

# Minutes of Authority meeting 30 January 2019

**Strategic delivery:**

Safe, ethical  
effective  
treatment

Consistent  
outcomes and  
support

Improving standards  
through intelligence

**Details:**

Meeting Authority

Agenda item 2

Paper number HFEA (13/03/19) 907

Meeting date 13 March 2019

Author Helen Crutcher, Risk and Business Planning Manager

**Output:**

For information or  
decision? For decision

Recommendation Members are asked to confirm the minutes as a true and accurate record of the meeting.

Resource implications

Implementation date

Communication(s)

Organisational risk  Low  Medium  High

Annexes

## Minutes of the Authority meeting on 30 January 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

|                     |   |   |
|---------------------|---|---|
| Members present     | Sally Cheshire<br>Margaret Gilmore<br>Anthony Rutherford<br>Emma Cave<br>Anita Bharucha<br>Gudrun Moore | Kate Brian<br>Rachel Cutting<br>Ruth Wilde<br>Yacoub Khalaf<br>Anne Lampe         |
| Apologies           | Jonathan Herring<br>Bobbie Farsides   |   |
| Observers           | Dafni Moschidou (Department of Health and Social Care)  |   |
| Staff in attendance | Peter Thompson<br>Clare Ettinghausen<br>Nick Jones<br>Richard Sydee<br>Catherine Drennan                | Paula Robinson<br>Caylin Joski-Jethi<br>Joanne Triggs<br>Helen Crutcher (minutes) |
| Other attendees     |   |   |

### Members

There were 11 members at the meeting; six lay members and five professional members.

## 1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the first meeting of 2019. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2.** Apologies were received from Bobbie Farsides and Jonathan Herring.
- 1.3.** Declarations of interest were made by:
  - Anthony Rutherford (Clinician at a licensed centre)
  - Rachel Cutting (Clinician at a licensed centre)
  - Yacoub Khalaf (Clinician at a licensed centre)

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## 2. Minutes of Authority meeting held on 14 November 2018

- 2.1.** Members agreed the minutes of the meeting held on 14 November 2018 for signature by the Chair of the meeting.
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## 3. Chair's report

- 3.1.** On 22 November 2018 the Chair attended the second HFEA leadership event for PRs, held in Manchester. This event, along with one earlier that month in London, was a success and marked a step change in the way in which we engage with the senior leadership of the sector. Members heard that we would be looking to hold further events on leadership, including a workshop at our annual conference.
- 3.2.** On 28 November the Chair and Chief Executive attended the Huxley Summit, which brings together leaders from business, policy making and science.
- 3.3.** On 5 December the Chair spoke at the Progress Educational Trust conference on whether the HFE Act should be updated.
- 3.4.** On 7 December the Chair chaired a Remuneration Committee.
- 3.5.** On 10 December the Chair attended our all staff awayday.
- 3.6.** On 24 January 2019 the Chair and Chief Executive visited Scotland and met the Minister for Public Health in Scotland, Jim Fitzpatrick MSP. They also attended the National Fertility Group Meeting and met some of the PR's and other staff that work in Scottish clinics. In the evening, the Chair took part in a debate organised by the Progress Educational Trust to mark 40 years in IVF. The Chair acknowledged the positive work being done in Scotland to provide full IVF provision according to the NICE guidelines.
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## 4. Chief Executive's report

- 4.1.** The Chief Executive and Senior Management Team joined the Chair for the second HFEA event for PRs in Manchester on 22 November.
- 4.2.** On 28 November the Chief Executive attended the Huxley Summit.
- 4.3.** On 4 December the Chief Executive attended the HFEA Audit & Governance Committee meeting.
- 4.4.** On 5 December the Chief Executive attended the Progress Educational Trust event on whether the HFE Act should be updated.
- 4.5.** On 7 December the Chief Executive attended the HFEA Remuneration Committee meeting.
- 4.6.** The Chief Executive advised members that the staff awayday, held on 10 December, provided the opportunity to agree how best to improve communication between teams, manage workload pressures better and give more time for learning and development. The discussion felt very open, acknowledged the pressures staff were under, and produced a set of actions which he believed would make a difference.

