

# Human Tissue Authority Board Meeting

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**Date:** 9 March 2023

**Time:** 10.00 – 12.00 Main meeting  
12.00 – 12.30 Board and Chief Executive only session  
12.30 – 13.15 Lunch  
13.15 – 15.00 Afternoon Board Session

**Venue:** 2 Redman Place, London, E20 1JQ – Thames Meeting Room

**Meeting Number:** 103

**Protective Marking:** OFFICIAL

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## Agenda

### Meeting Administration

1. Welcome and apologies (Oral) (LB)
2. Declarations of interest (Oral) (LB)

### Regular Reporting

3. Chairs Report (Oral) (LB)
4. Chief Executive's Report (HTA 01/23) (CS)
5. HTA Performance Report (HTA 02/23) (CS)
6. Update from DHSC Sponsor Team (Oral)

## **Items for discussion**

7. HTA's differentiated, risk-based approach to developing the inspection programme 2023/24 (HTA 03/23) (ANH)
8. Review of HTA Risk Tolerance (HTA 04/23) (RS)
9. Business Plan 2023/24 (Confidential item not included in this pack)

## **Reports from Committees**

10. Audit and Risk Assurance Committee Update (HTA 06/23) (GC)  
ARAC Terms of Reference (HTA 06a/23) (RS)
11. Remuneration Committee Update (HTA 07/23) (ED)

## **Items for information only**

12. Shared Services Update (HTA 08/23) (RS and LD)
13. Minutes of 3 November 2022 (HTA 9/23) (LB)
14. Matters arising from 3 November 2022 (HTA 10/23) (LB)

## **Any Other Business**

15. Any other business (Oral) (LB)

This version 27 February 2023

# Human Tissue Authority Board Meeting

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**Date:** 9 March 2023

**Paper reference:** HTA 01/23

**Agenda item:** 4

**Author:** Dr Colin Sullivan

**Protective marking:** OFFICIAL

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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 Q3

3. During Q3, we have continued to progress our regulatory and related activities against the Key Performance Indicators, sought to progress the 22/23 business plan, and responded to matters arising.
4. The HTA has continued to give full support to the Independent Inquiry into the issues raised by the David Fuller case, and this has included the provision of documents both proactively and on request. During Q3, we published revised guidance for establishments to help them meet the Standards in the Code of Practice for the Post-mortem sector and followed this up at the end of January by publishing revised guidance on meeting Standards in the Code of Practice for the Anatomy sector. The HTA Chair gave evidence to the inquiry during November. This followed the appearance of four current members of staff along with several previous employees at the inquiry in October. We continue to provide advice to the DHSC SoS on related matters.
5. One key issue facing the HTA in 22/23 has been the level of staff turnover and the number of vacancies impacting delivery of specific areas of HTA business.

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As with many other public sector organisations, we saw increased turnover in 2022. As of February 2023, the 12-month turnover figure was 28%, for a small organisation this was an area of concern. This number has significantly reduced to 3.7% in Q3 and currently tracking 1.8% for Q4. However, the number of vacancies arising in Q2 generated a significant volume of recruitment activity for HR colleagues and line managers, who have succeeded in reducing the impact of the previously high turnover. Finding the right talent at the right price point is an ongoing issue. At the end of February, the team had reduced that number to only a handful of vacant posts, primarily in technical roles with IT remaining a concern.

6. Proactively, in Q3 we reviewed and revised our planning for responding to a Critical Incident. We then tested the revised approach in a dedicated mock exercise in January which proved to be a very helpful action learning activity and enabled us to further refine the HTA's Critical Incident Response Plan. Thinking more widely, further work is ongoing to review and refine our Business Continuity Plan and we intend to carry out a test of this element of preparedness in Q1 of 23/24.
7. During Q3, my engagement with stakeholders included an instructive visit to see the different uses of human tissue at the University of Birmingham, accompanying an HTA inspection team to a Post-Mortem Inspection at Royal Oldham Hospital and attending a NHSBT Stakeholder meeting in December. I also met with the CEO of the Health Research Authority.

## Current Issues

8. The Board will recall the HTA has been supporting work to introduce Deemed Consent in Northern Ireland. The NI Assembly passed the Organ & Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 in February 2022 and it received Royal Assent on 30 March 2022. Since then, the NI Dept of Health have been working with partners to prepare for the introduction of deemed consent. The Human Tissue Authority's Code of Practice has been revised and the NI Public Health Agency has begun to roll out the first phases of a comprehensive public awareness and education campaign. In the absence of the NI Assembly, the legislation required to clarify which organs and tissues are covered by the provisions of the new law was approved by the UK Parliament on 22 February, with commencement projected for summer 2023.
9. The Board will be aware of the winter pressures in the NHS. Of course, we are not directly involved in operational delivery but one area arising of note to

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HTA is the increased pressure on mortuary capacity. We have monitored the weekly NHS mortuary capacity reports in England compiled for DHSC and a similar monitoring exercise undertaken by Welsh Government. During January and February, there has been a picture of increased utilisation in many mortuaries with a lengthened stay of the deceased. As an engaged regulator, we have worked closely with relevant establishments, being responsive to urgent requests for emergency license changes and extensions. We have also engaged with DHSC and devolved administration colleagues in Wales and NI. HTA put in place a process during Covid when there were similar issues and that has been revised for the current pressures. We issued a regulatory update in relation to mortuary capacity pressures on 10<sup>th</sup> January 2023.

10. In Q3, DHSC Commercial introduced more stringent controls on expenditure for Consultancy, Professional Services and Contingent Labour. These are designed to ensure best use of public money by avoiding unnecessary expenditure on expensive solutions. Within this new framework, we have received Ministerial approval for increased expenditure to assist with our respond to the Fuller Inquiry and provide the Secretary of State with related advice. We also received approval to conduct the proposed Review of Inspections, which is within our Business Plan for 22/23, to help us further modernise our approach to regulation by being more proportionate and risk based. The paper on today's agenda entitled "HTA's differentiated, risk-based approach to developing the Inspection Programme for 2023/24" is based on the recent HTA Sectors Risk Assessment presented to ARAC and is a step on that journey.
11. In line with our communication and stakeholder engagement strategy which the Board agreed in May 2022, we have revised the forum for sector engagement. We have a separate forum for each of the six sectors that we regulate. We have also commenced wider one-off roundtable discussions, each with a separate invitation list depending on the topic to be considered. We continue to grow and develop our engagement in social media and with the media. We have developed a narrative to support the HTA to tell a common story with stakeholders and internally. This living document aligns with our values and will flex and change as we progress with our Business Strategy.
12. In February, I accompanied the Chair to the joint ACE/PCF Conference at the Institute of Government. I also attended the Institute of Regulation's Annual

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Conference. In addition, I met the CEO of the NI Regulation & Quality Improvement Authority to discuss areas of mutual interest.

13. Internally, during Q3 and Q4, the Portfolio Management approach which commenced in Q2 has become more strongly embedded. In addition to normal multi-item weekly Senior Management Team (SMT) meetings, we are also convening Portfolio SMT discussions once a month which helps to focus the drive on higher performance. In parallel, this same team has also been progressing business planning for next year, 23/24, and there has been rich engagement with colleagues, early in the year. We have also reformed our informal Heads of Function meeting into a more focused Business Delivery Team that meets fortnightly to take practical ownership of our performance.
14. Staff remain positive and committed to our work. Following progress in developing our vision and mission, we have reviewed and made some refinements to the values that we work to within the HTA. The exercise to review these has been organisation-wide with everyone having the opportunity to contribute. The refined values that the organisation has developed are:

**Collaboration**

**Openness**

**Respect**

**Excellence**

15. These CORE values resonated with the organisation and can helpfully shape the work of colleagues and their interaction with each other and with stakeholders. There is further work to be done to integrate these values into the internal and external comms strategy and branding. Our work on values feeds into a revised behavioral framework and People Strategy which we wish to pursue, subject to available resources, in 23/24.
16. I should also highlight to Board members that the 2024 Board meeting schedule has been agreed by our Chair to be:
- 7 March 2024
  - 27 June 2024 (Public Meeting)
  - 19 September 2024
  - 5 December 2024

## **Recommendation**

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

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# Human Tissue Authority

## Board Meeting

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<b>Date:</b>	9 March 2023
<b>Paper reference:</b>	HTA 02/23
<b>Agenda item:</b>	5
<b>Author:</b>	CEO and Senior Management Team
<b>Protective marking:</b>	OFFICIAL

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## HTA Performance Report

### Purpose of paper

1. To inform the Board of the HTA's performance in Quarter 3 (Q3) against our objectives and operational delivery targets.

### Action required

2. The HTA Board is asked to note and comment on the performance recorded and the context provided.

### Operational delivery of Regulation

3. **Annex A** provides a summary of the Key Performance Indicators (KPIs) and two Performance Indicators (PIs) presented to the Board each quarter. Most relate to the Regulation Directorate, but Enquiries and Freedom of Information Act requests can arise in any area of the business.
4. Despite a number of external factors (such as rail and health service strikes) and internal factors (such as staff turnover and other matters impacting staff availability) leading to some re-scheduling and deferral of inspections, we remain on track at the end of Q3 against the significantly increased inspection target for this year.
5. Other performance indicators show a mixed picture over Q3 and in terms of trends over the first three quarters of 22/23. We continue to actively monitor

amber and red KPIs to identify and address underlying issues. Staff turnover and several exceptional regulatory issues have had an impact on workload and our ability to meet our operational targets.

6. Publication of at least 90% of inspection reports within 10 weeks of substantive completion of the inspection or audit is a measure we have failed to meet in all three quarters so far. There were near misses in Quarter 1 and Quarter 2 followed by a further reduction in performance in Quarter 3, with the year-to-date figure at 87% overall. This will be hard to reverse. Whilst some of the delayed publications relate to exceptional and complex inspection reports, there is also an element of this reflecting significant underlying workload issues and pressures which we continue to monitor and are trying to address. Our proposals outlined separately for the approach to inspections in 2023/24 should help reduce some of the overhead from the increased inspection numbers we are now undertaking and help improve many of these indicators.
7. The licence variation request KPI (at least 90% of outcomes to be communicated within 20 days) and the KPI for processing at least 90% of completed licence applications within 90 working days of payment, have both been missed for most of this year – this continued in Quarter 3. However, we have identified some significant issues with the quality of the data used to measure these KPIs. This has included issues with alerting the licensing team to new licence payments and cases being marked as “complete” which are not complete, and which require further information from the establishment. When incomplete cases are excluded from the count, Quarter 3 performance for completed applications is green. This highlights issues we are addressing in terms of our processes and data quality.
8. Whilst the KPI for turning round 100% of panel cases within 10 working days (and in line with other quality criteria) has been fully met for most of the year, the two cases that were not met in quarter 2 mean that the overall year-to-date average is 99% and hence shown as amber.
9. For the two performance indicators that are included in the Board Performance Report, Quarter 3 has shown another dip in performance in the measure relating to the timeliness of implementing CAPAs for major shortfalls. This is a complex measure where performance can relate to both the HTA’s timeliness in pursuing action on these CAPAs and establishments’ timeliness in implementing corrective action. The dip in performance in Quarter 3 is partly attributable to workload pressures in the HTA but also pressures in our establishments, particularly those in the NHS. Again, this is something we are

continuing to monitor and ensure that there is suitable escalation of any issues where there is undue delay.

