authority and the Chief Executive have their performance assessed by the Chair (or, in the case of the Chair, by the SDS). No issues of performance have been raised and as Chief Executive I am assured that the arrangements in place for internal control are robust and fit for purpose.

Annual reviews of committee effectiveness

As is good practice, every year our committees undertake a review of their effectiveness. In general, the feedback from the committees was good, with defensible, evidenced decisions being made on the basis of robust paperwork.

In addition, the Authority undertook a Board Effectiveness review as part of the Internal Audit plan for 2016/17. There was a high level of participation and its responses provided a positive assessment against the benchmark – with the outcome of the review demonstrating the Authority to be the best performing of all the Health sector ALBs recording above the benchmark scores in all 12 aspects of the assessment. Two recommendations were made, relating to the provision of timely updates on key developments to Authority members and training for new Authority members, these have been accepted and proposed changes have been implemented.

Highlights of Authority and committee reports

The Authority considered a wide variety of issues in 2016/17. Its focus has been primarily on the delivery of the final year of our 2014-17 strategy and development of the new strategy for 2017-2020, approving mitochondrial donation techniques for use, overseeing the IfQ programme and addressing issues in the sector in relation to consent and treatment add-ons.

The Audit and Governance Committee continues to give the Authority assurance that financial and risk management systems are in place and of appropriate scrutiny to ensure adherence. The Audit and Governance Committee continues to take a theme-based approach to its meetings, giving it a broad outlook over the organisation and its operations. It has exercised its delegated functions, including approval of this statement, on behalf of the Authority.

Our Licence Committee, Statutory Approvals Committee, and the Executive Licensing Panel have handled the core business of considering licence applications and issues, applications for embryo testing and applications for importing or exporting embryos, sperm and eggs.

The Scientific and Clinical Advances Advisory Committee has provided high-quality advice and exercised its delegated functions appropriately.

The Remuneration and Appointments committees continue to consider matters pertaining to human resources, remuneration, and the appointment of external committee members and advisers.

Risk and capability

Given the variety and complexity of the risks we face, our overall appetite for risk is low. The framework we have in place to identify and manage risk is appropriate and allows for reasonable controls to be in place, without impacting on the successful delivery of our objectives.

A comprehensive description of current risk management procedures is set out in our risk policy that was reviewed and updated in June 2016 and will be updated later in 2017/18.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately. Risks are formally managed at several different levels, as follows:

- strategic risk register – capturing risks to the delivery of our strategy and business plan
- operational risk logs – capturing team level risks to functional delivery
- project/programme risk logs – capturing risks to successful project delivery
- internal incidents system – an adjunct to the risk system, which enables understanding of, and corporate learning from, internal adverse events.

The Authority and its Audit and Governance Committee consider the strategic risk register, which is populated by CMG based on ongoing consideration of risks to delivering our strategy, including any major current operational risks. Teams each maintain a risk log capturing their own operational level risks, and the top risks are regularly shared at CMG risk meetings. This allows for the management of risk to be embedded in the organisation from the bottom up.

Projects are scrutinised by our Programme Board. Risk assessment and management are a substantial aspect of this oversight arrangement and the project manager (and sometimes also the project sponsor - usually a director) must report to the Programme Board at monthly intervals. In turn, the Programme Board reports to CMG every month, with a highlight report outlining progress, risks and issues for each live project.

The reputational and organisational significance of our IfQ programme is such that we have put in place a dedicated programme support team, which maintains a risk register specifically for that programme. The IfQ Programme Board reviews risk regularly and IfQ risks are reported on as a standing item to the monthly meetings of CMG. Similarly, the senior responsible officer of the IfQ programme provides assurance to the Authority and the Audit and Governance Committee at every meeting of the programme's progress.

The resources available for our wider program of work continues to be restrained by the wider public sector constraints on growth. Although we have seen an increase in our income this has not enabled us to increase expenditure on regulatory activity. We maintain our expenditure in line with budgets agreed with the Department of Health and our Stakeholders. This also impacts on our ability to respond or address emerging issues within the sector we regulate.

Our system of internal risk management gives assurance that the risks we face when exercising our statutory functions are managed appropriately and mitigated against proportionately.

Regulatory risk

We also take a risk-based approach to the way we regulate the fertility sector, in order to ensure that our regulatory action is targeted and proportionate. Our risk-based assessment tool allows such an approach and (like all other processes we use in carrying out our functions) is subject to a rigorous quality assurance regime, in line with the Macpherson review recommendations⁶.

Risk assessment

Systematic Regulatory risks such as the potential for poor quality or unsafe care, or any loss of our authority as a regulator is one of our key strategic risks which we maintain focus upon and track accordingly. Another important area of risk is the need to successfully deliver the IfQ programme and improve our engagement channels, the usage and accuracy of our Register information, and achieving promised efficiencies. Other risks include risks to our data or information accuracy, legal challenges, and our staff capacity and capability. Our ongoing mitigating activities are managed and monitored through the systems described earlier. The IfQ programme, once complete, will help in continuing to minimise the risk to our data and information, while our robust governance and decision-making arrangements mitigate against the controllable elements of the risk of legal challenge. Like all public sector organisations, we continue to face capacity and capability risks that we manage through good internal communications, staff engagement and our performance management process.

This year our internal audit carried out a cyber-risk assessment of our Cloud infrastructure and focussed on how secure our system and data are. This is an area that has increased relevance as we finalise our IT transformation programme. Having commenced risk assurance mapping in early 2016, where we focussed on capability and capacity risks, we have found such exercises help us to assess the effectiveness of our risk control framework and identify any improvements we can make. We will continue to conduct similar exercises annually, in conjunction with our internal auditors.

Information management and security

As the holder of the statutory Register of fertility treatments, we take our responsibilities for information security most seriously and have a low tolerance for information risks. Keeping secure the information we hold, particularly sensitive personal patient data, is of the highest priority, and this principle will frame our approach to the implementation of the IfQ programme in the coming year.

There were no data losses within the last year and we continue to work hard to ensure that remains the case.

Whistleblowing arrangements

Our Public Interest Disclosure (Whistleblowing) policy sets out how any concerns can be raised by staff and what action would be taken. It aims to reassure staff that they should raise concerns openly and that there will be no repercussions for them if they raise concerns in good faith. The policy has been communicated to staff through line management and our intranet.

As well as line management and HR channels, staff can approach the NAO hotline and Public Concern at Work for advice.

⁶ Available at www.gov.uk/government/publications/review-of-quality-assurance-of-government-models.

During the year, there have been no concerns raised under whistleblowing arrangements. Staff raise issues and make suggestions as part of day to day working in line with our culture.