- 4.7.** On 14 December the Chief Executive attended a meeting hosted by Sir Mark Sedwill, Cabinet Secretary and Head of the Civil Service. Following this, he participated in the annual general meeting of the Association of Chief Executives.
- 4.8.** On 3 January the Chief Executive attended the annual British Fertility Society conference in Birmingham. The Director of Compliance and Information and other staff represented the HFEA on other days.
- 4.9.** On 9 January the Chief Executive attended the first of a regular series of meetings on EU exit planning between Department of Health and Social Care (DHSC) arm's length body (ALB) Chief Executives and the Minister of State. An item on EU exit would follow later in the agenda.
- 4.10.** On 10 January the Chief Executive and Senior Management Team attended the DHSC and HFEA quarterly accountability meeting, which focussed on EU exit preparedness.
- 4.11.** On 23 January the Chief Executive attended the latest Health and Care Leaders Scheme senior talent board meeting.
- 4.12.** On 24 January, the Chief Executive accompanied the Chair to Scotland as above.

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## **5. Committee Chairs' reports**

### **Licence Committee**

- 5.1.** The Chair of the Licence Committee reported that the committee had met on 8 November 2018 and 10 January 2019.
- 5.2.** The Chair of the Licence Committee provided the members with an update on the 8 November 2018 meeting, the minutes for which had not been published at the time of the last Authority meeting. At this meeting the committee approved six research renewal applications. The committee considered one treatment and storage renewal, including a variation to change premises and refused this, with a proposal to revoke the licence. The committee also received one executive update with variations to change the Person Responsible and Licence Holder and it noted the update and approved the two variations.
- 5.3.** At its 10 January 2019 meeting the committee considered one revocation of licence, following the earlier proposal to revoke in November, and revoked the licence.
- 5.4.** The following items were also considered: one research renewal, one treatment and storage renewal, one serious untoward incident investigation report from an NHS Trust, following an earlier consideration of a grade A incident, and one executive update following an interim inspection. The minutes for these items were not yet signed, so the Chair of the committee could not provide details of the decisions made.

### **Statutory Approvals Committee**

- 5.5.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 October, 29 November and 13 December 2018.
- 5.6.** The Chair of the Statutory Approvals Committee updated members on the outcomes of the 25 October meeting, the minutes of which had not been signed off by the last

Authority meeting. The Committee considered three mitochondrial donation applications, one of which it adjourned and two it approved. It also considered five PGD applications all of which it approved, though one for a single type only.

- 5.7.** In November, the committee considered eight items: four PGD applications all of which it approved, though one for a single type only, and four special directions applications three of which it approved and one it refused.
- 5.8.** In December the committee considered six items: five PGD applications which were all approved and one HLA tissue typing application which was adjourned.
- 5.9.** The committee chair noted that the trend in special directions was unusual but the reason was not yet known. Busy was now the new normal. A new pool system for SAC members would help the committee to manage this workload.

### Executive Licensing Panel

- 5.10.** The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met four times since the last Authority meeting, on: 20 November, 12 December 2018, 2 January and 15 January 2019.
- 5.11.** The panel considered twelve items in total: two initial applications which were both approved, three renewals one of which was deferred and two approved, three interims all of which were approved, four variations which were all approved and it noted one executive update.
- 5.12.** The Chair of ELP reported that the Licensing Officer had considered 13 importing tissue establishment (ITE) certificate applications.

### Audit and Governance Committee

- 5.13.** The Deputy Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 4 December 2018.
- 5.14.** Aside from the usual standing items and updates from internal and external audit, the committee received reports on:
- An update on the Strategy and Corporate Affairs directorate
  - Digital Programme Update
  - Brexit
  - Estates Update
  - Reserves Policy
  - Review of AGC activities & effectiveness, terms of reference

### Remuneration Committee

- 5.15.** The Chair reported that the Remuneration Committee had met on 7 December 2018 to discuss senior managers' pay awards.