10. Following on from the publication of updated guidance to the Post Mortem sector standards in September 2022, the HTA has undertaken a review of its guidance in relation to the Anatomy sector licensing standards. This entailed an internal review followed by external engagement and feedback to stakeholders. The updated guidance was subsequently published on the HTA's website in Quarter 4 (on 31 January 2023).
11. The Head of Regulation for ODT continued to liaise with law enforcement colleagues about the possibility of individuals being trafficked into the UK for the purpose of unlawful transplantation, in breach of Section 32. Four training sessions were co-delivered to NHS staff on the requirements of the HT Act.
12. Several complex Living Organ Donation cases were assessed during Quarter 3, some of which were referred to a panel of Board Members and others which utilised the HTA's Regulatory Decision Making process. Decisions were made in all cases, although due to complexity some of these decisions took place in Quarter 4.
13. The Head of Regulation for ODT and a Policy Manager attended a meeting led by NHSBT, to discuss Xenotransplantation. Discussion focused on the current understanding of xenotransplantation, the direction of travel in the UK, the various frameworks involved and who should be involved in the future.
14. Within the Post Mortem Sector, an increase in enquiries relating to capacity concerns was noted over the Christmas holiday period. This resulted in one emergency licence being issued and one urgent Regulatory Decision-Making Meeting being held to address inappropriate storage concerns.

## Finance

**Table 1: Summary income and Expenditure**

	Year-to-date				Forecast Outturn			
	Actuals £'000s	Budget £'000s	Var £'000s	%	Forecast £'000s	Budget £'000s	Var £'000s	%
Income	5,348	5,105	(243)	4.8	5,382	5,381	(1)	0.02
Expenditure	4,003	4,350	(347)	7.9	4,894	5,381	(487)	9.0
<b>Net Income/ (Expenditure)</b>	<b>1,345</b>	<b>755</b>	<b>(590)</b>		<b>488</b>	<b>0</b>	<b>(488)</b>	

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15. **Table 1** is the summary position as of 31 January 2023 (month 10). We are posting a year-to-date surplus against budget of £590k. Below is an explanation of the two components that make up the surplus.

## Income

16. Our income consists of Grant in aid, Licence Fees including charges to Devolved Governments and secondee income (staff recharges). The in-year variance is a consequence of even budget profiling when income is received variably.

## Expenditure

17. Year to date we are underspending against the planned budget. The largest underspend is within staff costs which currently stands at £160k. There is a significant underspend with the Data, Technology and Development Directorate (£126k). It is not expected for this variance to reduce as we approach the final quarter of this financial year.

18. Other areas of significant underspend are as follows:

- Authority costs are underspent by £49k which is represented by reduced spend within Travel and Subsistence where there has been little travel by our Board. In addition, we are not incurring external venue hire as meetings are held either virtually or within 2 Redman Place.
- IT costs are £30k below budget with the most significant underspend within support costs (£15k) and telephone costs (£18k) which is due to a reduction in our mobile phone and landline costs.
- Accommodation costs are below budget by £74k. This is in part due to the lease for 2 Redman Place now being subject to a new accounting treatment, where our rent costs are capitalised thus reducing our revenue expenditure and increasing depreciation (non-cash) costs.

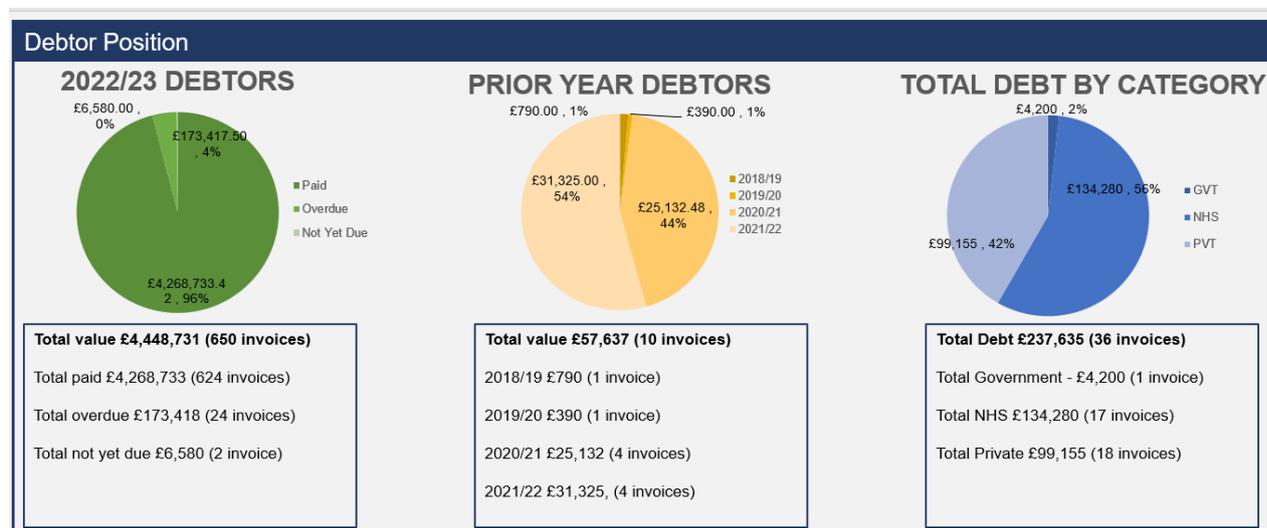
## Outturn

19. Our forecast outturn is a £487k surplus against budget. This underspend is due the large number of vacancies that have been carried throughout the year and to several projects being delayed whilst Ministerial approval of business cases was awaited from the Department, these projects had planned to spend circa £300k over the last 4 months of this business year.

## Other key performance indicators

### Debtors

20. Outstanding debt from licensing activities is provided below.



21. From left to right: The 2022/23 Debtors pie-chart shows the total licence fee income invoiced in 2022/23. At 31<sup>st</sup> January 2023, the total outstanding debt stands at £238k. In January over £50k has been received with one relating to prior year and seven to this current year.

22. Prior year debtors – this shows the debt outstanding from previous financial year(s). Of the £58k outstanding, £27k relates to establishments that have since revoked their HTA licence. In February a decision is expected as to whether we pursue the outstanding debt or write them off as the establishment are unlikely to have carried out any licensable activities.

23. Total debt by category is shown in the final chart and with the total outstanding debt (all years) by sector. To note, the NHS debtors represent 56% of outstanding debt with non-NHS representing 42%.

24. The addition of the finance officer recruited in mid-August has been a huge help in debt collection. Our debtors are lower than they were pre-pandemic during the same period. Debtors at the end of March 2020 were £428k.

## **Financial risks and mitigations**

25. Our finance risk remains low in spite of the projected underspend, but is still above tolerance.
26. As we prepare for the 23/24 financial year, we continue to monitor our spend. With a significant number of vacancies filled in the last quarter, this will impact on the year ahead reducing underspends within staff costs and with the new staff providing the support needed to embark on those projects that have been deferred due to staffing shortages.

## **People Issues**

27. We have a good handle on Recruitment now with most vacancies filled, except in the IT space which continues to be challenging.
28. Another two successful All Staff Days were held in early December and mid-January. A further event is planned for later in March. The organisation has re-defined values and the work to define the behaviours that align to these values is ongoing.
29. A further SMT development day was also held in February.
30. More detailed "People" information is made available to and discussed by the Board's Remuneration Committee (RemCo).

## **Digital, Data and Technology**

31. Quarter 3 and early Quarter 4 were dominated by recruitment activity across the full scope of the Digital, Data & Technology Directorate. In spite of several successful appointments including a new Head of Policy & Development and Project Manager, the team continues to be impacted by staffing shortages in some key areas. Ongoing vacancies in IT have hindered development work and progress in exploring an IT Shared Service model.
32. The number and nature of the vacancies has meant that alternative options have needed to be explored as deliverables have not been adjusted. Options have been limited and dependent on the subject, for example in policy, cover was provided by the Director and Policy Manager through additional hours and out of hours working. For IT Shared Services, the absence of any internal capacity has meant the drafting of the PID has been delayed until the recent appointment of a Project Manager. Alternative options have also been necessary where external assistance was due to be engaged to support delivery. Additional steps in the external approval of consultancy spend have resulted in two projects, specifically, assessing the impact of HTA activities

and developing the use of our current data, being reframed in Q4 within the reduced resource envelope.

33. Progress to note in late Q3 and early Q4 includes:

- Revision of Code F Deemed Consent, Northern Ireland and its progress towards implementation and adoption.
- Submission of the HTA's interim assessment against the Data Security & Protection Toolkit (DSPT) 2022/23
- Ongoing delivery of the Comms & Engagement Strategy with the continued piloting of innovative approaches to engagement and strengthening our use of social media.
- Replacement and roll out of new IT equipment for all staff to support more efficient and effective mobile working.

34. Throughout the period, the HTA has continued to actively engage and stand ready to support any requests from the Covid Inquiry. However, at the time of writing this report, the HTA has not received any requests to contribute to the inquiry.

## Communication and Engagement

35. In Q3 with more capacity in the team we have been able to make progress against the communication strategy. Defining and agreeing the refreshed approach to communication with Stakeholders, with four stakeholder engagement forums planned for Q4. The plan is to supplement these twice-yearly forums with roundtables focused on specific issues. The first of these roundtable discussions was held in November.

36. We developed and agreed an approach to improve the visibility of our regulatory work, introducing a new *regulatory update*, which will be used alongside *regulatory alerts*. HTA regulatory alerts will be issued when immediate action may be required to protect patient safety. HTA regulatory updates will be issued about regulatory changes or activity requiring action or awareness. In Q3 we issued two regulatory updates and have issued two updates and an alert, so far in Q4.

37. In January we introduced a refreshed format to the all-staff weekly exchange call. This has seen an uptick in attendance to the call, is receiving some positive feedback and is helping to improve information sharing across the organisation. We've increased the number of blog posts being shared internally with a variety of internal and external colleagues writing these pieces.

38. In Q3 our twitter account gained a modest 65 followers and our activity earned 31.1K impressions, with a 5.4% engagement rate. The engagement rate compares well with industry standards, but given our relatively low numbers of followers, we expect the engagement rate to fall as followers increase.
39. In Q3 and Q4 we handled 13 media inquiries, which is an uplift compared to previous quarters. Colleagues from the anatomy regulation team gave interviews in connection with body donation including how bodies and material are imported. We ran a poll on twitter to ask if the Channel 4 My Dead Body documentary made our twitter followers more or less likely to donate their body. From 53 votes, nearly two-thirds (62.3%) said they were more likely to donate their body. We are in early discussions with the anatomy sector about supporting their efforts to increase body donations.
40. Working with the ODT team, plans are well underway to raise the organisation's profile amongst key stakeholders with the HTA exhibiting our work at the joint British Transplantation Society/NHS Blood & Transplant annual congress in Edinburgh in early March.