Internal incidents

Our Executive maintains an internal incident procedure, which ensures that any process failures are quickly and thoroughly investigated. This allows SMT to learn lessons and correct potential procedural failures. The system and associated documentation was reviewed during the year to bring it in line with our other documentation and overall brand.

Overall conclusion

We have now successfully concluded delivery of the strategy introduced in 2014, launching our future strategy for 2017-2020 at our recent annual conference. This new strategy will ensure that patients, donors and donor-conceived people are at the heart of our strategy, and our work.

We have embedded improved risk management processes and I am assured that a robust governance and assurance framework is in place, that our risks are managed proportionately, and that appropriate financial controls are in effect. My assessment has been informed also by internal audit reviews during the year of our income generation process and the data that supports it, information governance around our patient information, the risks of cyber penetration and Board effectiveness. I have noted the moderate annual opinion of our internal audit which relate to risk management, governance and control. As we look to the future, I have full confidence that we will continue to develop assurance mechanisms, while improving the quality of our work and seeking to provide best value for public finances and patients.



Peter Thompson
Chief Executive
Accounting Officer

5 July 2017

Remuneration report

Audit

Specific areas of the Remuneration report are audited by NAO, the HFEA's external auditors. These sections cover salary and pension data in the tables, non-cash benefits and amounts payable to third parties for services of senior staff.

Reward systems and approval mechanisms for staff

Our remuneration recommendations are based on the Civil Service pay guidance issued annually by HM Treasury.

Pay awards were made to eligible staff in 2016/17 in accordance with the Government limit of 1% of the total pay-bill. This is the same as the previous year.

Pay levels are reviewed annually through the Remuneration Committee, which has specific responsibility to monitor overall levels of remuneration and to approve the remuneration of the Chief Executive and the directors (see below).

Duration of contracts, notice periods and termination payments

Members of staff in bands one (assistant grade) and two (officers) must provide six weeks' notice of termination of their contracts. Members of staff in band three (managers) and above must provide three months' notice of termination of their contracts. Termination payments are made only in appropriate circumstances. In cases where gross misconduct has occurred, no termination payments are made.

Authority members

The remuneration levels of Authority members are set nationally and are summarised in the table below. Revisions are made in accordance with the agreement on the pay framework for ALB chairs and non-executive directors, announced in March 2006. We implement the revisions when instructed.

No pension contributions or bonuses were paid on behalf of any Authority member in 2016/17.

Appeals Committee

The Appeals Committee Chair receives a fee of £273 per day. The Deputy Chair receives a fee of £208 per day and the committee's members receive a fee of £190 per day. No pension contributions were paid on behalf of any Appeals Committee member.

The Chair of the Appeals Committee, Mr Marcus Smith Q.C was appointed on 1 October 2015 and resigned on 11 January 2017 after being appointed to the judiciary. Mr Smith received a payment of £273.

Mr Peter Freeman CBE, QC Hon was appointed on 13 March 2017 and received no payment in the period ended 31 March 2017. A payment of £208 was made to the Deputy Chair of the Appeals Committee, Ms Julie Matheson, during the year. Other Appeals Committee members Samuel Stein, David Kyle, Peter North and Dr Elizabeth Haxby received £190 each.

End of service

Staff can access their Civil Service pension at different times, depending on the scheme they are in. The normal pension age for those in the classic/premium scheme is 60, for those in the Nuvos scheme it is 65 and for those in the Alpha scheme it is the later of 65 or the state pension age. However, some staff may wish to work beyond these ages.

Early termination, other than for misconduct, would result in the individual receiving compensation as set out in the Civil Service Compensation Scheme.

Remuneration and benefits to Authority members for the year ending 31 March 2017

| Name | Salary range £000s | Expenses (to nearest £100) ⁷ £ | Total £000s | Salary range £000s | Expenses (to nearest £100) £ | Total £000s |
|----------------------------------|-----------------------|--|----------------|-----------------------|---------------------------------------|----------------|
| | 2016/17 | 2016/17 | 2016/17 | 2015/16 | 2015/16 | 2015/16 |
| Sally Cheshire (Chair) | 45-50 | 19,000 | 65-70 | 45-50 | 14,500 | 60-65 |
| David Archard (Deputy Chair)* | 5-10 | 4,500 | 10-15 | 5-10 | 5,300 | 10-15 |
| Rebekah Dundas* | 10-15 | 4,500 | 15-20 | 10-15 | 5,600 | 15-20 |
| Andy Greenfield | 5-10 | 1,900 | 5-10 | 5-10 | 1,400 | 5-10 |
| Lee Rayfield | 5-10 | 700 | 5-10 | 5-10 | 1,100 | 5-10 |
| Kate Brian | 5-10 | 0 | 5-10 | 5-10 | 0 | 5-10 |
| Anthony Rutherford | 5-10 | 200 | 5-10 | 5-10 | 900 | 5-10 |
| Yacoub Khalaf | 5-10 | 100 | 5-10 | 5-10 | 0 | 5-10 |
| Margaret Gilmore | 5-10 | 2,100 | 10-15 | 5-10 | 1,700 | 5-10 |
| Anita Bharucha | 5-10 | 1,400 | 10-15 | 5-10 | 800 | 5-10 |
| Anne Lampe | 5-10 | 3,300 | 10-15 | 0-5 | 900 | 0-5 |
| Ruth Wilde | 5-10 | 700 | 5-10 | 0-5 | 200 | 0-5 |
| Bobbie Farsides* | 0-5 | 200 | 0-5 | N/a | N/a | N/a |

*Members who joined/left part way through the year.

⁷ These expenses are shown net of tax and national insurance

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by us and treated by HMRC as a taxable emolument. We have agreed a PAYE settlement agreement (PSA) with HMRC in regards to taxable emoluments of Authority members and some of our compliance staff, for the travel, accommodation, meals and subsistence for which we pay the tax and national insurance due.

Information regarding travel and subsistence claimed by Authority members and senior management is published on our website www.hfea.gov.uk.

Chief Executive and directors

The Chief Executive's pay is set in accordance with the recommendation of the Chair, subject to the review of the Remuneration Committee and with the agreement of the DH. This is in accordance with the pay framework for very senior managers in ALBs, informed by the Senior Staff Salaries Review Board.

Remuneration of the directors must be approved by the Remuneration Committee and is based on proposals received from the Chief Executive, in accordance with the pay framework for very senior managers in ALBs.