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## 6. Performance report

- 6.1.** The Director of Compliance and Information provided an update about the data submission system (PRISM) and data migration to support this. Members heard that a careful, risk-based approach was being taken. Regular updates had been provided to AGC to assure the Authority of effective governance and these would continue, until the programme was complete. The Director assured members that there was no risk in the continued use of the existing submission system, although it was sub-optimal. Clinics were being updated regularly.
- 6.2.** The Director of Compliance and Information advised members of progress with appointing a provider for the donor conceived voluntary contact register. Following an item to the Authority in November the executive and Chair had arrived at a model that would ensure provision of support and an effective, well managed service. Members had provided comments and agreed this approach. All organisations that had previously expressed an interest had been invited to respond to a tender, to demonstrate how they would work with the HFEA to provide the service.
- 6.3.** Having a new supplier in place by April was a priority. The possibility of bridging any end of contract gap would be explored with the current providers, the National Gamete Donation Trust. A paper would be provided to the Authority to assure members that the design of the service was effective in practice. Members confirmed their satisfaction with the progress that had been made.
- 6.4.** The Director of Strategy and Corporate Affairs provided an update on key activities. She noted that the new 9<sup>th</sup> edition of the Code of Practice had come into force on 2 January 2019 and thanked staff for their hard work on this. The treatment add-ons consensus statement had also been launched and received positive coverage in the press.
- 6.5.** The Director of Strategy and Corporate affairs noted some upcoming parliamentary activity relevant to the HFEA.
- 6.6.** The HFEA had worked with various professional bodies to produce commissioning guidance and this was now being tested with Clinical Commissioning Groups.
- 6.7.** A Women's Health Taskforce had been set up and the Director of Strategy and Corporate Affairs would be attending on behalf of the HFEA. This would be a good opportunity for the HFEA to engage with stakeholders on key issues, such as fertility education.
- 6.8.** The Chair noted that the coverage on add-ons was positive and this collaborative approach would be a tactic we would take on other issues.
- 6.9.** Members heard that work was ongoing on the next Fertility Trends report and key trends were being identified. Meanwhile, the impacts of the National Fertility Patient Survey results were being considered.
- 6.10.** The Director of Finance and Resources provided members with information on the financial forecast.
- 6.11.** The Director noted that DHSC had asked all ALBs about the extent to which non-essential expenditure could be deferred until the following financial year, so that funds

could be returned to the centre. We had proposed an amount and the department had taken us up on this. This sum was made up of additional income from IVF activity which was higher than forecast and a reserve for litigation which would not be spent this year.

- 6.12.** Members heard that this agreement not to spend would have no material impact on organisational plans before the end of the financial year.
- 6.13.** Work would be underway in the following weeks to look at the financial forecast for 2019/2020. The details of this review would follow to the Authority in March.
- 6.14.** The Chair thanked staff for their ongoing hard work across the organisation during a very busy time.

### Decision

- 6.15.** The members noted the latest performance report.

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## 7. Standing Orders

- 7.1.** The Head of Planning and Governance presented a report on three small proposed revisions to the HFEA's standing orders.
- 7.2.** The Head of Planning and Governance reminded members that revisions to standing orders require a notice of motion to be sent to members in advance and that in this instance this was circulated on 15 January 2019.
- 7.3.** Accepting revised standing orders also requires:
  - Two thirds of members to be present at the meeting.
  - At least half of members present to vote in favour.
- 7.4.** If approved, the changes would have effect from 31 January 2019.
- 7.5.** The Head of Planning and Governance provided members with details about each of the proposed revisions.

### SAC terms of reference

- 7.6.** In order to include new Authority members in decision making, and in recognition of the workload of the Committee, it was proposed that SAC would operate from a rotating pool of seven members. In accordance with current standing orders, the committee would continue to sit with a maximum of six members at each meeting.
- 7.7.** It was proposed that the authorisation of mitochondrial donation treatment would also be added to the list of decision types in the SAC terms of reference.

### SCAAC terms of reference

- 7.8.** The membership of SCAAC had been revised to reflect recent turnover in Authority membership (this requires no changes to standing orders). The members heard that the Chair took this opportunity to review the current expert adviser appointments on the committee, in light of upcoming areas of work.
- 7.9.** As a result, it was proposed that paragraph 6.4 be amended to increase the number of external expert advisers appointed to the committee from eight to eleven.