## Governance

41. The Risk Summary document can be found at **Annex B** (HTA 02b-23) to this paper. This was reviewed by ARAC in January.
42. At its most recent assessment of strategic risks, SMT concluded that none of the risks had changed. SMT noted that Risk 2 – Failure to manage the impact of an incident is above tolerance but there are plans in place to test resilience through a critical incidence test exercise, and this will provide evidence that could potentially lower this risk score. Risk 4, SMT believe that the levels of staff turnover continue to be a concern but significant progress on recruitment is being made.
43. Risk 5 – Insufficient, or ineffective, management of financial resource is above tolerance and is likely to remain so as we continue to be constrained by the spend controls which impact on those current projects such as the Inspections Review whereby, we would need to procure Professional Services.
44. SMT will undertake a detailed review of all risks against the 2023/24 business plan deliverables.
45. The Portfolio SMT process and monthly review meeting has continued, with detailed scrutiny of our performance and reprioritisation of our activities within our available resources. As this process matures, we are refining our

approach and looking to provide greater support to project delivery through individual project dashboards and training sessions.

46. In 23/24 we propose to revise **Annex A** to this paper to provide the Board with a wider subset of the data that informs the monthly Portfolio SMT process. The Annex A format for 23/24 will include analysis of all KPIs across our various business areas and will also cover progress updates against each of our agreed projects for the year.

47. During Q3, the HTA received 4 Freedom of Information (FOI) requests. All FOI requests received were dealt with in line with HTA procedures in meeting statutory timeframes. In Q3, no complaints were received by the HTA.

## **Recommendation**

48. The HTA Board is asked to note and comment on the performance recorded and the context provided.

### Annex A – Quarterly Board Data Overview

Business Plan KPIs & PIs		4 On track			4 Amber	3 Off track
		Q1 22/23	Q2 22/23	Q3 22/23	22/23 YTD	
K P I	210 Inspections covering all sectors				149 ↑	
	At least 90% of draft inspection reports are sent to DI for a factual accuracy check within 20 working days of the substantive completion of the inspection	93% (42/45)	95% (54/57)	85% (50/59)	91% (146/161) ↓	
	At least 90% of inspection/audit reports are published on the HTA website within 10 weeks of the substantive completion of the inspection/audit	89% (42/47)	88% (58/66)	84% (43/51)	87% (143/164) ↓	
	At least 95% of enquiries are answered within ten working days of receipt	94% (320/340)	87% (261/301)	93% (287/308)	91% (868/949) ↑	
	All FOIs d/w in line with HTA procedures and meet statutory timetable	80% (4/5)	100% (6/6)	100% (4/4)	93% (14/15) ↑	
	At least 90% of licence variation request outcomes are communicated within 20 working days	90% (55/61)	70% (40/57)	78% (39/50)	80% (135/168) ↑	
	At least 90% of completed applications are processed within 90 working days of payment	75% (6/8)	80% (8/10)	17% (1/6)	63% (15/24) ↓	
	100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days	100% (36/36)	97% (58/60)	100% (75/75)	99% (169/171) ↑	
	100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days	100(166/166)	99% (206/207)	100%(194/194)	100% (566/567) ↑	
	At least 90% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed within agreed timescales	74% (31/42)	97% (32/33)	75% (40/53)	80% (103/128) ↓	
P I	A decision is reached on at least 90% of PPDs within 20 working days of receipt of the completed dossier or any additional information requested by the HTA	80% (8/10)	100% (9/9)	93% (13/14)	91% (30/33) ↓	

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## Annex B

Latest review date – 12/01/2023

## Strategic risk register 2022/23 – Risk Summary: residual risks

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	<b>9 – Medium</b>	Director of Regulation	Below tolerance	<b>10</b>	↔↑↔↓
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	<b>9 - Medium</b>	Director of Regulation	Above tolerance	<b>6</b>	↔↓↔↔
R3: Failure to manage expectations of regulation	Delivery (e) and Development (c)	<b>8 - Medium</b>	Director of Regulation	Below tolerance	<b>9</b>	↔↓↔↔
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	<b>12 - High</b>	Director of Resources	Above tolerance	<b>9</b>	↔↔↑↔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	<b>4 - Low</b>	Director of Resources	Above tolerance	<b>3</b>	↔↔↔↔
R6: Failure to achieve the benefits of organisational transformation	Development (a-d) objectives	<b>12 - High</b>	Director of Data, Technology and Development	Above tolerance	<b>9</b>	↔↔↔↔
R7: Failure to optimise the safe use of existing and available digital data and technology	Delivery (a-e), Development (a-d) Deployment (a, c and d)	<b>12 - High</b>	Director of Data, Technology and Development	Above tolerance	<b>9</b>	↔↔↑↔

\* Strategic objectives 2021-2024: \*\* This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g. ↔↔↑↔).

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**R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15 - High	3	3	9 - Medium
<b>Tolerance threshold:</b>					<b>10 - Medium</b>

### Commentary

#### Below tolerance.

We have a good regulatory framework, having received moderate assurance on the most recently completed internal audit focusing on our regulatory role (on the Effectiveness of the Inspection Process, final report issued 11 April 2022) and previously substantial assurance on the internal audit on key regulatory processes (final report issued 16 April 2019).

The HTA is on track to meet this year's significantly increased inspection target of 210 (for existing licenses) through a combination of onsite and virtual regulatory assessments, in addition to assessing a significantly increased number of licence application assessments. We have in particular increased inspection coverage in the PM sector to about 40% (with a target of 77 PM inspections this year compared to 44 in 2021/22) in response to recognised risks in this sector. Our re-introduced KPIs and Portfolio Management Process includes reporting on delivery of our core business and provides visibility at SMT and board level.

We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued.

Whilst we are involved in a number of more uncommon and unusual regulatory matters, including a small number of cases related to regulated activity on which criminal investigation and prosecution under other legislation is being pursued, we have no indication of any systemic issues that might jeopardise public safety or confidence.

SMT believes this risk is now reduced to just below tolerance.

**R2: There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	3	3	9 – Medium
<b>Tolerance threshold:</b>					<b>6 – Medium</b>

### Commentary

This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control.

The HTA believes that our incident management response plans have been tested and found effective through their deployment in several different circumstances over the past two years. These have included managing the impact of the pandemic and related restrictions, in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the Fuller trial.

Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial, we now believe that the likelihood of this risk materialising has reduced but given continuing uncertainties, we believe it is still above the tolerance level and has remained unchanged from the last review.

We have accepted the recommendations of a specialist consultant who has reviewed our Critical Incident Response Plan and processes and are planning to do more work to implement those, including a test exercise in January. We anticipate concluding this work by the end of March 2023 and that this will feed through into a lower risk level by the year end.

**R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12 - High	2	4	8 – Medium
<b>Tolerance threshold:</b>					<b>9 – Medium</b>

### Commentary

#### Below tolerance.

We have no indications of any current specific factors that would contribute to this risk. The HTA continues to communicate our remit and advise where appropriate.

The HTA is in ongoing dialogue with DHSC (Department of Health and Social Care) and wider stakeholders regarding actions being undertaken following the conclusion of the Fuller trial, including Sir Jonathan Michael's Independent Inquiry. We have provided evidence to the Inquiry and assisted former colleagues by providing them with suitable secure access to relevant information to enable them to give their evidence. We published updated guidance to Standards in the Post Mortem sector in October concerning security and dignity of the deceased and have undertaken an informal consultation on similar changes in the Anatomy sector guidance, which we hope to publish shortly.

The HTA has an established Horizon Scanning process and is building its Policy function, including updating and engaging with DHSC on our legislative log.

The HTA has worked with colleagues in the Northern Ireland Executive and NHSBT (NHS Blood and Transplant) to ensure there can be effective implementation of the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 which will introduce deemed consent for organ and tissue donation through changes to Code of Practice F, Part 2.

We have also worked with stakeholders on the impacts for the HTA of the recent amendment to s32 Human Tissue Act 2004 by the Health and Social Care Act 2022 to introduce an offence for

'organ tourism'. This may require an update to the HTA's Police Referral and Warrants Policy. We continue to engage with NHSBT and other relevant stakeholders, including the police, to ensure that a suitable referral mechanism is in place.

All these matters are being actively managed.

SMT consider this risk to be below tolerance.

**R4: Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	4	3	12 – High
<b>Tolerance threshold:</b>					<b>9 – Medium</b>

### Commentary

#### Above tolerance.

Over the past quarter there has been a significant increase in the number of vacancies advertised and unfilled across the HTA. This is a combination of high organisational churn as well as the need to fill a number of short-term project and admin roles to support wider activity.

The time from advert to new colleagues joining the HTA is around 2 - 3 months, leading to significant pressure in some teams who have been carrying vacancies in key roles for a number of months. Although we are filling the majority of vacancies this is not always at the first attempt and there have been some vacancies where we have repeatedly advertised before securing a viable candidate.

There is some evidence that the continued controls on public sector pay are contributing to high churn levels and making it more difficult to recruit, the HTA will need to ensure it remains competitive amongst other public sector employers in similar sectors.

We believe this risk remains above tolerance levels in December 2022, we will start the new calendar year with c 10 post to fill and will review our risk level in January when we expect a number of vacancies to have been filled (awaiting start dates).

**R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	2	4 – Low
<b>Tolerance threshold:</b>					<b>3 – Low</b>

### Commentary

#### Above tolerance.

Budgets for 2022/23 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £80k) and depreciation and amortisation costs (Ring Fenced RDEL).

Our underspend continues to grow as we fail to fill a number of vacancies across the organisation and the controls on agency and consultancy spend placed upon us by DHSC have constrained our ability to commence a number of key activities in support of the 2022/23 business plan – this will have an impact on in year spend and could place additional pressures in to the next business year if programmes of work now need to straddle financial years. We have offered to return £150k of the additional GIA funding the Department provided for costs incurred in assisting the FII (for 2022/23 only), we believe this is affordable in year.

Our income budget and fees for 2023/24 have been set and agreed with the Authority, and these will be published at the end of December 2022. Expenditure risks for 2023/24 will be linked to public sector pay, both in terms of pay remit restrictions and external drivers to appoint at higher salary levels – pay represents c 70% of all expenditure and controls in this area will limit wider inflationary pressures on the organisation.

SMT have agreed that this risk is unchanged, although acknowledge that we are unlikely to deliver against our 3% variance target for spend against budget.

**R6: Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.**

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	3	4	12 – High
<b>Tolerance threshold:</b>					<b>9 – Medium</b>

### Commentary

#### Above tolerance.

Following the Q2 review of the projects identified across the business as development priorities in 2022/23, resources were agreed to support the individual projects. Since October each project has worked in different ways to secure the additional contracted, external resource. These actions have included business cases, attempts to recruit specialist roles on time limited contracts and specifications to support procurement of services and support.