The members of the Remuneration Committee during the year were Sally Cheshire (Chair), David Archard and Rebekah Dundas.

| Remuneration and pension benefits of the senior management team | | | | | | | | | | | |
|---|----------------------|---------|------------------------|---------|-------------------------------------|---------|---------------------------------------|---------|---------------|---------|--|
| Name | Salary (£'000) | | Bonus payments (£'000) | | Benefits in kind (to nearest £'000) | | Pension benefits ⁸ (£'000) | | Total (£'000) | | |
| | 2016/17 | 2015/16 | 2016/17 | 2015/16 | 2016/17 | 2015/16 | 2016/17 | 2015/16 | 2016/17 | 2015/16 | |
| Peter Thompson | 135-140 | 135-140 | 0 | 0 | 0 | 0 | 28 | 49 | 165-170 | 185-190 | |
| Nick Jones | 95-100 | 95-100 | 0 | 0 | 0 | 0 | 38 | 37 | 135-150 | 130-135 | |
| Richard Sydee ⁸ | 35-40 (Fte 90-95) | N/a | 0 | N/a | 0 | N/a | 15 | N/a | 50-55 | N/a | |
| Juliet Tizzard | 90-95 | 90-95 | 2 | 0 | 0 | 0 | 40 | 41 | 130-135 | 130-135 | |
| Sue Gallone ⁹ | 10-15 | 40-45 | N/a | N/a | N/a | N/a | N/a | N/a | 10-15 | 40-45 | |

⁸ The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less (the contributions made by the individual). The real increases exclude increases due to inflation or any increase or decreases due to a transfer of pension rights.

⁹ Richard Sydee is employed by the HFEA and seconded to the HTA. A portion of his costs are charge to the HTA. Sue Gallone was employed by the HTA and seconded to HFEA. A proportion of her costs were charged to us. Sue resigned on 20 September 2016.

Median pay and multiples

| | 2016/17 | 2015/16 |
|---|-------------|--------------------|
| Band of highest paid director's gross salary only | £135k-£140k | £135k-£140k |
| Median total remuneration | £37,127 | £36,541 |
| Ratio – gross salary only | 3.70 | 3.76 ¹⁰ |

The FReM reporting requirements require public sector bodies to disclose the relationship between the total remuneration of the highest-paid director in their organisation and the median remuneration of the organisation's workforce.

The banded remuneration of the highest-paid director in the financial year 2016-17 was £135,000-140,000 (2015/16 £135,000-£140,000). This was 3.7 times (2015/16, 3.73) the median remuneration of the workforce, which was £37,100 (2015/16 £36,541). In 2016/17, 0 (2015/16, 0) employees received remuneration in excess of the highest-paid director. Remuneration ranged £24,000 to £140,000.

Total remuneration includes salary, non-consolidated performance-related pay and benefits-in-kind. It does not include severance payments, employer pension contributions and the cash equivalent transfer value of pensions. We are a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay remains higher than that for a number of other public sector bodies.

Staff report

The HFEA has a headcount of 64 staff members excluding Authority members and including the SMT. Below is a breakdown of staff costs and an analysis of directly employed staff.

| | Permanently employed staff | Members | 2016/17 Total | 2015/16 Total |
|---|----------------------------|----------------|------------------|------------------|
| | £ | £ | £ | £ |
| Salaries and wages | 2,847,999 | 137,796 | 2,985,795 | 3,186,288 |
| Social security costs | 264,037 | 6,262 | 270,299 | 202,959 |
| Other pension costs | 560,182 | 0 | 560,182 | 545,329 |
| Net staff costs | 3,672,218 | 144,058 | 3,816,276 | 3,934,576 |
| Less recoveries in respect of outward secondments | (25,957) | 0 | (25,957) | 0 |
| Total Net Staff costs¹¹ | 3,646,261 | 144,058 | 3,790,319 | 3,954,576 |

¹⁰ The median ratio has been amended as the calculation changed.

¹¹ Staff costs are lower this year due to vacancies carried and a reduction in the use of contingent labour. These costs also include cost of contingent labour (temporary staff cost of £144,784).

Average number of persons permanently employed and outwardly seconded

| | Permanently employed | Seconded | 2016/17 Total | 2015/16 Total ¹² |
|--------------|----------------------|--------------------|---------------|-----------------------------|
| SCS | 3.0 | 0.41 ¹³ | 3.41 | 3.45 |
| Other | 60.57 | 0 | 60.57 | 62.39 |
| Total | 63.57 | 0.41 | 63.98 | 65.84 |

Sickness and absences

Our sickness absence aim is to lose no more than 3% of time in staff sickness absence and in 2016/17 we achieved 2.1%. This compares favourably with the public-sector sickness absence rate average which is 3.5% (IRS Survey 2011).

Off-payroll assurance statement

We have not entered into any off-payroll engagements during the 2016/17 financial year (2015/16 nil).

Consultancy

Our expenditure on Consultancy is £374,318 as listed within the financial statements on page 50 and relates to legal costs incurred.

Remuneration and pension entitlements

The Government financial reporting manual (FReM) requires us to provide information on the remuneration and pension rights of the named individuals who are our most senior managers.

The following table provides details of the remuneration and pensions of the Chief Executive and directors. These figures are subject to audit.

¹² Figures restated as Sue Gallone was employed by the HTA and therefore shown as 0.8Fte in the HTA's accounts.

¹³ Richard Sydee replaced Sue Gallone in November 2016 and is included as seconded staff from November to March

The pension entitlements of the most senior managers in the HFEA

| Name and position | Total accrued pension at age 65 as at 31 March 2017 | Real increase in pension and related lump sum at age 65 | CETV at 31 March 2016 | CETV at 31 March 2017 | Real increase in CETV as funded by HFEA |
|--|---|---|-----------------------|-----------------------|---|
| | Band | Band | | | |
| | £'000 | £'000 | £'000 | £'000 | £'000 |
| Peter Thompson Chief Executive | 50-55 | 0-2.5 | 833 | 897 | 23 |
| Richard Sydee Director of Finance and Resources | 0-5 | 0-2.5 | 0 | 8 | 6 |
| Nick Jones Director of Compliance and Information | 15-20 | 0-2.5 | 173 | 205 | 20 |
| Juliet Tizzard Director of Strategy and Corporate Affairs | 10-15 | 0-2.5 | 152 | 181 | 17 |

All senior managers listed are employed on a permanent basis and are covered by the terms of the Principal Civil Service Pension Scheme. Sue Gallone was employed by the HTA and seconded to us for part of her time and resigned in September 2016.

Definitions

'Salary' includes gross salary, performance pay or bonuses and any other allowance that is subject to UK taxation.

'Total remuneration' includes salary, non-consolidated performance-related pay and benefits in kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

'Benefits in kind' covers the monetary value of any benefits provided by the employer.

This report is based on payments made by us and thus recorded in these accounts.

Civil Service Pensions

Pension benefits are provided through the Civil Service pension arrangements. From 1 April 2015 a new pension scheme for civil servants was introduced – the Civil Servants and Others Pension Scheme (CSOPS) or Alpha, which provides benefits on a career average basis with a normal pension age equal to the member's state pension age (or 65 if higher). From that date, all newly appointed civil servants and the majority of those already in service joined Alpha. Prior to that date, civil servants participated in the Principal Civil Service Pension Scheme (PCSPS). The PCSPS has four sections: three providing benefits

on a final salary basis (classic, premium or classic plus) with a normal pension age of 60; and one providing benefits on a whole career basis (Nuvos) with a normal pension age of 65.