- 7.10.** This reflects an identified need for further expertise to complement the existing SCAAC membership, in developmental biology genetics and embryo research, clinical 'big data' and andrology.

#### **Register Research Panel terms of reference**

- 7.11.** The proposal for Register Research Panel (RRP) was to extend its role and function to include making decisions for access to 'safeguarded' data requests. This additional scope has been introduced through a Data Research Project which aims to provide more useful and timely data to researchers, where this can deliver public benefit.
- 7.12.** The membership of RRP also needed to be revised to reflect recent turnover in HFEA staff, and to recognise the new expertise we have in the organisation, following the organisational restructure (including the Head of Research and Intelligence and Research Managers).
- 7.13.** To ensure that appropriate independence is retained when making decisions, while recognising that the risk and impact of decisions taken at RRP can vary significantly, it was proposed to amend the membership considerations to include 'due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions.'
- 7.14.** It was also proposed to make explicit the requirement for the Chair of the panel to sign off all decisions and minutes.
- 7.15.** Members discussed the change to a pool system for SAC and the need for continuity of decision-making for all committees. For items returning to committees, minutes could be provided from the previous discussion and the same members selected to hear the item, to ensure consistency. A member noted that the wording of the changes to the SAC could be clearer and suggested it be reworded to 'The SAC shall operate from a pool of members, with no more than six members attending each meeting'.
- 7.16.** Members discussed the SCAAC changes and stressed the importance of identifying gaps in SCAAC expertise and ensuring that the committee had the required capabilities.
- 7.17.** The Chief Executive noted that the RRP changes were appropriate and consistent with the way this committee would operate in the future.

#### **Decision**

- 7.18.** Members unanimously voted to approve the revised Standing Orders, subject to the suggested wording change.

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## **8. EU exit preparations**

- 8.1.** The Chief Executive and Director of Compliance and Information presented a paper setting out the arrangements relating to the Authority's preparedness for EU Exit.
- 8.2.** The Director of Compliance and Information explained that the Department of Health and Social Care (DHSC) is leading and co-ordinating planning across the health and social care sector and all its 15 ALBs have been asked to play their part.



- 8.3.** Members heard how the UK's membership of the EU affects the provision of assisted reproduction and research involving human embryos in two principal ways: legally and operationally. The Director of Compliance and Information provided information about the HFEA's readiness in both respects.
- 8.4.** Regarding legal readiness, the Director of Compliance and Information highlighted the five pieces of EU law that are relevant to the responsibilities of the HFEA and explained that all five Directives were transposed into domestic UK law.
- 8.5.** Members heard that there was one outstanding legal issue, concerning the draft Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 which were laid in Parliament in November 2018.
- 8.6.** Regarding operational readiness across the fertility sector, members heard that the role of the HFEA differed from some other regulators since it was not a delivery body, but we had a role in ensuring the sector provided patients with continuity of care. Members heard that the HFEA had surveyed licensed clinics in May 2018, this feedback indicated that the sector was not facing serious problems in relation to staffing levels and any consequences to those levels resulting from EU exit.
- 8.7.** The Director of Compliance and Information provided information about communications that had been made to the sector directly from the HFEA and information passed on from DHSC. He also set out the ongoing communication and supporting role the HFEA would play. A clear position would need to be reached about how the Authority would respond if EU exit caused regulatory issues for clinics.
- 8.8.** Members heard how the actions that clinics will need to take to prepare for EU Exit will in part depend upon whether they are within the NHS or independent sector.
- 8.9.** Members also heard how the HFEA had been asked to implement 'no deal' plans of which this paper was a part. The Director of Compliance and Information had been appointed as SRO (senior responsible officer) and was participating in various regular official meetings. The main concern was to ensure that the HFEA maintained the delivery of its statutory duties and continuity of care for patients.