At the end of Q3 resource commissions have been posted for:

- IT Consultancy support to deliver a PID for the IT shared services project. This commission will also map out the approach to be taken to in exploring and evaluation potential options
- Data collection and analysis to aid the next stage of development of the Regulatory Insight Model and Index
- The review of inspections

In addition, there has been a further commission to support the evaluation of the HTA's impact and contribution to the sectors, innovation and growth of life sciences and as a regulator working as a partner in the wider health system. It is anticipated that this commission will provide further insight and evidence to inform and prioritise future developments. Current capacity in the organisation has been a constraint and has been a significant factor in setting the risk level above tolerance. It is hoped that securing resource via these commissions will assist in making progress and reducing risk levels at the next review.

SMT believe that some areas of activity are at risk of slipping and this would have impact on anticipated benefit realisation although the extension of timescales on some projects may reduce risk without impacting on the overall output. Oversight of the progress will be maintained by SMT.

### R7: Failure to optimise the safe use of existing and available digital data and technology

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16 – High	4	3	12 – High
<b>Tolerance threshold:</b>					<b>9 – Medium</b>

<b>Commentary</b>
<p>Over the last 2 years the HTA has been progressing with the planned development of its digital data and technology (systems and architecture) as part of the Development Programme. The planned development had been incremental based on available resources and aimed to future proof business needs. Following the review of the Development Programme in Q1 2022/23 two projects have been identified to support the use of existing and available digital and technological capabilities. These are the adoption of an IT Shared Services model and the stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 action has been taken in Q3 to commission external and specialist resource to support progressing the planned developments.</p> <p>Utilising internal resource and integrating actions with BAU activities progress has been made to strengthen existing capabilities through the review and consolidation of licenses, establishing internal reporting on the use and performance of systems and in identifying a further action for Q4 to map current systems and interdependencies to inform and prioritise future upgrades and potential replacements.</p> <p>It is anticipated that the additional resource and focus on BAU activities will assist in reducing the likelihood of the residual risk level.</p>

## Reviews and revisions

### **(23/02/22) SMT review March 2022**

Risks 1, 2 and 4 were discussed in detail. SMT agreed that the impact score of risk 1 should be reduced as the tools in place continue to work; risk 2 likelihood score was also adjusted down; and risk 4 likelihood has been reduced from 3 to 2 reducing overall rating to 8 as key posts have been recruited to.

### **(19/05/22) SMT review April/May 2022**

The SMT reviewed the current register in light of the finalised business plan and agreed the following:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk 4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-framed to reflect the fact that it is broader than just the Development programme.

### **(09/06/22) SMT review June 2022**

Following the full review of risks for the new business year SMT reviewed the risk register following a detailed discussion at the HTA ARAC meeting:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk 4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-frame to reflect the fact that it is broader than just the Development programme.

### **(26/07/22) SMT review July 2022**

### **(08/09/22) SMT review September 2022**

SMT reviewed the register at its meeting on 8 September. The following changes were made to the risk scores:

- Risk 1 it was agreed that the likelihood should be increased based upon recent issues that may materialise, which together would increase its likelihood;

- Risk 4 was increased. In part the reason relates to the number of recruitments currently underway and the challenge it continues to be to recruit to certain roles. The SMT believed the likelihood is increasing;
- Risk 5 has not changed however, SMT recognise the impact that restrictions on recruitment may pose if there is a change in focus of the DHSC and Cabinet Office;
- Risk 6, SMT believe that there is a thread which impacts risks 4 – 6 from the potential savings we are being asked to make. The various pieces of work (IT Shared Services, Inspections Review) will be affected should we be required to make further savings.

#### **(27/10/22) SMT review October 2022**

SMT reviewed all seven risks and agreed that Risk 1 scoring should be reduced from 12 to 9 as it was felt that the work we have done around Living Organ Donation, latest position re Fuller has impacted this risk.

#### **(29/11/22) SMT review November 2022**

Overall, there has been no changes to the risk scores. SMT discussed risk 4 and the possibility of the Board agreeing to accept where we are due to issues that are outside of our control such as the challenges around recruiting to specific posts and its impact on the organisation as a whole. Risk 3 was discussed and the associated increase in obtaining legal advice.

#### **(20/12/22) SMT review December 2022**

SMT discussed each of the risks in detail and agreed that none of the risk scores required a change. However, risk 4 '*Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives*' had become an issue that will need to be flagged to the Board via ARAC. The challenges around recruitment for key posts is having an impact across the organisation despite all efforts to explore other avenues to go to market.

## Strategic Aims

**Delivery:** Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.

- (a) Deliver effective regulation of living donation.
- (b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
- (c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- (d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

**Development:** Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.

- (a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
- (b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
- (c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

**Deployment:** Manage and develop our people in line with the HTA's People Strategy

- (a) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
  - Provide a suitable working environment and effective business technology, with due regard for data protection and information security
  - Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation

## Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HTA's strategy or purpose.

Whether it is possible for the HTA to do anything to control the risk (so external risks such as weather events are not included).

## Rank

The risk summary is arranged in risk order.

## Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

**Likelihood:** 1=Rare      2=Unlikely      3=Possible      4=Likely      5=Almost certain

**Impact:** 1=Very low      2=Low      3=Medium      4=High      5=Very High

Risk Scoring Matrix						
<b>IMPACT</b>	<b>5. Very High</b>	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	<b>4. High</b>	4 Low	8 Medium	12 High	16 High	20 Very High
	<b>3. Medium</b>	3 Low	6 Medium	9 Medium	12 High	15 High
	<b>2. Low</b>	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	<b>1. Very Low</b>	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Likelihood						
<b>Risk score = Impact x Likelihood</b>	<b>1.Rare (≤3%)</b>	<b>2.Unlikely (3%-10%)</b>	<b>3.Possible (10%-50%)</b>	<b>4.Likely (50%-90%)</b>	<b>5.Almost certain (≥90%)</b>	

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## **Risk appetite and tolerance**

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HTA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change unless the organisation's role or environment changes dramatically.

Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

## **Assessing inherent risk**

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it.' This can be taken to mean 'if no controls at all are in place.' However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

## **Contingency actions**

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

# Human Tissue Authority Board Meeting

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**Date:** 09 March 2023

**Paper reference:** HTA 03/23

**Agenda item:** 7

**Author:** Nicolette Harrison, Director of Regulation

**Protective marking:** OFFICIAL

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## HTA's differentiated, risk-based approach to developing the inspection programme 2023/24

### Purpose of paper

1. To describe the approach taken to use current data to assess relative sector risks.
2. To indicate how the analysis of sector risks has been translated into our planned inspection programme for 2023/24 and an increasingly differentiated approach to the inspection programme based on risk segmentation.

### Decision making to date

3. ARAC considered a detailed sector risk assessment paper at its meeting on 26 January 2023.

### Action required

4. The Board is asked to note and discuss the HTA's developing approach to using data to inform the approach to regulatory risk assessment through the implementation of a segmented approach to our inspection work. This approach has been used to inform the inspection programme for 2022/23.

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## Background

5. In recent years, the HTA developed an Inspection Assessment Decision Making Framework that set out our understanding of risk in each sector and described an initial differentiation in our approach to inspection by sector.
6. That approach has now been further refined with the development of a conceptual segmentation model, under which the HTA is adopting a differentiated approach to assessing regulatory compliance based on risk segment, of which sector-based risk is a key element.
7. This paper does not present the detail of individual establishment risk, that will be overlaid on the sector risk profile to determine the specific inspection programme as we proceed through the year.
8. The sector risk paper presented to ARAC on 26 January set out our current assessment of the regulatory risks posed by our various sectors based on analysis of existing data.
9. The HTA has continued to iterate this model as set out in **Annex A**.
10. That prototype model has informed the outline inspection programme for 2023/24, which is shown at **Annex B, Table 1**. The Board should note that the planned inspection programme is, as ever, subject to continual review and revision in light of our ongoing assessment of risk, resource availability and business priorities. Hence other factors may lead the HTA to reassess in-year how to deploy the limited resource we have available, recognising that compliance assessment and inspection is only one of a range of regulatory tools we use.
11. **Annex B, Tables 2-4** summarise the inspection programme being worked through for 2022/23, by sector and inspection type.
12. The differentiated approach to assessing regulatory compliance aligns with the HTA's Target Operating Model (TOM), as developed in recent years and which underpinned our previous Development Programme. The HTA has been using the Communication and Engagement Strategy to develop the authoritative voice aspect of that model. The HTA will also wish to develop other aspects of the TOM, for example relationship management. This would align with the segmentation model being developed for inspection.

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## Discussion

13. The Review of Inspections project and the Regulatory Insight Model and Index (RIMI) / Data projects will both assist in developing the segmentation model and its practical application in the inspection programme. A combination of factors, primarily linked to resourcing difficulties, resulted in limited progress on both projects in 2022/23. Hence the concepts and approach outlined here are still quite rudimentary. Dedicated internal and external resource will be needed to develop and properly operationalise these concepts during 2023/24.
14. Inspection is the umbrella term the HTA uses for the scheduled programme of assessing regulatory compliance, although the Board should note there is also a significant demand-led programme in initial license application assessment and inspection. (The Board should also note that we use the term audit, not inspection, in the ODT sector).
15. However, the term inspection is increasingly encompassing a wide range of types of assessment, which will continue to develop as set out in the ARAC paper. This differentiation is also indicated in the summaries of risk and inspection profiles in the two Annexes to this paper. For the highest risk establishments, an inspection is likely to be an in-depth, possibly unannounced, inspection. By contrast, for the lowest risk establishments, a compliance assessment inspection is likely to comprise an evaluated, standardised self-assessment.
16. This differentiation in terms of depth and intensity of inspection will enable the HTA to prioritise putting resource to areas of greatest risk whilst increasing coverage rates and maintaining effective monitoring of risk across its licensed establishments.
17. The Board is invited to note the following points:
  - the approach being taken to increasingly use data to inform regulatory compliance risk assessment;
  - the limitations of this approach, which is still early in the journey and will require additional investment to be further developed and refined;
  - the importance of the continuing commitment of resource to developing our capability in collecting and using data to inform regulatory risk profiling through the development of the Regulatory Insight Model and Index (RIMI);

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- this model is an early prototype, albeit building on previous experience of risk profiling within sectors. The HTA will seek to develop a robust ongoing mechanism to assess and evaluate our approach, as we progress through this test and learn phase in order to further enhance the model and approach;
- The data used for this modelling is itself a limiting factor on the usefulness and credibility of the current risk model. We know that much of the data is:
  - from previous years (hence the need to prioritise investment in data collection);
  - limited, not comprehensive;
  - not in a suitable form to support risk assessment, for example, much of our data is in qualitative form; and
  - there are questions around data quality arising for a variety of reasons, all of which also need to be addressed;
- our inspection programme is scheduled up to 12 weeks in advance, hence there will be a continuing and phased introduction of the differentiated approach over the first half of 2023/24.

18. Despite these reservations, we believe it is important to maximise the use and usefulness of the data we currently hold. The limitations outlined mean the outcomes from using this data will inform, rather than direct, decisions: but even with the best data there will always be a place for judgements based on experience.

19. The HTA will undertake further practical development, evaluation and refinement of this approach, in parallel with the early implementation of this approach during 2023/24.