These statutory arrangements are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under Classic, Premium, Classic Plus, Nuvos and Alpha are increased annually in line with pensions increase legislation. Existing members of the PCSPS who were within 10 years of their normal pension age on 1 April 2012 remained in the PCSPS after 1 April 2015. Those who were between 10 years and 13 years and five months from their normal pension age on 1 April 2012 will switch into Alpha sometime between 1 June 2015 and 1 February 2022. All members who switch to Alpha have their PCSPS benefits 'banked', with those with earlier benefits in one of the final salary sections of the PCSPS having those benefits based on their final salary when they leave Alpha. (The pension figures quoted for officials show pension earned in PCSPS or Alpha – as appropriate. Where the official has benefits in both the PCSPS and alpha the figure quoted is the combined value of their benefits in the two schemes.) Members joining from October 2002 may opt for either the appropriate defined benefit arrangement or a 'money purchase' stakeholder pension with an employer contribution (partnership pension account).

Employee contributions are salary-related and range between 3% and 8.05% of pensionable earnings for members of Classic (and members of Alpha who were members of Classic immediately before joining Alpha) and between 4.6% and 8.05% for members of Premium, Classic Plus, Nuvos and all other members of Alpha. Benefits in Classic accrue at the rate of 1/80th of final pensionable earnings for each year of service. In addition, a lump sum equivalent to three years initial pension is payable on retirement. For Premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike Classic, there is no automatic lump sum. Classic Plus is essentially a hybrid with benefits for service before 1 October 2002 calculated broadly as per Classic and benefits for service from October 2002 worked out as in Premium. In Nuvos a member builds up a pension based on his pensionable earnings during their period of scheme membership. At the end of the scheme year (31 March) the member's earned pension account is credited with 2.3% of their pensionable earnings in that scheme year and the accrued pension is uprated in line with pensions increase legislation. Benefits in Alpha build up in a similar way to Nuvos, except that the accrual rate is 2.32%. In all cases members may opt to give up (commute) pension for a lump sum up to the limits set by the Finance Act 2004.

The partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% up to 30 September 2015 and 8% and 14.75% from 1 October 2015 (depending on the age of the member) into a stakeholder pension product chosen by the employee from a panel of providers. The employee does not have to contribute, but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary up to 30 September 2015 and 0.5% of pensionable salary from 1 October 2015 to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

The accrued pension quoted is the pension the member is entitled to receive when they reach pension age, or immediately on ceasing to be an active member of the scheme if they are already at or over pension age. Pension age is 60 for members of Classic, Premium and Classic Plus, 65 for members of Nuvos, and the higher of 65 or state pension age for members of Alpha. (The pension figures quoted for officials show pension earned in PCSPS or Alpha – as appropriate. Where the official has benefits in both the PCSPS and Alpha the figure quoted is the combined value of their benefits in the two schemes, but note that part of that pension may be payable from different ages.)

For 2016/17, employer's contributions of £560,182 were payable to the PCSPS in respect of staff directly employed by us (2015/16: £531.566) at one of four rates in the range 20.0% to 24.3% of pensionable pay, based on salary bands. The Scheme Actuary reviews employer contributions usually every four years

following a full scheme valuation. The contribution rates are set to meet the cost of the benefits accruing during 2016-17 to be paid when the member retires and not the benefits paid during this period to existing pensioners.

Further details about the Civil Service pension arrangements can be found at the website www.civilservicepensionscheme.org.uk.

A Cash Equivalent Transfer Value (CETV) is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A CETV is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity to which disclosure applies.

The figures include the value of any pension benefit in another scheme or arrangement which the member has transferred to the Civil Service pension arrangements. They also include any additional pension benefit accrued to the member as a result of their buying additional pension benefits at their own cost. CETVs are worked out in accordance with 'The occupational pension schemes (transfer values) (amendment) regulations 2008' and do not take account of any actual or potential reduction to benefits resulting from lifetime allowance tax which may be due when pension benefits are taken.

Real increase in CETV

This reflects the increase in CETV that is funded by the employer. It does not include the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

Audit

All tabular data contained in this remuneration report together with employer pension contributions are subject to audit.



Peter Thompson
Chief Executive
Accounting Officer

5 July 2017

Parliamentary accountability and audit report

Accountability

Fees and charges

Our licence fees are set to recover the full cost incurred in the granting of licences and regulation. The table below shows the income from the sector for licensing activities and the associated costs of licensing.

| | March 2016/17 | March 2015/16 |
|--|----------------|---------------|
| | £ | £ |
| Licence fee income | 5,322,910 | 4,215,582 |
| Costs allocated to regulatory activity | (4,455,488) | (4,190,850) |
| Surplus/(Deficit) | 867,422 | 24,732 |

We confirm that we have complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

Licence fee income is derived from a fixed fee charged on the number of treatment cycles that are undertaken across the sector in the financial year. The surplus generated in 2016/17 is a result of an unanticipated increase in treatment cycles, it has proven difficult to predict with any certainty the levels of activity that will transpire in any given period. We have committed to undertake further work to develop our capability in this area and improve our ability to set fees at an appropriate level to cover our costs.

In addition, there are elements of our work that do not relate directly to the cost of regulating the sectors below. The DH accordingly contributes to the funding of these activities through the provision of grant-in-aid.

Losses and special payments

Losses and special payments are items that Parliament would not have contemplated when it agreed funds for health service or passed legislation. By their nature they are items that should not arise and are therefore subject to special controls. The HFEA had no losses or special payments in 2016/17.

Remote contingent liabilities

There are no remote contingent liabilities this year.

The certificate and report of the Controller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of Human Fertilisation and Embryology Authority (“the Authority”) for the year ended 31 March 2017 under the HFE Act 1990. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers’ Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration and Staff Report and the Parliamentary Accountability Disclosures that is described in that report as having been audited.

Respective responsibilities of the Authority, Accounting Officer and Auditor

As explained more fully in the Statement of the Accounting Officer’s Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the HFE Act 1990. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board’s Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Authority’s Circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by me in the course of performing the audit. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on regularity

In my opinion, in all material respects the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on financial statements

In my opinion:

- the financial statements give a true and fair view of the state of the Authority’s affairs as at 31 March 2017 and of its net expenditure, changes in taxpayers’ equity and cash flows for the year then ended; and

- the financial statements have been properly prepared in accordance with the Human Fertilisation & Embryology Act 1990 and Secretary of State directions issued thereunder.