### Decision

- 8.10.** The members discussed the paper. Members who work in clinics described their own experiences and organisational readiness for EU exit. Members suggested that some parts of the sector (particularly those clinics not in an NHS Trust or a large independent healthcare group) may not have the same degree of knowledge and resources available to consider implications and prepare effectively. Members agreed that it was important for the Authority to enable clinics to share their experiences and plans with others in the sector.
- 8.11.** Members discussed the important role of the Authority in ensuring clinics could respond to any concerns from patients about how EU exit might affect their treatment.
- 8.12.** Members discussed the administrative consequences of EU exit for the Authority's inspection and licensing functions. The Head of Legal confirmed that the power of the SAC to agree Special Directions would not change and regulatory standards would be consistent at the point of EU exit. Inspectors would be contacting clinics. The extent of

the impact on clinics may vary depending on the type of EU exit and this was a challenge for preparations. The timeliness of advice was important and although this might change over time, the Authority would continue to provide guidance.

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## 9. Communications strategy

- 9.1.** The Head of Engagement presented a paper on the delivery of the 2017-2020 communications strategy, which runs alongside the main organisational strategy.
- 9.2.** Members heard that the key aims of the communications strategy were to:
- raise awareness of the HFEA
  - equip patients with reliable/impartial information
  - raise the quality of care
  - use the media to maintain our public reputation as a robust regulator
  - get better engagement with clinic staff
  - promote better engagement with HFEA staff.
- 9.3.** The Head of Engagement provided an overview of communications work that had been delivered with different HFEA audiences and stakeholders. Key successes included: the launch of the new HFEA website, increased social media presence, a redesign of the Clinic Focus newsletter for clinic staff and development of the knowledge base section of the clinic portal.
- 9.4.** Members heard that future work could include:
- Ongoing development of the campaigning and social and digital media work
  - The consideration of a new, more proactive approach to media management
  - Bolder approaches on key issues. Ongoing work on treatment add-ons.
  - More work with key partners to identify spokespeople in the sector.
  - More work on how to communicate with clinic staff
- 9.5.** Members were asked for their thoughts on how HFEA moved forward on key areas during the final year of the communications strategy, including the approach to:
- Social/digital media
  - Print/broadcast media
  - Clinic communications
- 9.6.** The Director of Strategy and Corporate Affairs noted that the capacity of the organisation both in terms of staffing and resource was limited. However, the opportunity to take advantage of collective activity and low-cost initiatives was great and this was an underused and cost-effective area for HFEA to consider further work in.
- 9.7.** Members discussed the paper and identified some key areas for future focus, providing the following comments:

### Print and broadcast media

- 9.8.** Members discussed how taking full advantage of communications capabilities would enable us to benefit more from partnerships and connections. Members stressed that taking a proactive approach was important for addressing issues raised in the press and by clinics, we should take advantage of connections in the sector and continue the good work to raise the profile of the organisation on key issues. They highlighted a need to do more to identify 'go-to' spokespeople, to make sure that our voice was heard in the media.

### Social/digital media

- 9.9.** Members made comments on the channels and approaches available to the organisation, particularly for approaching patients. It was not clear exactly which channels patients used to access information about the HFEA and fertility treatment and it was important to establish this first to ensure that the use of resources was worthwhile and effective.
- 9.10.** Members discussed the need to be involved in communication before patients reached a clinic. GPs provided this initial information to many patients and we should consider how we could begin to engage with them. Members also discussed the importance of fertility education and heard that efforts were being made by other bodies such as the British Fertility Society in this area. A member noted that male fertility should be part of our communication with patients.

### Clinic communications

- 9.11.** On communications with clinics, members noted that the removal of the clinic element on the HFEA website meant that it was now hard to find key information for clinicians and professionals and that it could be made quicker for clinics to find information on the Clinic Portal. This was also an area of the website that other professionals such as journalists and researchers used to use, and they may not be able to find the right information now through the HFEA. Members asked the executive to reconsider the way this information was provided on the website.

### Decision

- 9.12.** Members complimented staff on the progress made, particularly towards working with professional organisations and other partners. They were conscious of the importance of providing information in the right way without simply telling patients what to do. Members noted that communications should be derived from the strategy and aligned with the key organisational objectives. This included the approach to building relationships with political and other stakeholders and developing a wider public affairs strategy.
- 9.13.** The executive agreed to reflect on the points raised and consider implementation methods. Merely providing information would not guarantee the desired behavioural changes. The public affairs element would be key in this and offered a significant opportunity to achieve bigger effects.
- 9.14.** The Chair noted that this was a strong base to build on and getting communications right would set the organisation up well for delivering the final year of this strategy and the next one.