20. Any potential resource savings or efficiency gains will therefore be limited until that process is complete. For example, additional business resource will be needed to help with developing new operational policies, Standard Operating Procedures, business templates and operational processes. That will come later but will have an impact across the Regulation Directorate and in other areas, for example Communications (e.g. how will the self-assessment inspections be reported to the public) and IT (with changes likely to be needed to IT systems) as well as wider investment in staff training. We will seek to phase in these developments balancing the additional time and resource pressures with delivery of the inspection plan for 2023/24.

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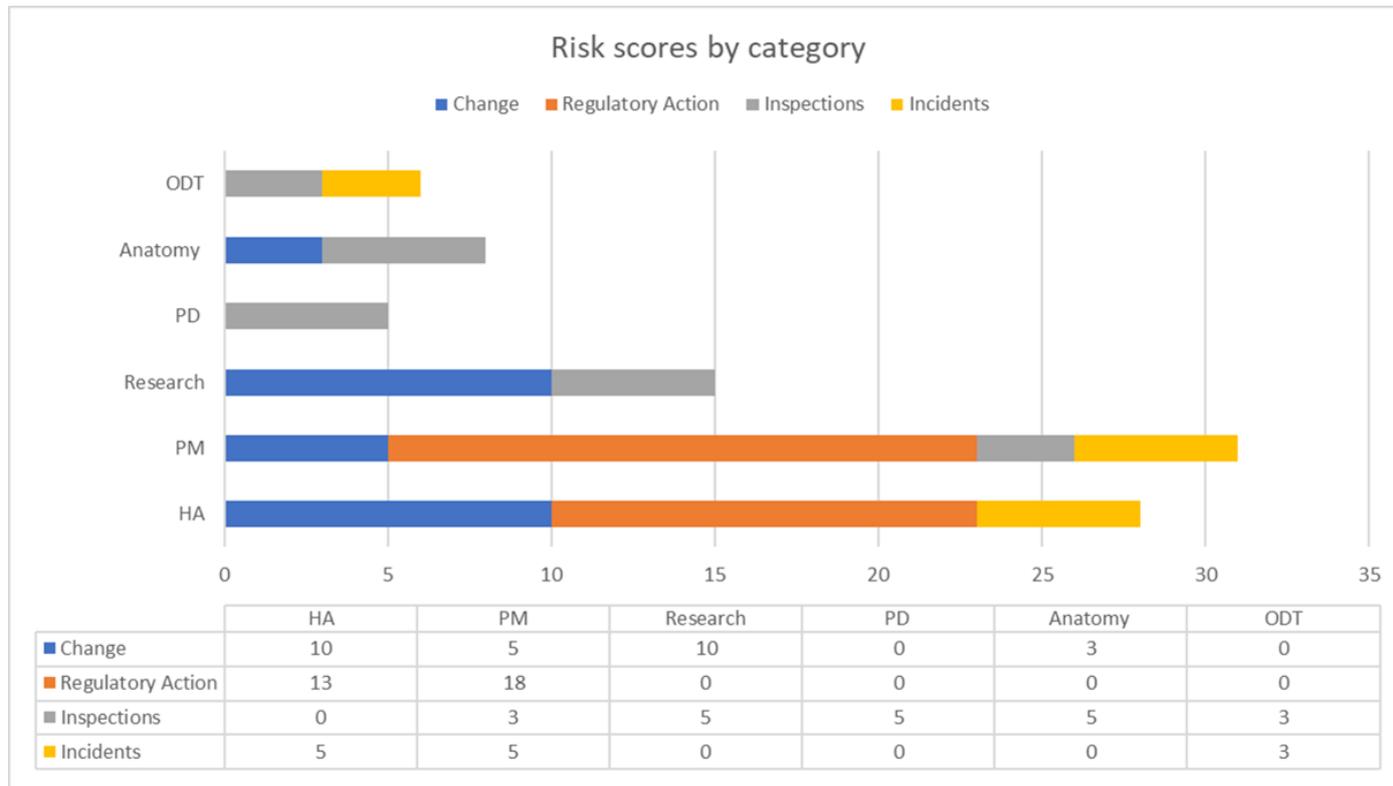
## **Recommendation**

21. The Board is asked to note and discuss the HTA's developing approach to using data to inform the approach to regulatory risk assessment through the implementation of a segmented approach to our inspection work. This approach has been used to inform the inspection programme for 2023/24.

## Annex A: Prototype sector risk profile

Figure 1 is a third version of the model. Further, but limited, refinement of the model has been undertaken following the ARAC meeting on 26 January 2023 in order to understand, and where possible address, factors that contributed to a perceived skewing of the relative risk profiles for each sector. In the first model, for example, the relative risk score for public display was considered to be disproportionately high. The profile below is better aligned with our current view of risk in each sector and the relative numbers of inspections carried out in each sector in 2022/23, but the model is simplistic, possibly overly so. Additional work is needed to assess whether there is merit in further developing this tool to help with inspection scheduling, either when used in isolation or in conjunction with other sector-specific risk data sets.

**Figure 1. Prototype risk model with the relative risk scoring of the six sectors**



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## Annex B: Outline inspection programme for 2023/24

**Table 1. Summary of assessment proposals versus sector for business year 2023-24**

Sector  (n=number of main licences)	Assessment proposals for 2023-24 business year				
	Total	Main type of assessment (*)  (Indicative number and proportion [%] of inspections planned for that sector for 2023/24)			
		Evaluated self-assessment	VRA only	VRA and site [includes themed, targeted or full inspections]	Site visit inspection only
HA (n=154)	72	No	No	Yes 58 [80%]	Yes 14 [20%]
PM (n=173)	72	No	Yes 5 [7%]	Yes 54 [75%]	Yes 13 [18%]
R (n=193)	50	Yes 30 [60%]	Yes 15 [30%]	Yes 5 [10%]	By exception only
A (n=44)	12	No	By exception only	Yes 11 [c.90%]	Yes 1 [c.10%]
ODT (n=36)	12	No	No	Yes 4 [33%]	Yes 8 [67%]
PD (n=12)	4	Yes 2 [50%]	Yes 2 [50%]	No	By exception only
	<b>222</b>				

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*\*Please note that other factors will determine the actual format and scope of the assessment, including the number of assessors, the range of standards assessed, whether the inspection is targeted or themed and whether unannounced or planned.*

For context, the profile of inspections for 2022/23 is set out in the tables below.

## Table 2: 2022/23 Inspection profile by type

[SVI = Site visit inspection, VRA = Virtual Regulatory Assessment]

Unannounced SVI	3
Non-routine SVI	0
Full ('Routine' or hybrid 'SVI + VRA')	139
Themed ('Themed' or 'CAPA Follow Up')	37
VRA	31
Compliance update and review	0
	210

## Table 3: 2022/23 Inspection profile by sector

Anatomy	6
Research	31
PM	79
PD	4
HA	74
ODT	16
	210

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**Table 4: 2022/23 Inspection profile by sector and inspection type**

	Anatomy	Research	PM	PD	HA	ODT
Unannounced SVI			3			
Non-routine SVI						
Full ('Routine' or hybrid 'SVI + VRA')	6	2	68	3	44	16
Themed ('Themed' or 'CAPA Follow Up')			7		30	
VRA		29	1	1		
Compliance update and review						

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# Human Tissue Authority Board Meeting

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**Date:** 09 March 2023

**Paper reference:** HTA 04/23

**Agenda item:** 8

**Author:** Richard Sydee, Director of Resources

**Protective marking:** OFFICIAL

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## Review of HTA's Risk Tolerance

### Purpose of paper

1. To review and approve the revised risk tolerance statements for HTA's strategic risks 2, 3 and 7.

### Decision making to date

2. The Audit and Risk Assurance Committee discussed this item at their meeting on 26 January 2023.
3. The SMT approved this paper for presentation to the Board on 24 February 2023.

### Action required

4. The Board is asked to approve the revised risk tolerance statements for HTA's strategic risks 2, 3 and 7.

### Background

5. In June 2022 the HTA Board reviewed and agreed a revised risk appetite and tolerance statement. In doing so the Board requested that during the 2022/23 business year ARAC should further review the statements with a particular focus on risks 2, 3 and 7, where the Board felt that the statements as drafted may be too restrictive given the pressures facing the organisation and the plans for organisational change.

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6. ARAC discussed this matter at their meeting in January and proposed a number of amendments to differentiate between the actions which could be taken to mitigate risks and the proportionality of these related to the risk tolerance levels. The Executive was asked to make revisions to the drafting of the risk tolerance statements and present these to the Board for approval.
7. The proposed revised statements are attached at Annex A and definitions of risk tolerance at Annex B.

## **Recommendation**

8. The Board is asked to approve the revised risk tolerance statements for HTA's strategic risks 2, 3 and 7.

## Annex A

### Risk Appetite Statement

- Risk appetite is the amount of risk an organisation is willing to accept in pursuit of its strategic goals.
- Following our review of the existing approach to risk we propose that the risk appetite statement considers separately five key areas of risk to which the HTA is exposed and provides an outline of the HTA's appetite for managing these types of risks. The HTA does not have a single risk appetite, but rather appetites across the range of its activities. We recognise that in pursuit of our strategic priorities and outcomes we may choose to accept different degrees of risk in different areas of the business.
- Where we choose to accept an increased level of risk, we will do so, subject always to ensuring that the potential benefits and threats are fully understood before actions are authorised, that there is sufficient capacity, and that sensible and proportionate measures to mitigate risks are established.
- The Executive will manage strategic risks in a manner that is consistent with this statement. The strategic plan and the business plans within the HTA should also be consistent with this statement.
- Below are the risk appetite descriptions established for each key activity identified.

### Business Area Risk Appetite Levels

#### Regulation

Risk 1 – There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Risk 2 – There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

- The HTA has **NO** appetite for any activity that disregards the need to obtain consent and any incidents that lead to serious public harm or breach of DPA (Data Protection Act).
- There is **LOW** appetite for risks that may result in the HTA providing advice that could be misconstrued and indirectly lead to an adverse impact on patient safety.

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## Corporate Governance

- There is a **LOW** appetite for activity that may result in non-compliance with legislation, statutory obligations, and government policies. The HTA has a **ZERO** tolerance for deliberate non-compliance with legal, statutory and policy requirements, except in exceptional circumstances.

## Reputational

Risk 3 – There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

- The HTA will explore innovative ways of regulating in line with better regulation principles and will have a clear view on its regulatory risk and areas of oversight. The HTA acknowledges that proportionality is needed in managing and communicating about our activities that could contribute to misperceptions of our role, either because of limitations in current legislation (that is not within our gift to change) or for other reasons. The HTA has a **MODERATE** appetite for innovation in our approach to regulation, recognising that some more disruptive changes may not receive full support from all stakeholders. The HTA will not tolerate (**ZERO**) any action likely to cause reputational damage.

## Capabilities

Risk 4 - Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives.

Risk 6 – Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

- Although the HTA will not tolerate (**ZERO**) any action that could cause reputational damage it will explore innovative ways of regulating in line with better regulation principles and will have a clear view on its regulatory risk and areas of oversight.

