

Human Tissue Authority Board Meeting

Date: 21 September 2023

Paper reference: HTA 20/23

Agenda item: 5.

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Chief Executive's Report

Purpose of paper

1. To inform the HTA Board of key or current issues from the CEO's perspective.

Action required

2. The HTA Board is asked to note and comment on the issues raised.

Update on Quarter 1

3. During Quarter 1, we continued to progress our regulatory and related activities against the Key Performance Indicators, sought to progress the 2023/24 business plan, and responded to matters arising.
4. The HTA continued to give full support to the Secretary of State's Independent Inquiry led by Sir Jonathan Michael into the issues raised by David Fuller's offending. The Inquiry has now commenced Phase 2 (the wider, more strategic picture) whilst it works to conclude Phase 1 (the background to the offending). Since the Inquiry commenced, we have assigned a high priority to providing thorough and timely support to requests from the Inquiry Team, to ensure they are able to progress their areas of investigation as promptly as possible. In addition to providing responses to information requested by the Inquiry and to the DHSC SoS, the HTA has been developing a response for relevant areas of the Phase 2 coverage.

5. On the Living Organ Donation front, we continue to see increased activity for HTA during 2023/24 compared to previous years with more police referral considerations, primarily but not exclusively, arising from the introduction of section 32A Human Tissue Act. We are in discussion with the DHSC Sponsor Team both in relation to dealing with immediate pressures and more strategic issues to refine the approach adopted to assess applications for living organs donations and for supporting the police when breaches of Section 32 do occur. With regard to the latter, I had an interesting discussion with one of our more experienced Independent Assessors (IAs) to more fully understand the different issues faced by IAs in their important and impartial role. Our discussion highlighted the vital role played by the IA in bringing together donor and recipient to review consent, and the areas of training provided to new IAs.
6. At the last Board meeting, we anticipated an improved outcome for the 2022/23 annual assessment against the Data Protection and Security Toolkit (DSPT). During 2022/23, considerable time has been spent on producing evidence of greater compliance and we have engaged the services of an Information Governance Lead and a Project Manager. This work has been monitored at ARAC meetings and early indications were that HTA has made good progress with a notable improvement compared to last year. The final outturn reported at the end of Q1 was that the HTA had achieved an overall risk assessment of 'moderate'. This is a great achievement, for a small organisation and a significant improvement with a "high" assurance level based on the confidence level of the independent audit in the veracity of the HTA's self-assessment. The auditors advised that due to the complex scoring mechanism the 'substantial' rating is almost impossible for any organisation to achieve unless there is significant and ongoing investment in this area, which would be unaffordable for HTA.
7. I have previously drawn attention to the levels of staff turnover during 2022/23, and these have reduced in 2023/24. Q1 turnover rate for 2023 is 5.36%. This is in comparison to Q1 last year when the rate was 6.3% and then increased further in Q2. There has been a reduction in staff turnover during Q2. We have continued to be assisted by the Health & Social Care Leadership Centre for organisational development activity. They have provided inputs to All Staff Days in April and June, with another planned for the end of September. In May, the HSC Leadership Centre also ran a development / team building day for SMT.
8. In Quarter 1, my external engagements included continuing participation in the National Health CEOs Forum bimonthly, ALB joint Chairs/CEOs meetings convened by the DHSC Permanent Secretary, and meetings arranged by the Association of CEOs. I represented the HTA at an event in Belfast to mark the launch of Deemed Consent in NI on 1st June. I was also interviewed by the team who are currently finalising the Public Body Review (PBR) for the Human Fertilisation and Embryology Authority (HFEA). This was a helpful opportunity to

highlight how we work successfully in collaboration with HFEA and have done so for many years, as well as, providing useful insights into the areas of interest to the PBR team, mindful we are still to go through the process.

Current Issues

9. During July, Gareth Davies, the Comptroller and Auditor General (C&AG) at the National Audit Office (NAO) certified the HTA accounts for 2022/23 and they were laid before Parliament before recess. This is a significant piece of work, not least for a small organisation with a shared finance team. I am very grateful to the Head of Finance who provided great support to me as Accounting Officer. The draft Annual Report and Accounts (ARA) were discussed by the Audit and Risk Committee (ARAC) at the 8 June meeting.
10. As noted in more detail in the Performance Report, this year's financial forecast is already looking very different to last year with additional and unexpected cost pressures, such as the cost-of-living payment for staff (almost totalling £80,000) and a much-improved workforce position, with reduced vacancies but also savings on salaries. We have also noticed a small reduction in income due to several licence revocations. Taken together, we do not have in-year the same level of liquidity to fund development projects as previously and based on current projects and work that we have sought to progress at risk, we are currently forecasting an overspend. Of course, the rules under which the HTA operates do not permit an overspend and we are assessing areas of the Business Plan which may need to be delayed to next year to accommodate in-year savings. This position is being kept under review and will be something I, as Accounting Officer, will be monitoring very closely. We are working closely with Departmental colleagues on this.
11. HR Shared Services - These continue to roll out with CQC HR colleagues now undertaking all new recruitment of staff selected after 1st July 2023. In Q2, they are also providing senior Business Partnering input and generic Case Management advice. When we have the data protection impact assessment completed and data shared with CQC colleagues, by Q3, we should be in receipt of specific Case Management support, People Statistics analytics and Onboarding assistance. The last phase will see support on Learning and Development and Organisational Development coming onstream. The transition has proved more challenging than was hoped due to a number of key HR staff being unavailable at a critical time. The associated risks are being discussed at both the Board's HR forum (RemCo) and at ARAC and we will keep the full Board informed of progress. Whilst slightly behind schedule, the position is improving and, in line with the original schedule, we should be able to complete the transition during 2023/24.