Opinion on other matters

In my opinion:

- the parts of the Remuneration and Staff Report and the Parliamentary Accountability disclosures to be audited have been properly prepared in accordance with the Secretary of State directions made under the Human Fertilisation & Embryology Act 1990 ; and
- the information given in the Performance Report and Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Remuneration and Staff Report and the Parliamentary Accountability disclosures to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance

Report

I have no observations to make on these financial statements.

Amyas C E Morse
Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road, Victoria, London

5 July 2017

Financial statements

**Statement of comprehensive net expenditure for the year ended
31 March 2017**

| | NOTE | March 2016/17 £ | March 2015/16 £ |
|---|------|-----------------------|-----------------------|
| Income | | | |
| Income from activities | 4 | 5,322,910 | 4,215,582 |
| Other operating income | 4 | 25,967 | 522 |
| | | 5,348,877 | 4,216,104 |
| Expenditure | | | |
| Staff costs | 3 | 3,816,276 | 3,934,576 |
| Purchase of goods and services | 3 | 438,794 | 255,697 |
| Depreciation and impairment charges | 3 | 44,888 | 47,578 |
| Loss on disposal of assets | 3 | 780 | 864 |
| Other operating expenditure | 3 | 1,112,448 | 906,848 |
| | | 5,413,186 | 5,145,563 |
| Net operating expenditure | | (64,309) | (929,459) |
| Finance income | 4 | 3,695 | 54,965 |
| Finance expense | | 0 | 0 |
| Net expenditure for the year | | (60,614) | (874,494) |
| Taxation | | (710) | (10,989) |
| Net comprehensive (expenditure) for the year | | (61,324) | (885,483) |

The notes on pages 45 to 59 form part of these accounts.

Human Fertilisation & Embryology Authority
Annual Report and Accounts 2016/17

Statement of financial position as at
31 March 2017

| | | 31 March 2017 | 31 March 2016 |
|--|------|--------------------|---------------|
| | NOTE | £ | £ |
| Non-current assets: | | | |
| Property, information technology and office equipment | 5 | 68,946 | 85,029 |
| Intangible assets | 6 | 1,010,954 | 467,122 |
| Total non-current assets | | 1,079,900 | 552,151 |
| Current assets: | | | |
| Trade and other receivables | 8 | 1,175,968 | 757,006 |
| Cash and cash equivalents | 9 | 2,352,904 | 2,157,260 |
| Total current assets | | 3,528,872 | 2,914,266 |
| Total assets | | 4,608,772 | 3,466,417 |
| Current liabilities | | | |
| Trade and other payables | 10 | (573,507) | (422,614) |
| Provisions | 11 | (118,000) | (98,214) |
| Total current liabilities | | (691,507) | (520,828) |
| Non-current assets less net current liabilities | | 3,917,265 | 2,945,589 |
| FINANCED BY: | | | |
| Taxpayers' equity | | | |
| I&E reserve | | (3,917,265) | (2,945,589) |
| Total taxpayers' equity: | | (3,917,265) | (2,945,589) |

The notes on pages 45 to 59 form part of these accounts.

The financial statements on pages 41 to 44 were approved by the board on 13 June 2017 and signed on its behalf by:



Peter Thompson
Chief Executive

Date: 5 July 2017

**Statement of cash flows for the year ended
31 March 2017**

| | NOTE | 2016/17 £ | 2015/16 £ |
|---|------|--------------------------------|--------------------------------|
| Cash flows from operating activities | | | |
| Net operating surplus/(deficit) after interest | | (60,614) | (874,494) |
| Depreciation and amortisation | 3 | 44,888 | 47,578 |
| (Increase)/decrease in trade and other receivables | 8 | (418,962) | 190,587 |
| Increase/(decrease) in trade and other payables | 10 | 150,893 | 74,122 |
| Loss on disposals of non-current assets | 3 | 780 | 864 |
| Taxation | | (710) | (10,989) |
| Use of provisions | 11 | 19,786 | (8,495) |
| Net cash inflow/(outflow) from operating activities | | <u>(263,939)</u> | <u>(580,828)</u> |
| Cash flows from investing activities | | | |
| Purchase of property, plant and equipment | 5 | (13,865) | (62,035) |
| Purchase of intangible assets | 6 | (560,064) | (440,568) |
| Proceeds of disposal of property, plant and equipment | | 512 | 100 |
| Net cash inflow/(outflow) from investing activities | | <u>(573,417)</u> | <u>(502,503)</u> |
| Cash flows from financing activities | | | |
| Grants from sponsoring department | | 1,033,000 | 1,220,000 |
| Net cash inflow/(outflow) from financing activities | | <u>1,033,000</u> | <u>1,220,000</u> |
| Net financing | | <u>195,644</u> | <u>136,669</u> |
| Net increase/(decrease) in cash and cash equivalents in the period | 9 | 195,644 | 136,669 |
| Cash and cash equivalents at the beginning of the period | 9 | <u>2,157,260</u> | <u>2,020,591</u> |
| Cash and cash equivalents at the end of the period | | <u><u>2,352,904</u></u> | <u><u>2,157,260</u></u> |

As at 31 March 2017 there were no fixed asset accruals (2015/16 £Nil).

The notes on pages 45 to 59 form part of these accounts

**Statement of changes in taxpayers' equity
For the year ended 31 March 2017**

| | Total I&E reserve |
|---|----------------------------------|
| | £ |
| Balance at 1 April 2015 | 2,611,072 |
| Changes in taxpayers' equity for 2015/16 | |
| Grant from Department of Health | 1,220,000 |
| Comprehensive income/(expenditure) for the year | (885,483) |
| Balance at 31 March 2016 | <u>2,945,589</u> |
| Changes in taxpayers' equity for the year ended 31 March 2017 | |
| Grant from Department of Health | 1,033,000 |
| Comprehensive income/(expenditure) for the year | (61,324) |
| Balance at 31 March 2017 | <u><u>3,917,265</u></u> |

The notes on pages 45 to 59 form part of these accounts

Notes to the accounts

1. Statement of accounting policies

The HFEA accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 (as amended) and an Accounts Direction issued by the Secretary of State for Health in June 2007.

The accounts are prepared in accordance with the accounting and disclosure requirements given in HM Treasury's Financial Reporting Manual (FReM), insofar as these are appropriate to the HFEA and are in force for the financial year for which the statements are prepared. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context.

Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be the most appropriate to the particular circumstance of the HFEA for the purpose of giving a true and fair view has been selected.

The particular policies adopted by the HFEA are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.1 Accounting convention

These financial statements are prepared under the historical cost convention.