## Information security and management

Risk 7 – Failure to optimise the safe use of existing and available digital data and technology.

- The HTA has a **LOW** appetite for risk that could lead to information or data security breaches and a **LOW** appetite for system failures that could disrupt normal business. We have **NO** appetite for activities that may increase our exposure to threats on our assets arising from external malicious threats. We recognise and accept that there may be attempts to infiltrate our systems through a range of channels. However, the systematic monitoring of the effectiveness of controls, identification of vulnerabilities

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and challenge to activities that may increase risk must continue to be a priority in day to day operations, in the use of our systems and in the assurance provided.

- The HTA has **LOW** appetite for activities that may compromise processes governing the use of information, its management and publication. The HTA has **ZERO** tolerance for the deliberate misuse of its information.

#### Risk 5 – Finance

- The HTA has a **LOW** risk appetite in relation to management of its finance. It will not tolerate annual expenditure in excess of income or any form of spend that contravenes HMT guidance. In addition, The HTA has **ZERO** appetite for any incidence of fraud and fraudulent behaviour.

## Annex B

### Risk Tolerances

- Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

Extent of Risk Appetite	Risk Tolerance Level	Risk Management Approach
<b>High Appetite (Seek)</b> The HTA will be eager to innovate and to choose options offering potentially higher rewards (despite greater inherent risk)	High Tolerance	Innovate/explore
<b>Moderate Appetite (Acceptable)</b> The HTA is willing to consider all potential delivery options and choose options providing an acceptable level of reward and value for money	Moderate / Medium Tolerance	Open
<b>Low Appetite (Tolerable)</b> The HTA has a preference for safe delivery options that have a low degree of inherent risk and may only have limited potential for reward	Limited / Low Tolerance	Cautious
<b>Minimal Appetite</b> The HTA has a preference for ultra-safe delivery options that have a low degree of inherent risk and only limited reward potential	As little as possible	Minimal
<b>No Appetite / Zero (Unacceptable)</b> The HTA will avoid the risk and uncertainty – key organisational objective	Zero Tolerance	Avoid

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# Human Tissue Authority Board Meeting

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## **Item 9: Business Plan 2023/24 Confidential item**

# Human Tissue Authority Board meeting

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**Date:** 9 March 2023  
**Paper reference:** HTA 06/23  
**Agenda item:** 10  
**Approved by:** Professor Gary Crowe, ARAC Chair

## OFFICIAL

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### **Audit, Risk and Assurance Committee update**

#### **Purpose of paper**

1. This paper provides an overview of the business of the Audit, Risk and Assurance Committee (ARAC) meeting held on 26 January 2023.

#### **Action required**

2. The Board is asked to note the content of this report.

#### **Background**

3. The Committee discussed the following items as material elements of the meeting.

#### *Internal Audit*

4. The Committee received a report from GIAA on the progress against the HTA internal audit plan for 2022/23 and proposals for the planned audits for 2023/24.

The Committee noted the progress to date and requested and received assurances that the clearance of outstanding GIAA recommendations had the required attention.

The Committee considered the previous focus of GIAA reports and the current strategic risks and then approved the proposed GIAA plan for 2023/24, as drafted.

The Committee requested and received assurances that GIAA had the required resources to complete the 2023/24 plan and the Executive had the capacity to support the scheduling.

#### *External Audit*

5. KPMG and NAO presented their plan for audit of the HTA's Annual Report and Accounts for 2022/23. The Committee noted the management risks highlighted and the proposed approach to the audit for this financial year.

#### *Data Security and Protection Toolkit (DSPT)*

6. The Committee received a detailed update from the Executive on progress against the 2023 DSPT assertions. The Committee noted the report and progress outlined, it accepted that the HTA would not likely meet all the mandatory assertions but that improvement from last year's position was expected.

#### *Strategic Risk Register*

7. The revised Strategic Risk Register (SRR) was considered by the Committee.
8. The Committee noted that the Executive review this register each month and amend the risk ratings as required.
9. The Committee noted the actions taken by the Executive to mitigate the potential risks. The Committee asked that future updates provide more clarity on actions to reduce risks currently above agreed tolerance levels, this was felt to be of increased significance given 5 of 7 risks were currently above tolerance.
10. The Committee welcomed and noted a requested deep dive report outlining the HTA's proposed approach to individual Sector Risk Assessment. The approach was supported by the Committee, and it was agreed to receive an annual Sector Risk Assessment.

11. The Committee discussed the risk appetite and tolerance levels for the HTA as requested by the Board in June 2022. The Committee requested several revisions to the text and the revised document be submitted to the Board for approval at its next meeting.

*Other items*

12. The Committee noted and agreed revisions to the HTA's Whistleblowing Policy and Procedure.
13. The Committee reviewed the ARAC handbook and ARAC Terms of Reference, asking for minor amendments to the latter relating to quoracy before submission to the Board for agreement.
14. The Committee noted the additions to the HTA's Gifts and Hospitality register for this year and were advised that there were no reports to be made relating to grievances or disputes.
15. Finally, the committee noted a Dear Accounting Officer letter from His Majesty's Treasury (HMT) relating to a requirement to share relevant internal audit reports across Government and closed the meeting following the Chair's outline of the approach to its annual review of committee effectiveness that would be conducted at its next meeting.

**Recommendation**

16. The Board is asked to note the content of this report.

# Human Tissue Authority Board Meeting

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**Date:** 09 March 2023

**Paper reference:** HTA 06a/23

**Agenda item:** 10

**Author:** Richard Sydee, Director of Resources

**Protective marking:** OFFICIAL

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## ARAC Terms of Reference

### Purpose of paper

1. To review and approve the Terms of Reference for the Audit and Risk Assurance Committee (ARAC).

### Decision making to date

2. The Audit and Risk Assurance Committee discussed their Terms of Reference at their meeting on 26 January 2023 and recommended two changes regarding quorate for the meetings and secretarial support to the Committee. A tracked changes document showing these proposed amendments are annexed to this paper.
3. The SMT approved this paper for presentation to the Board on 9 February 2022.

### Action required

4. The Board is asked to approve the Terms of Reference for the Audit and Risk Committee.

### Background

5. Under Article 95 of the HTA Standing Orders the Board will keep under review the structure and remit of its committees.
6. The Terms of Reference for ARAC were reviewed at the beginning of 2023.

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7. At its last meeting, held on 26 January 2023, ARAC discussed both the Terms of Reference and the ARAC Handbook.
8. The Committee proposed that section 18 should be amended to include the ARAC Chair in the quorate, due to the reduced number of Committee Members.
9. The Committee also noted that section 31 should be amended to reflect the secretarial support from the Private Office. These proposed changes are shown in the attached tracked changes document.

## **Recommendation**

10. The Board is asked to approve the Terms of Reference for the Audit and Risk Committee.

## Terms of reference

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### Audit and Risk Assurance Committee (ARAC)

<b>Reference number</b>	HTA-TOR-001	<b>Version</b>	15.5
<b>Owner</b>	Resources Directorate	<b>Date approved</b>	January 2023
<b>Author(s)</b>	Head of Finance and Governance	<b>Next review date</b>	December 2023
<b>Reviewed by</b>	Head of Finance and Governance /	<b>Distribution</b>	Internal and external
<b>Approved by</b>	HTA <u>Board</u>		

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### Constitution

1. The Authority has established an Audit and Risk Assurance Committee (known to Human Tissue Authority (HTA) staff as ARAC) to support it in its responsibilities for risk management and governance. The ARAC will achieve this by advising the Board and the Accounting Officer on the exercise of their responsibilities, ensuring the comprehensiveness of assurances that these responsibilities are being met and reviewing the reliability and integrity of these assurances.
2. The ARAC will make recommendations to the Board regarding the adoption of the Annual Report and Accounts.

### Duties and functions

3. The ARAC will advise the Accounting Officer and Board on:
  - a. the strategic processes for risk, control and governance and the Annual Governance Statement;
  - b. the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to External Audit;

- c. the planned activity and results of both Internal and External Audit;
- d. adequacy of management response to issues identified by audit activity, including External Audit's audit completion report;
- e. assurance relating to corporate governance requirements for the HTA;
- f. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (permanently delegated to ARAC by the Remuneration Committee);
- g. (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non-audit services from contractors who provide audit services; and
- h. where necessary, anti-fraud policies, whistle-blowing processes, organisational culture and arrangements for special investigations.

## **Rights**

- 4. The ARAC has the following rights:
  - a. it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);
  - b. it may procure independent specialist ad-hoc advice, at the expense of the HTA, subject to budgets agreed by the Board; and
  - c. it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.

## **Access**

- 5. Internal and External Audit will have free and confidential access to the Chair of the ARAC. In addition, a confidential session with Internal and External Auditors for ARAC members will be scheduled each year.

## **Information requirements**

- 6. As appropriate to the meeting the ARAC will be provided with:
  - a. a report summarising any significant changes to the organisation's Risk Register;

- b. a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;
  - c. management response to audit recommendations;
  - d. changes to the Internal Audit Plan;
  - e. details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;
  - f. a progress report from the External Audit representative summarising work done and emerging findings; and
  - g. progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.
7. As and when appropriate the ARAC will also be provided with:
- a. the Internal Audit Plan;
  - b. Internal Audit's annual opinion and report;
  - c. External Audit's annual report and opinion
  - d. the draft accounts of the organisation;
  - e. the draft Annual Governance Statement;
  - f. a report on any changes to accounting policies;
  - g. a report on any proposals to tender for audit functions;
  - h. a report on co-operation between Internal and External Audit; and
  - i. a report on any fraud or financial misdemeanour and any whistleblowing.

## **Reporting to the Authority**

- 8. The Board will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.
- 9. The ARAC will formally report back (either verbally or in writing) to the Board after each of its meetings.

10. The ARAC will provide the Board with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.

## Reviewing effectiveness

11. The ARAC will use the National Audit Office's [self-assessment checklist for Audit Committees](#) in order to undertake annual reviews of its own effectiveness and agree actions for improvement. The ARAC will report the results of the review to the Authority.

## Recruitment and membership

12. The ARAC will be chaired by a lay Board Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.
13. All other members of the Committee should be Board Members, but not the Board Chair. Including the ARAC Chair, there will be a minimum of three Board Members and a maximum of five Board Members on the Committee at any time.
14. At least one Board Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.
15. Recruitment of Board Members to the ARAC will be through 'expressions of interest' with personal statements in application. The applications will be reviewed by the Board Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Board Chair will appoint the Member who has the most appropriate skills and experience to the role.
16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as Board Members. It should be noted that Board Members may be reappointed to the ARAC in accordance with the HTA's business needs.
17. Members of the ARAC must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

## Attendance

18. A minimum of two members of the ARAC (including the ARAC Chair) will be present for the meeting to be deemed quorate.

19. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting if possible. If a member does not attend more than two consecutive meetings the Committee Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.
20. Board Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.
21. If the ARAC Chair is not present at a meeting, an alternative Board member will be co-opted to chair that meeting.
22. The Chair of the Board may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. A Board Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.
23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.
24. Up to two observers from the Department of Health and Social Care will normally be invited to attend meetings of the Committee.
25. The ARAC may ask any other officials of the Board to attend to assist it with its discussions on any particular matter.
26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

## **Frequency of meetings**

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the Board.
28. The Chair of the ARAC may convene additional meetings as they deem necessary.
29. External Audit may request a meeting of the Committee if they consider one necessary.