Senior members of the CQC team assigned to HTA have been very supportive and are due to attend our next All Staff Day (28 September) to provide feedback and

hold a Q&A session for HTA staff as part of the change management exercise. Under these new arrangements, we will see an enhanced HR service and at a shared/reduced cost.

12. This work is consistent with the DHSC Reform and Efficiency initiative. In addition to reforming how we deliver support services at reduced cost and with greater resilience, Board members will be aware that we have embarked on a programme of innovation and reform in how we undertake our front-line regulatory responsibilities. Building on delivering 210 inspections last year, this year's ambition is 222 and we aim to further innovate as we progress. The next steps being considered by the Executive are brought for consideration of the Board in a paper on today's agenda.
13. In parallel, and also linked to our contribution to the Department's Reform and Efficiency initiative, from next year, there will be a reduced level of Grant-in-Aid support from DHSC to be replaced with increased income generation from HTA's licence-holders. HTA will need to generate an additional £0.25m in 2024/25, and a further £0.25m in 2025/26, by increasing fees charged to licensed establishments.
14. In Q1, the HTA commenced the publication of open data sets related to regulatory activity. These published data sets supplement information already published under the HTA's publication scheme. Since June, we have published 10 data sets, details of which are set out below:
 - Inspections (April 2017 – March 2022)
 - Inspections (April 2022- March 2023)
 - General enquiries (April 2017 – March 2022)
 - General enquiries (April 2022 – March 2023)
 - Shortfalls (April 2017 – April 2021)
 - Shortfalls (April 2022 – March 2023)
 - Licences granted (As of 1 August 2023)
 - Licences ceased (As of 1 August 2023)
 - Licence Variations, Licence Applications, and Licence Revocation Requests (April 2017 – March 2022)
 - Licence Variations, Licence Applications, and Licence Revocation Requests (April 2022 – March 2023)
15. During June, we also launched a data collection exercise to update the data we hold for establishments. The exercise has been primarily focused on gathering data to inform risk profiling across licensed sectors and support development of data-informed, risk-based approach to regulation, through sector specific questionnaires. The data collected will provide a snapshot of sector establishments to support profile building of individual establishments and across sectors.

Establishments were asked to use the HTA's online portal to upload their data and to-date around 95% of responses have been received. Formal data analysis and reporting will commence later, with feedback to licensed establishments highlighting key themes planned.

16. At Autumn Statement 2022, the Chancellor announced a Pro-innovation Regulation of Technologies Review to advise how the UK can better regulate emerging technologies. This review (led by Dame Angela McLean) was published in late May and includes a series of recommendations on how regulation can support key areas of growth. Several of the recommendations are relevant to the HTA either through direct or contributory action. The HTA has a history of encouraging and participating in collaboration with other ALBs and is keen to continue that approach in this case. In July, the HTA participated in a cross regulatory session led by the Chair and Chief Executive of the MHRA that suggested a number of possible actions. At the time of writing this report, the HTA has been actively engaging with MHRA on progressing a number of these during the Autumn. Full details of the McLean review can be found here [Pro-innovation Regulation of Technologies Review - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/pro-innovation-regulation-of-technologies-review).
17. The HTA continues to seek to support innovation. A good example is the first UK uterine transplant, publicised in August. We worked with the establishment to ensure appropriate licensing arrangements were in place for the transplant and liaised with the surgeons involved. Professor Richard Smith presented his research and intention to undertake the first uterine transplant in the UK to the HTA Transplantation Advisory Group in October 2018. We provided feedback on the patient information developed and liaised with the IA in advance of the interviews with donor and recipient. The case was referred to and approved by a panel of Board Members in line with our policy which requires novel donations to be assessed by a panel.
18. In August, we welcomed Tom Skrinar to the HTA as our new Director of Finance and Resources. He was previously at DHSC and brings his professional finance expertise along with much relevant civil service and NHS knowledge and experience to his new role.

Recommendation

19. The HTA Board is asked to note and comment on the issues raised.