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## 10. The register research panel (RRP) and data research

- 10.1.** The Head of Research and Intelligence presented a paper on the Register Research Panel (RRP) and data research, which had three main aims:
- To provide an overview of the work conducted in 2018 which falls under the RRP's delegated functions.
  - To provide an update on the steps we have taken so far towards improving data research.
  - To provide a summary of the data access process in the future.
- 10.2.** The Head of Research and Intelligence provided members with some background information, including how in its 2017-2020 strategy the HFEA committed to 'improve the quality of treatment, by encouraging world class research and clinical trials'. Data research was key to understanding and improving the safety and efficacy of fertility treatment.
- 10.3.** Members also heard that the HFEA held the largest register of fertility treatment data in the world, with experience of world class research being carried out using our data, either alone or, since 2010, by linking to other datasets.
- 10.4.** The Head of Research and Intelligence explained that since October 2009, patients who registered for fertility treatment were asked to consent to their information being included in studies where patient 'identifiers' were needed. However, the overall consent rate for some years (2009-2012) was quite low at around 50%. By working with clinics, the HFEA had improved the status of data research and members heard how consent rates were now around 70%.
- 10.5.** The Head of Research and Intelligence highlighted the benefits of large-scale linkage studies which use identifiable data. She provided an overview of the new data access process, to make it easier for high quality research which will benefit the public to take place.
- 10.6.** The remit of the RRP, under the 2010 regulations, is to consider and, where appropriate, authorise access for research studies which require identifiable data. Such identifiable data can only be released through an RRP determination (with due regard to the regulations) and for patients who have consented to the use of their data being used.
- 10.7.** The Authority, in its role as the 'Oversight Committee', considers an annual report submitted by the RRP.
- 10.8.** The Authority was asked to note the activity conducted by the RRP, the steps taken to improve data research and the process in place for accessing data.

### Decision

- 10.9.** Members discussed the paper and stressed the importance of the renewed energy and focus on data research. Members highlighted possible links the Authority could make with other organisations in the field of data research, to increase stakeholder engagement in this area. Further information would be provided to the Authority in future.

**10.10.** Members noted the progress made in the last year and the plans to improve things further in future.

**10.11.** The Chair noted this was the last meeting of the Head of Research and Intelligence and thanked her and the whole Intelligence team for the progress they had made.

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## 11. Estates update

**11.1.** The Director of Finance and Resources presented a paper setting out the circumstances around the relocation of the HFEA away from Spring Gardens in 2020. The move was being managed as part of a wider DHSC programme to coordinate the movement of several of its ALBs to outer London hubs.

**11.2.** The Director of Finance and Resources provided an update to members on the DHSC programme and the recommendation that Stratford was the preferred future location.

**11.3.** Members noted the proposed governance timeline, although they also noted that a meeting that day had suggested this could be delayed from the original DHSC plans. The most recent steering committee meeting had also agreed that the Stratford project would now be managed as a two-stage approach, which may mitigate some possible delays for the HFEA. However, the required sign-off process may mean further delays.

**11.4.** Members heard that the formal business case decision would be brought to a later Authority meeting.

### Decision

**11.5.** The members noted the above points, and positively acknowledged the progress that had been made to date.

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## 12. Any other business

**12.1.** The Chair noted that this was Director of Compliance and Information, Nick Jones' last Authority meeting before he departed to become CEO of the General Chiropractic Council. The Chair thanked Nick on behalf of the Authority and the Chief Executive also expressed his thanks on behalf of staff.

**12.2.** Members added their thanks on behalf of the sector, particularly noting his positive outlook and problem-solving abilities, which had been appreciated greatly.

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## 13. Chair's signature

I confirm this is a true and accurate record of the meeting.

### Signature



**Chair:** Sally Cheshire

**Date:** 13 March 2019