30. The Accounting Officer or the Board may ask the ARAC to convene further meetings to discuss particular issues on which the Committee's advice is sought.

## Secretariat responsibilities

31. The ~~Executive Assistant~~Private Office will have secretariat responsibility for the Committee.
32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.
33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.
34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.
35. The minutes will be approved by the ARAC Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.
36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee's Chair prior to being sent to the Head of Communications for publication.

## Version history

37. These Terms of Reference will be reviewed annually by the ARAC and will be approved by the Board following that review.

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Director of Resources / Governance and Quality Manager	Authority Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Director of Resources / Head of Finance and Governance	
15.2	2 November 2016	Updated per November 2016 minutes	Head of Finance and Governance	ARAC Members 09-11-2017
15.3	18 September 2018 (reviewed again 13 July 2020)	Amend role to Board Secretary	Head of Finance and Governance	Board Members
15.4	January 2022	Updated to align with other governance documents	Head of Finance and Governance	Board Members
<u>15.5</u>	<u>January 2023</u>	<u>Reviewed with small amendments</u>	<u>Head of Finance and Governance</u>	

## Human Tissue Authority Board meeting

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**Date:** 9 March 2023  
**Paper reference:** HTA 07/23  
**Agenda item:** 11  
**Approved by:** Ellen Donovan

### OFFICIAL

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## Remuneration Committee Update

### Purpose of paper

1. This paper provides an overview of the business of the Remuneration Committee meetings held on 17 November 2022 and 18 January 2023.

### Action required

2. The Board is asked to note the content of this report.

### Remco meeting – 17 November 2022

3. The Committee met on the 17 November 2022 and approved the minutes of the meeting held on 22 September 2022.
4. In its one substantive item the Committee noted the Senior Salaries Review Body recommendations relating to 2022 pay increases for those on the Executive Senior Manager (ESM) scales, the Government's response to these recommendations and the guidance on implementation received from the DHSC Remuneration Committee.

5. The Committee agreed to award all eligible HTA Directors the full 3% permissible increase but elected not to pursue non-consolidated performance awards in 2022.

### **Remco meeting – 18 January 2023**

6. The Committee met on the 18 January 2023, approving the minutes of the meeting held on 17 November 2022 and that the actions had been completed. The Committee considered three substantive items.

#### *Exceptional case to exceed HTA Pay band*

7. The Committee considered an exception request to award a starting salary above the maximum of the evaluated pay band. The Committee received assurance from DHSC that it had the appropriate discretion to make such an award and having considered supporting information on both the small amount requested and that this individual would be within pay scale from August 2023, agreed to this request. The Committee confirmed that this did not set a precedent and that any future instances would be considered by Remco on their individual merits.

#### *Organisational Development /Culture Programme*

8. The Committee received a verbal update on the progress of the HTA organisation development activity. It noted the high levels of engagement reported and the progress on agreeing a new Vision and Mission for the organisation and the development of revised values and behaviours. The Committee were pleased that this first phase would be complete by March 2023, in line with business plan commitments.

#### *Home worker travel to office costs*

9. Finally, the Committee noted a paper on recent changes to tax advice relating to home to office travel for HTA employees engaged on homeworking contracts. The Committee noted the revised advice provided from the Central Government Tax Centre of Excellence and consultations that the HTA Executive had undertaken with other Arms Length Bodies who offer home worker terms similar to those enjoyed by HTA employees.

10. The Committee noted the consistency of the HTA approach with that and other Arms Length bodies and agreed, subject to confirmation by DHSC, with the Executives proposal that the current arrangements should remain unchanged.

**Recommendation**

11. The Board is asked to note the content of this report.

# Human Tissue Authority

## Board Meeting

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**Date:** 09 March 2023

**Paper reference:** HTA 08/23

**Agenda item:** 12

**Author:** Richard Sydee, Director of Resources / Louise Dineley, Director of Data, Technology & Development

**Protective marking:** OFFICIAL

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## Outsourced Shared Services – HR & IT

### Purpose of paper

1. To provide an update on the work to progress and transition to an outsourced shared service for HR and IT operations.

### Decision making to date

2. To note the decision on a preferred provider and discussions to date.
3. The SMT agreed this paper on 20 February 2023 for submission to the HTA Board.

### Action required

4. The Board are asked to note progress to date and the timeline for decision, and possible transition to an external HR & IT shared service provision.

## HR Outsourcing

### Background

5. The HTA Executive has been considering the possibility of delivering its Human Resource function through an outsourced/shared service function. Given the particular nuances and complexity of the HTA's position as an ALB of DHSC, with a combination of Civil Service and NHS terms and conditions, careful consideration had been given to potential partners.
6. Outsourcing to a commercial partner was dismissed given the material increased cost compared to the in-house provision with no demonstrable increase in resilience or expertise relating to our particular circumstances.
7. Possible partners were sought from both other ALBs and NHS bodies, with initial discussions providing further insight into the likely provision available and indications that this could be achieved at comparable costs to existing budgets.
8. The Executive considered the feedback from this initial consultation exercise and agreed that the Care Quality Commission (CQC), as both a Health ALB and Regulator, provided the best option for further discussions. CQC are now the preferred partner for any option to outsource HR services.

### Progress to date

9. Initial discussions with CQC have been promising, CQC already provide full HR services to two smaller independent bodies of comparable scale to HTA, although both bodies have fully adopted CQC policies and conditions of employment for all staff.
10. In principle agreement has been reached with CQC Executive to take on HR services for HTA, and discussions are now focussed on a concurrent feasibility and design phase to establish a formal "service offer" to HTA.
11. Discussions have been delayed by wider operating issues, CQC are currently engaged in their own corporate service redesign and hence the CQC resource available to progress matters has been unable to match the HTA's appetite and preferred speed of transition. We still retain some optimism that a formal proposal for decision by the HTA Executive can be provided before the end of this financial year and should the option for the CQC shared service provision be confirmed, transition could commence in quarter one of the 2023/24 business year.

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12. Given the need to align several policies and systems, as well as a preferred approach to ensuring CQC colleagues can build a good working knowledge of the HTA and its bespoke requirements, we anticipate the handover process not being completed until December 2023.
13. An indicative high-level plan is contained at **Annex A** to this paper.

## IT Shared Service

### Case for change

14. The HTA IT function has historically experienced a significant level of underinvestment. As work has progressed to explore the process of transitioning to an IT Shared Service model, the impact of this underinvestment and the work needed to support a safe move and transition is becoming increasingly obvious. This “housekeeping” activity extends to outside of IT and relates to the wider use of HTA systems.
15. The initial scoping of this project has focused on systems maintenance, licenses and the provision of support specifically first line support. The draft service catalogue details the requirements in more detail and identified additional functions and activities historically co-ordinated through IT for further consideration. An example of additional activities is the provision of IT training for staff to strengthen staff capability and confidence to optimise the use of HTA systems, such as, in using the full functionality of deployed applications to the resolution of common helpdesk requests.
16. To date, resource estimates for future requirements have been informed by existing resources (financial budgets and staffing establishment) and resource models in comparable organisations. Early indications based on estimated costs and resource modelling is that the HTA’s current operating budget for IT is lower than required.
17. In addition to the core project to transition IT services to a Shared Service model, we need to ensure the “health” of existing systems in order to minimise any risk to business continuity. An early baseline review has identified activities that are required to help prepare for a transition of services and provide resilience during any transition. Progress of this work along with the overall project is and has been constrained by the resources available.
18. Throughout Q3 of 2022/23, the HTA has been actively recruiting additional resources and specifically technical expertise to support this project and the

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preparatory work that is needed. In mid-January we appointed a Project Manager to support this and other projects across the Directorate. Whilst this appointment will provide valuable resource and capacity to the management of the project, the gap in technical expertise and operational capacity remains a significant constraint.

19. At the time of writing, alternative models for securing this technical resource including options for collaborating with other ALB partners are being explored.

## **Benefits to be realised**

20. The IT Shared Service project is part of a longer term strategy to develop the required capacity and capability for the HTA to support and benefit from digital and technological innovation in our ways of working.

21. The transition to an IT Shared Service model will enable the HTA to:

- strengthen the capacity and capability of its systems and improve the overall resilience of the function through access to additional resources and greater investment in digital and technological innovations.
- move from a standalone approach to systems maintenance, licenses and the provision of support, (specifically first line support), to an integrated approach to interoperability of systems, reporting and future capability
- support capacity and capability building across systems

## **Work to date**

22. The appointment of a Project Manager in recent weeks has enabled work to recommence on the scoping of the project and the development of a high-level road map of delivery. This work, which includes key milestones, deliverables including dependencies with business-as-usual operations and the identification of risks and issues, will be used to finalise the full business case. It is anticipated that the full business case will be considered by the Executive in early Q1 2023/24.