1.2 Non-current assets

Non-current assets include property, information technology, and office equipment together with intangible assets which relate to constructed software and software licenses. Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

All property, plant and equipment and intangible assets held by the HFEA at 31 March 2017 are carried in the statement of financial position at depreciated (property, plant and equipment) or amortised (intangible assets) historical cost. The depreciated or amortised historical cost is used as a proxy for fair value, for the classes of assets listed below, since the useful life over which the asset class is depreciated or amortised is considered to be a realistic reflection of the consumption of that asset class.

1.3 Critical accounting judgements and key sources of estimation uncertainty

In the application of the HFEA accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered relevant. Actual results may differ from those estimates. The estimates and underlying assumptions are reviewed annually. Revisions to accounting estimates are recognised in the period of the revision and future periods if the revision affects both current and future periods.

1.4 Depreciation and amortisation

Depreciation is provided on all non-current assets on a monthly basis from the date of acquisition at rates calculated to write off the cost of each asset evenly over its expected useful life.

Expected useful lives are as follows:

| | |
|----------------------------------|---------|
| Information technology | 4 years |
| Office equipment | 5 years |
| Furniture, fixtures and fittings | 5 years |

Amortisation is provided on intangible non-current assets (which comprise constructed software and software licences) on a monthly basis at a rate calculated to write off the cost of each intangible asset over its expected useful life. The expected useful life of this software is four years.

1.5 Grant-in-aid

Grant-in-aid received is used to finance activities and expenditure which supports the statutory and other objectives of the HFEA and is treated as financing and credited to the I&E reserve, because it is regarded as contributions from a controlling party.

1.6 Operating income

Licence fee income is recognised at the time of treatment date.

An estimate of the income for treatments provided by the clinics, but not reported to the HFEA, at 31 March 2017, is accrued. This is calculated by clinics in a report from the automated billing system (ABS) based on the typical delay between the clinic providing the treatment to the patient and reporting the treatment to the HFEA and the clinic's recently reported monthly treatment numbers.

Deferred income is recognised in respect of income for annual licence fees.

1.7 Operating leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

1.8 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS). The defined benefit elements of the scheme are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the scheme, the HFEA recognises the contributions payable for the year.

Further information in respect of Civil Service Pensions is provided in the remuneration report.

1.9 Cash

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours.

1.10 Financial instruments

Financial assets and financial liabilities arise from the Authority's normal operational activities and are recognised in accordance with standard accruals accounting principles.

The HFEA's financial assets comprise cash at bank and in hand, license fee debtors, balances with central Government bodies, and other debtors. The HFEA's financial liabilities comprise trade creditors and other creditors.

The fair values of financial assets and liabilities are deemed to be their book values, unless there is appropriate cause to apply an alternative basis of valuation.

The HFEA has not entered into any transactions involving derivatives.

1.11 Provisions

Provisions are recognised when the HFEA has a present legal or constructive obligation as a result of a past event, it is probable that the HFEA will be required to settle the obligation, and a reliable estimate can be made of the obligation. The amount recognised as a provision is the best estimate of expenditure required to settle the obligation at the end of the reporting period, taking into account the risks and uncertainties.

1.12. IFRSs, amendments and interpretations in issue but not yet effective

The Treasury FReM does not require the following standards and interpretations to be applied in 2016/17. The application of the standards as revised would not have a material impact on the accounts in 2016/17, were they applied in that year.

IFRS 9 Financial Instruments

IFRS 16 Leases

2. Operating segments

Under the definition of IFRS 8 the HFEA is a single operating segment as the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos, setting standards for, and the issue of licences to, centres together with the provision of information for the public and determining the policy framework for fertility issues.

**Human Fertilisation & Embryology Authority
Annual Report and Accounts 2016/17**

3a. Staff costs

| | Total | Permanently Employed | March 2016/17 Members | March 2016/17 Temporary staff | March 2015/16 Total |
|--|--------------------------------|---------------------------------|--------------------------------------|--|------------------------------------|
| | £ | £ | £ | £ | £ |
| Wages and salaries | 2,985,794 | 2,703,215 | 137,796 | 144,784 | 2,846,315 |
| Social security costs | 270,299 | 264,037 | 6,262 | 0 | 232,343 |
| Other pension costs | 560,182 | 560,182 | 0 | 0 | 492,068 |
| Staff costs | <u>3,816,276</u> | <u>3,527,434</u> | <u>144,058</u> | <u>144,784</u> | <u>3,570,725</u> |
| Less recoveries in respect of outward secondments | (25,957) | (25,957) | 0 | 0 | 0 |
| Total Net staff costs | <u><u>3,790,319</u></u> | <u><u>3,501,476</u></u> | <u><u>144,058</u></u> | <u><u>144,784</u></u> | <u><u>3,570,725</u></u> |

As set out in note 1.8, further information in respect of Civil Service Pensions is provided in the remuneration report on pages 34 to 36.

Average number of staff employed

The average numbers of persons employed during the period were as follows

| | Permanent staff | 2016/17 Seconded staff | 2016/17 Total | 2015/16 Total |
|--------------|----------------------------|---------------------------------------|--------------------------|--------------------------|
| SCS | 3.00 | 0.41 | 3.41 | 3.00 |
| Other | 60.57 | 0.00 | 60.57 | 62.18 |
| Total | <u>63.00</u> | <u>0.41</u> | <u>63.98</u> | <u>65.18</u> |

The average number of Wte staff directly employed for the period ended 31 March 2017 was 64 (2015/16, 65).

Temporary staff costs of £144,784 are included within salaries and wages. Below are the average number of temp staff utilised in the 2016/17 financial year

| | |
|-----------|-----------|
| <u>11</u> | <u>16</u> |
|-----------|-----------|

**Human Fertilisation & Embryology Authority
Annual Report and Accounts 2016/17**

| | Note | March 2016/17 £ | March 2015/16 £ |
|--|------|-------------------------|-------------------------|
| 3. Operating expenditure | | | |
| 3.1 Staff costs | | | |
| Salaries and wages | | 3,527,434 | 3,545,671 |
| Members' allowances | | 144,058 | 146,348 |
| Agency and other temporary costs | | 144,784 | 242,557 |
| | 3a) | <u>3,816,276</u> | <u>3,934,576</u> |
| 3.2 Purchase of goods and services | | | |
| Professional & administrative fees | (a) | 374,318 | 199,149 |
| Auditors' remuneration and expenses | (b) | 64,476 | 56,548 |
| | | <u>438,794</u> | <u>255,697</u> |
| 3.3 Depreciation and impairment charges | | | |
| Depreciation & amortisation | 5,6 | 44,888 | 47,578 |
| Loss on disposal of assets | | 780 | 864 |
| | | <u>45,668</u> | <u>48,442</u> |
| 3.4 Other operating expenses | | | |
| Rentals under operating leases | | 329,763 | 256,718 |
| Running costs | | 428,906 | 418,205 |
| Other staff costs | | 235,779 | 221,188 |
| Provision provided/(released) in year | 11 | 118,000 | 10,737 |
| | | <u>1,112,448</u> | <u>906,848</u> |
| Total | | <u>5,413,186</u> | <u>5,145,563</u> |

Notes

(a) Professional and administrative fees are legal costs incurred this year.

b) Audit expenditure is as follows:

| | 2016/17 £ | 2015/16 £ |
|----------------|---------------|---------------|
| External audit | 28,000 | 27,500 |
| Internal audit | 36,476 | 29,048 |
| | <u>64,476</u> | <u>56,548</u> |

External audit expenditure is the accrued fee for the NAO for 12 months. The internal audit costs relate to audits carried out in 2016-17 .