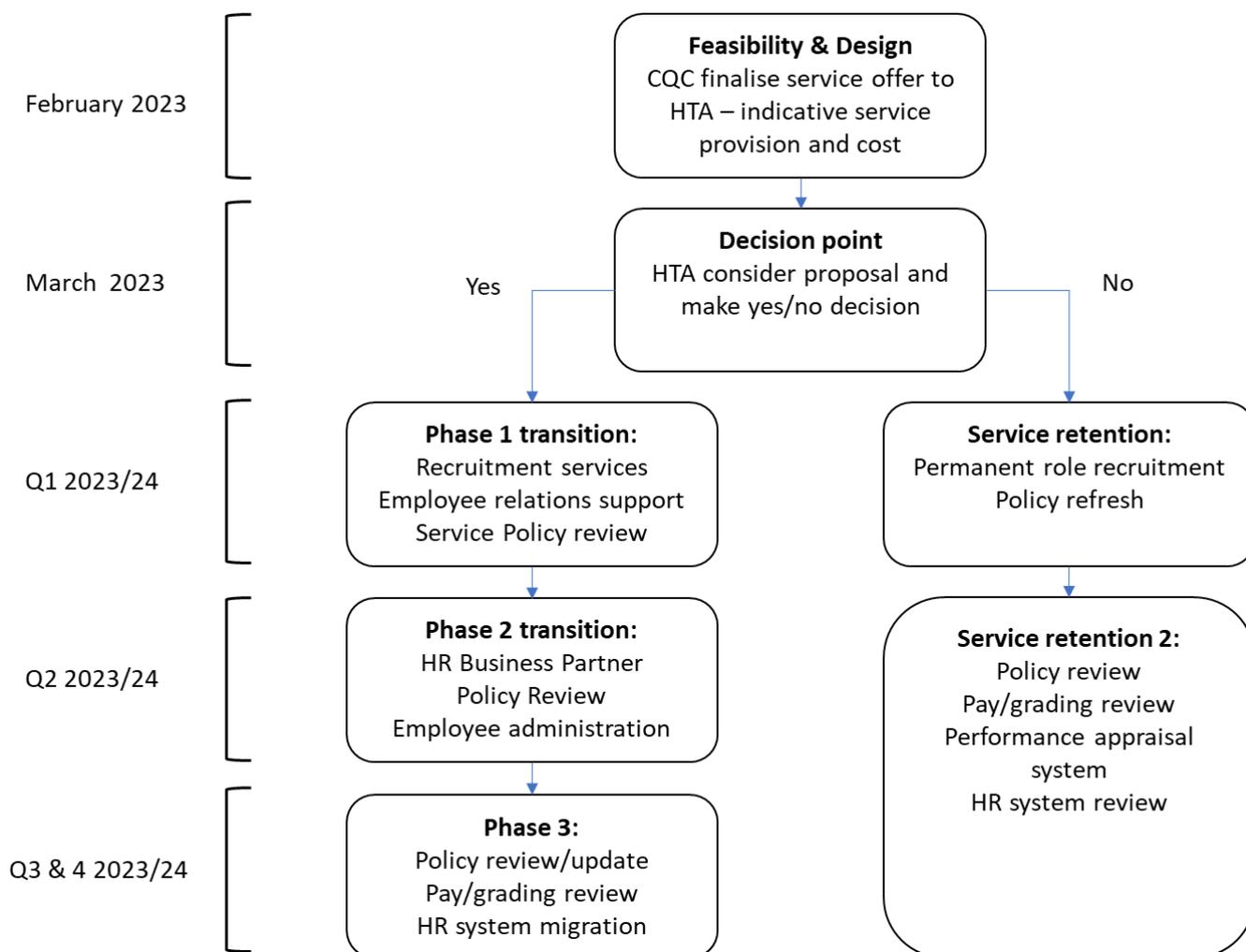
## **Recommendation**

23. The Board are asked to note progress to date and the timeline for decision, and possible transition to an external HR & IT shared service provision.

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## Annex A – High level plan to decision and possible service transition for HTA HR function.



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# Minutes of the meeting of the Human Tissue Authority Board

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**Date:** 3 November 2022

**Time:** 10.00 – 12.00 hrs

**Venue:** 2RP

**Meeting Number:** 102

**Protective Marking:** OFFICIAL

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## Attendees:

### Board Members

Lynne Berry, HTA Chair  
Professor Deborah Bowman  
Tom Chakraborti  
Professor Gary Crowe  
Helen Dodds  
Ellen Donovan  
Andy Greenfield  
Dave Lewis

### Observers

Maria Nyberg, Deputy Director Health  
Ethics, DHSC  
Jacky Cooper, Team Leader Human  
Tissue Policy and Ethics of Consent,  
DHSC

### HTA attendees

Dr Colin Sullivan, Chief Executive  
Louise Dineley, Director of Data,  
Technology and Development  
Nicolette Harrison, Director of  
Regulation, HTA  
John McDermott, Deputy Director for  
Performance & Corporate  
Governance  
Richard Sydee, Director of Resources  
Alison Margrave, Board Support  
(minutes)

### HTA Staff Observers

Jon Spencer, Head of Communication  
and Engagement  
Karen Wright, Customer Service  
Admin

## Item 1 – Welcome and apologies

1. The Chair welcomed Board Members, HTA Staff and observers from the Department of Health and Social Care to the meeting.
2. The Chair, on behalf of the Board, expressed thanked to Dr Charmaine Griffiths who had recently retired from the HTA Board.

## **Item 2 – Declarations of interest**

3. The Chair asked Members if there were any declarations of interest of relevance to the agenda; none was declared.

## **Item 3 – Chair's Report**

4. The Chair provided an oral update on the following items:
  - Meetings with the Chief Executive and Senior Management Team, especially regarding preparing for the various Governance Meetings.
  - Participating in the staff weekly exchange call.
  - One-to-one meetings with all Board Members.
  - Correspondence with the Secretary of State.
  - Preparation for the ALB Chief Executives and Chairs meeting taking place on 4 November.

## **Item 4 – Chief Executive's Report (HTA 30/22)**

5. Dr Colin Sullivan introduced the report and highlighted a number of key issues in Quarter 2 and the beginning of Quarter 3, including the Fuller Independent Inquiry, organ tourism, meetings with other ALBs and public expenditure pressures.
6. In response to a question, he provided further information about the meetings with CQC
7. In response to a query with regards to staffing, he provided further insight about staff recruitment and retention and the possible impact on delivery. He also spoke about the measures implemented for staff wellbeing and the work undertaken in organisational development.
8. In response to a question, he provided further information regarding expenditure restrictions and the additional checks that HTA had implemented to ensure they adopted restrictions required by DHSC. The Board spoke of the importance for HTA to deliver on in-year essential development and the aspirations for future growth, and the need to ensure that progress is communicated clearly to DHSC through the accountability review meetings.

9. The Board noted the report.

### **Item 5 – HTA Performance Report (HTA 31/22)**

10. Dr Colin Sullivan introduced the report and provided highlights to Board Members regarding operational performance, the financial position; the review of the Strategic Risk Register; KPI reporting in the data annex and people matters.
11. In response to a question regarding KPI's, he outlined to the Board the new monthly Business Portfolio Reporting process and that revised KPI data would be brought to the next Board meeting drawing upon the pack developed for Portfolio Management.
12. In response to questions, he provided further information about the proposed shared services projects, the scope of these and the work proposed for the review of inspections.
13. The Board discussed the interdependency of several issues, mostly linked to recruiting sufficient staff to progress development activities. The Board discussed the role and importance of the HTA within the wider regulatory system.
14. The Board noted the report.

### **Item 6 – Update from DHSC Sponsor Team**

15. Representatives from DHSC provided an update to the HTA Board regarding the changes in the Ministerial Team and confirmed that HTA's Sponsor Minister would be Maria Caulfield.
16. Confirmation was given for the next accountability review meeting taking place in early December. DHSC representatives thanked HTA for the invitation to participate in the roundtable discussions with representatives from the devolved governments of Wales and Northern Ireland.

## **Item 7 – Fees Proposal (HTA 32/22)**

17. Richard Sydee introduced the report and provided further information regarding the fees model used by HTA, assumptions made within the report, the detailed discussion by the Audit & Risk Committee and their recommendations. He talked through the recommendations contained in the report and provided further information, as required.
18. The Board discussed the paper in-depth, noting the proposed engagement with sectors that would be affected by any proposed increases. The Board discussed the potential impact of decreased levels of Grant-In-Aid and how this could affect HTA's overall budget and service provision.

### **Action 1**

19. The Board agreed, in relation to fees/income:
- SMT's recommendation at paragraph 16 of HTA 32/22, to adjust the amounts recovered from each sector to better reflect the regulatory effort expended in each sector with a two-year phasing in of the increased charges for the PM sector
  - The adoption of the revised fees as set out in Annex C of HTA 32/22
  - The 4.1% increase in the HTA's budget for 2023/24

## **Item 8 – Audit, Risk and Assurance Committee Update (HTA 33/22)**

20. Professor Gary Crowe, Chair of the Audit and Risk Assurance Committee, presented the report to the Board. He provided several highlights to the Board on the Committee's discussions.
21. He reported that the Committee had received adequate assurance that a recovery plan is in place for HTA's submission for DSPT (Data Security & Protection Toolkit).
22. The Committee had held a deep dive discussion on a particular risk on the Strategic Risk Register (the risk linked to Finance) and arising from these discussions had asked the Executive to provide further evidence of actions taken to mitigate these risks and bring them back into tolerance level.
23. The Board noted the report.

### **Item 9 – Remuneration Committee Update (HTA 34/22)**

24. Ellen Donovan, Chair of the Remuneration Committee, presented the report to the Board. She provided several highlights on the Committee's discussion regarding organisational development and communication.
25. The Board noted the report.

### **Item 10 – Minutes of 14 July 2022 (HTA 35/22)**

26. The Board agreed the draft minutes as an accurate record of the meeting 14 July 2022.

### **Item 11 – Matters arising from 14 July 2022 (HTA 36/22)**

27. The Board noted the matters arising report.

### **Item 12 – Business Planning**

28. John McDermott provided the Board with a short presentation regarding the review of the current Business Plan and preparation for the 23/24 Business Plan. He highlighted the key dates in preparing next year's plan and posed several questions regarding challenges and priorities.
29. The Board then held an in-depth discussion about priorities for next year. It was highlighted that for future developments to succeed, priorities should include the essential building blocks for the future. These will allow the HTA to continue to deliver its regulatory obligations whilst being creative and innovative in a complex political situation.

### **Item 13 – Any other business**

30. There being no further business the Chair thanked members for their contributions and closed the meeting. She also thanked all who had prepared papers and attended the meeting.

## **Date of Next Meeting**

9 March 2023

## **Meeting actions**

### **Action 1**

The Board agreed, in relation to fees/income:

- SMT's recommendation at paragraph 16 of HTA 32/22, to adjust the amounts recovered from each sector to better reflect the regulatory effort expended in each sector with a two-year phasing in of the increased charges for the PM sector
- The adoption of the revised fees as set out in Annex C of HTA 32/22
- The 4.1% increase in the HTA's budget for 2023/24

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# Human Tissue Authority Board meeting

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**Date:** 9 March 2023  
**Paper reference:** HTA 10/23  
**Agenda item:** 14  
**Author:** Alison Margrave, Board Support

**OFFICIAL**

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## Matters Arising from previous HTA Board meetings

### Purpose of paper

1. To provide an update to the Board on the actions arising from previous Board Meetings. Colour coding used is blue = completed, green = on target and amber = at risk of not meeting target date.

### Decision making to date

2. The SMT agreed this paper on 9 February 2023 for submission to the Board.

### Action required

3. The Board is to note the report.

Number	Date Added	Action	Assigned to	Target date	Revised date	Status
B_2022_10	July 22	The Board noted the review of the former Development Programme and the reframed work and endorsed the revised scope of work. The Board also agreed that a Programme Initiation Document (PID), be shared with the Board following agreement by SMT in Q2.	Director of Data, Technology and Development	Sept 22	March 2023	Delay in appointment of the Project Manager until mid January. Initial draft of the PID completed, aim to finalise by the end March.
B_2022_12	July 22	The Board agreed in principle to the redefined strategic risks for the 2022/23 business year as shown at annex A of HTA 25/22 and asked the Audit & Risk Assurance Committee to consider the questions raised in relation to risks 2, 3 and 7.	Director of Resources	Oct 22	Jan 23	<b>Completed</b> ARAC discussed at their January 23 Meeting.
B_2022_13	Nov 22	The Board agreed, in relation to fees/income: <ul style="list-style-type: none"> <li>SMT's recommendation at paragraph 16 of HTA 32/22, to adjust the amounts recovered from each sector to better reflect the regulatory effort expended in each sector with a two-year phasing in of the increased charges for the PM sector</li> <li>The adoption of the revised fees as set out in Annex C of HTA 32/22</li> <li>The 4.1% increase in the HTA's budget for 2023/24</li> </ul>	Director of Resources	Mar 23		<b>Completed.</b>

blue = completed, green = on target and amber = at risk of not meeting target date