4. Income

Gross income is made up of licence fee and other incomes which are recorded on an accruals basis.

Analysis of income

| | 31 March 2017 | 31 March 2016 |
|----------------------------------|--------------------------|-------------------------|
| | £ | £ |
| Licence fee income | 5,322,910 | 4,215,582 |
| Other income-interest | 3,695 | 54,965 |
| Other operating income | 25,967 | 522 |
| Total income for the year | <u>5,352,572</u> | <u>4,271,069</u> |

Other operating income includes income from seconded staff to the HTA

5. Property, plant and equipment

| 2016/17 | Information technology £ | Office equipment £ | Furniture & fittings £ | Total £ |
|--|--------------------------------|--------------------------|------------------------------|----------------|
| Cost or valuation: | | | | |
| At 1 April 2016 | 405,786 | 20,746 | 21,029 | 447,561 |
| Additions purchased | 10,345 | 3,520 | 0 | 13,865 |
| Disposals | (216,318) | (6,796) | (21,029) | (244,143) |
| At 31 March 2017 | 199,813 | 17,470 | 0 | 217,283 |
| Depreciation | | | | |
| At 1 April 2016 | 326,122 | 16,180 | 20,230 | 362,532 |
| Charged during the year | 25,778 | 2,856 | 22 | 28,656 |
| Disposals | (215,801) | (6,798) | (20,252) | (242,851) |
| At 31 March 2017 | 136,099 | 12,238 | 0 | 148,337 |
| Net Book Value at 31 March 2017 | 63,714 | 5,232 | 0 | 68,946 |
| Net Book Value at 31 March 2016 | 79,664 | 4,566 | 799 | 85,029 |
| Asset financing: | | | | |
| Owned | 63,714 | 5,232 | 0 | 68,946 |
| Total at 31 March 2017 | 63,714 | 5,232 | 0 | 68,946 |
| 2015/16 | | | | |
| Cost or valuation: | | | | |
| At 1 April 2015 | 379,975 | 28,728 | 41,310 | 450,013 |
| Additions purchased | 62,035 | 0 | 0 | 62,035 |
| Disposals | (36,224) | (7,982) | (20,281) | (64,487) |
| At 31 March 2016 | 405,786 | 20,746 | 21,029 | 447,561 |
| Depreciation | | | | |
| At 1 April 2015 | 340,672 | 20,527 | 40,238 | 401,437 |
| Charged during the year | 20,912 | 3,434 | 273 | 24,619 |
| Disposals | (35,462) | (7,781) | (20,281) | (63,524) |
| At 31 March 2016 | 326,122 | 16,180 | 20,230 | 362,532 |
| Net Book Value at 31 March 2016 | 79,664 | 4,566 | 799 | 85,029 |
| Net Book Value at 31 March 2015 | 39,303 | 8,201 | 1,072 | 48,576 |
| Asset financing: | | | | |
| Owned | 79,664 | 4,566 | 799 | 85,029 |
| Total at 31 March 2016 | 79,664 | 4,566 | 799 | 85,029 |

6. Intangible assets

| | Software licenses | Constructed software | Asset under construction development expenditure | Total |
|--|-------------------|----------------------|--|------------------|
| | £ | £ | £ | £ |
| 2016/17 | | | | |
| Cost or valuation: | | | | |
| At 1 April 2016 | 265,533 | 498,706 | 440,568 | 1,204,807 |
| Additions purchased | 22,989 | 0 | 537,075 | 560,064 |
| Adjustments and transfer | 0 | 0 | 0 | 0 |
| Disposals | (27,309) | 0 | 0 | (27,309) |
| At 31 March 2017 | 261,213 | 498,706 | 977,643 | 1,737,562 |
| Depreciation | | | | |
| At 1 April 2016 | 238,979 | 498,706 | 0 | 737,685 |
| Charged during the year | 16,232 | 0 | 0 | 16,232 |
| Disposals | (27,309) | 0 | 0 | (27,309) |
| At 31 March 2017 | 227,902 | 498,706 | 0 | 726,608 |
| Net Book Value at 31 March 2017 | 33,311 | 0 | 977,643 | 1,010,954 |
| Net Book Value at 31 March 2016 | 26,554 | 0 | 440,568 | 467,122 |
| Asset financing: | | | | |
| Owned | 33,311 | 0 | 977,643 | 1,010,954 |
| Total at 31 March 2017 | 33,311 | 0 | 977,643 | 1,010,954 |
| 2015/16 | | | | |
| | Software Licenses | Constructed Software | Asset under Construction | Total |
| | £ | £ | £ | £ |
| Cost or valuation: | | | | |
| At 1 April 2015 | 308,240 | 498,706 | 0 | 806,946 |
| Additions purchased | 0 | 0 | 440,568 | 440,568 |
| Disposals | (42,707) | 0 | 0 | (42,707) |
| At 31 March 2016 | 265,533 | 498,706 | 440,568 | 1,204,807 |
| Depreciation | | | | |
| At 1 April 2015 | 260,298 | 497,135 | 0 | 757,433 |
| Charged during the year | 21,388 | 1,571 | 0 | 22,959 |
| Disposals | (42,707) | 0 | 0 | (42,708) |
| At 31 March 2016 | 238,979 | 498,706 | 0 | 737,685 |
| Net Book Value at 31 March 2016 | 26,554 | 0 | 440,568 | 467,122 |
| Net Book Value at 31 March 2015 | 47,942 | 1,571 | 0 | 49,513 |
| Asset financing: | | | | |
| Owned | 26,554 | 0 | 440,568 | 467,122 |
| Total at 31 March 2016 | 26,554 | 0 | 440,568 | 467,122 |

7. Financial instruments

IFRS 7 requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces when undertaking its activities. Financial instruments play a much more limited role in creating or changing risk than would be typical of the listed companies to which IFRS 7 mainly applies. The HFEA has no powers to borrow funds, and financial assets and liabilities are generated by day-to-day operational activities rather than being held to manage the risks facing the HFEA in undertaking its activities.

a) Liquidity risk

The majority of the HFEA's income comes from treatment fees. The fees are based on information provided directly from licenced clinics. This information is processed and returned to clinics in the form of invoices.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. The remaining main source of revenue is from Government grants made on a cash basis. Therefore, the HFEA is not exposed to significant liquidity risk.

b) Investments and interest rate risk

The HFEA follows an investment policy of placing any surplus funds on overnight deposit in an interest bearing bank account.

Gross interest income was 0.07% of the total revenues of the HFEA. Therefore, the HFEA has no significant exposure to interest rate risk.

c) Credit risk

The HFEA receives most of its income from the clinics it regulates. It operates a robust debt management policy and, where necessary, provides for the risk of particular debts not being discharged by the relevant party, therefore it is not exposed to significant credit risk.

d) Financial assets and liabilities

The only financial asset held at a variable rate was cash at bank of £2,352,904. As at 31 March 2017, none of the HFEA's financial liabilities were carried at a variable rate. The fair value of the financial assets and liabilities was equal to the book value.

e) Foreign currency risk

Consistent with previous accounting periods there were minimal foreign currency transactions conducted by the HFEA during the period ended 31 March 2017. There was therefore no significant foreign currency risk during the year.

8. Trade and other receivables

| | 31 March 2017 £ | 31 March 2016 £ |
|---|--------------------------------|-----------------------|
| Analysis by type | | |
| Trade receivables - licence fee debtors | 360,023 | 236,426 |
| Prepayments and accrued income | 729,294 | 504,417 |
| Other receivables | 86,651 | 16,163 |
| Total | <u>1,175,968</u> | <u>757,006</u> |

Prepayments and accrued income include calculations of the fees due to be invoiced to clinics after the date of the statement of financial position in respect of chargeable treatments undertaken before that date.

All debts were due for settlement within one year of the date of the statement of financial position. No provision for bad or doubtful debts has been made as all debts are anticipated to be recoverable.

9. Cash and cash equivalents

| | 31 March 2017 £ |
|---------------------------------|--------------------------------|
| Balance at 31 March 2015 | 2,020,591 |
| Net change in cash | 136,669 |
| Balance at 31 March 2016 | <u>2,157,260</u> |
| Net change in cash | 195,644 |
| Balance at 31 March 2017 | <u><u>2,352,904</u></u> |

£1,995,397 of the balance at 31 March 2017 was held with the Government Banking Services (£1,859,411 in 2015/16). The remaining balance was held at commercial banks.

No cash equivalents were held during the year.

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10. Trade payables and other current liabilities

| | 31 March 2017 £ | 31 March 2016 £ |
|------------------------------|-----------------------|-----------------------|
| Analysis by type | | |
| Trade payables | 260,941 | 9,708 |
| Accruals and deferred income | 305,198 | 404,770 |
| Other payables | 7,368 | 8,136 |
| Total | 573,507 | 422,614 |

All creditors were due for settlement within one year of the balance sheet date.

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11. Provisions

| | Legal costs | Early retirement and reorganisation costs | 2016/17 Totals | 2015/16 Totals |
|-------------------------------------|--------------|--|-------------------|-------------------|
| | £ | £ | £ | |
| Balance at 1 April 2016 | 1,500 | 96,714 | 98,214 | 106,709 |
| Provided in period | 0 | 118,000 | 118,000 | 10,737 |
| Utilised in the period | 0 | (96,714) | (96,714) | (19,232) |
| Release of provision for the period | (1,500) | 0 | (1,500) | 0 |
| Balance at 31 March 2017 | 0 | 118,000 | 118,000 | 98,214 |

| Analysis of expected timing of payment or release of provisions | Legal Costs | Early retirement and reorganisation costs | 2016/17 Totals | 2015/16 Totals |
|---|-------------|--|-------------------|-------------------|
| | £ | £ | £ | £ |
| No later than one year | 0 | 118,000 | 118,000 | 98,214 |
| Later than one year and not later than five years | 0 | 0 | 0 | 0 |
| Later than five years | 0 | 0 | 0 | 0 |
| | 0 | 118,000 | 118,000 | 98,214 |

As noted in the remuneration report for financial year 2008/09, early retirement costs were provided in that financial year and the provision reviewed annually. The early retirement costs have materialised and have been offset against the provision. The provision for this year reflects possible cost incurred during the restructure of parts of the organisation.

12. Capital commitments

There were no capital commitments as at 31 March 2017 (2015/16 £Nil).

13. Commitments under leases

Operating leases

The HFEA is committed to the following operating lease payments.

| | 31 March 2017 | 31 March 2016 |
|---|------------------|------------------|
| | £ | £ |
| Total future minimum lease payments payable: | | |
| Not later than one year | 330,000 | 359,665 |
| Later than one year not later than five years | 907,500 | 1,320,000 |
| | 1,237,500 | 1,679,665 |

The HFEA is a sub-tenant of the National Institute for Health and Care Excellence (NICE). Our lease runs to 31 December 2020.

14. Contingent liabilities

The HFEA regulates a sector that addresses some highly charged issues, of both a personal and clinical nature, which may generate close scrutiny. Some of the projects and work that the HFEA has undertaken, as well as certain decisions that the HFEA has made in 2016/17, may give rise to later challenge, including a risk of legal action.

At the date of finalising these accounts, there were two matters in litigation that may have financial consequences for the HFEA. For both, judgement is awaited and the liability will not be known until after then.

15. Related party transactions

a) The Department of Health is regarded as a related party. During the period the HFEA had various material transactions with the Department of Health and with some NHS trusts for which the Department of Health is regarded as the parent department.

During the period the HFEA received £1,033,000 (2015/16 £1,120,000) from the Department of Health in relation to operational grant-in-aid and £467,000 (2015/16 £100,000) cover for capital expenditure; our IfQ programme. This sum was funded from HFEA reserves. At the 31 March 2017 £Nil in grant-in-aid was due to the HFEA from the Department of Health and £Nil balances were due to the Department of Health from the HFEA.

The Department of Health invoiced the HFEA £30,686 in addition, we have accrued £7,805 in respect of internal audit work for the 2016/17 business year.

b) The National Institute for Health and Care Excellence (NICE) is regarded as a related party. During the period the HFEA had various material transactions with the NICE.

The NICE invoiced the HFEA £339,991 in relation to rent, rates and other facility costs. At 31 March 2017 we have accrued £6,425 representing service charges for the last quarter of 2016/17. £Nil was due to the HFEA from the NICE.

c) The Human Tissue Authority (HTA) is regarded as a related party. During the period the HFEA had transactions with the HTA to the value of £103,654.

16. Events after the reporting period

The Accounting Officer authorised these financial statements for issue on the date on which the accounts are certified by the Comptroller and Auditor General.

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