

# Human Tissue Authority Board Meeting

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**Paper reference:** HTA 29/23  
**Agenda item:** 6  
**Author:** CEO and Senior Management Team

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## HTA Performance Report

### Purpose of paper

1. This paper informs the Board of the HTA's performance in Quarter 2 (Q2) against our objectives and operational delivery targets.
2. In addition, it provides an early indication of the initial performance in Quarter 3 (Q3).
3. Core operations areas from our Business Plan with formal Key Performance Indicators (KPIs) have been included as topics within this paper, in the order and nomenclature from that document, so as to allow the Board easy read across. **Annex A** provides the KPI and Project Data Overview for Q2 (final) and **Annex B** gives the KPI and Project Data Overview for Q3 (latest).

### Action required

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

### Regulation

5. There are four Regulation Directorate KPIs. At the end of September all operational KPIs were green. Whilst the KPI for successful completion of all HA inspections due for the year within the statutory two-year time period is only reported at the end of the business year, at the end of Quarter 2 we were on track to meet this KPI.

6. By contrast, during Quarter 2, all four projects managed from within Regulation Directorate were at Red status, in each case principally because of resourcing issues. The Chief Executive's Report refers to the SMT Portfolio Board's consideration of these issues within the overall 23/24 Business Plan, with some adjustments required to scope, timescales and resource allocation for these projects as we moved into Quarter 3.
7. Planned activity to continue to develop our regulatory role in connection with organ donation and transplantation, which includes responding to the introduction of the amendment to s32 of the Human Tissue Act, to provide for some extra-territorial jurisdiction for the offence of commercial dealings in organs, remains at Red due to resource pressures. However, the actions to which we have committed to strengthen our existing Living Organ Donation (LOD) approvals process are progressing and were on track at the end of Quarter 2. The resourcing issues may impact our ability to keep this on track later in the year.
8. The LOD Team has continued to be busy above and beyond normal levels of activity with complex casework and enquiries. During Quarter 2, the HTA referred two cases of potential Human Tissue Act offences relating to LOD to the police. This is continuing to create a significant resource pressure for which additional support from DHSC (Department of Health & Social Care) is being sought.
9. The Data Collection exercise started in Quarter 1. Lack of resource delayed the project during Quarter 2 but it has re-started during Quarter 3 and will conclude within 23/24.
10. Phase 1 of the Review of Inspections work was initiated at the end of Quarter 1, with the draft report received and considered by the HTA in Quarter 2. This helped inform the "Innovation in Inspections" paper that was discussed by the Board at the September meeting. Given resource constraints emerging in-year, Phase 2 will now be reviewed and delayed to the 24/25 business year.
11. Work to develop and embed the Evaluated Self-Assessments (ESAs) approach has continued throughout Q2, with a total of 13 ESAs completed in the Research sector. This work also informed the Innovation in Inspection paper discussed at the previous Board meeting and is a good example of home-grown development to increase our regulatory reach and efficiency. We are rolling out this approach further in the second half of 23/24.

## **Communications (including stakeholder engagement)**

12. In line with the communications KPI, the communications team handled all media enquiries within set deadlines. A number of the enquiries related to the use of umbilical cord blood and the HTA's approval of the UK's first womb transplant. We supported the passing of Deemed Consent in NI, issuing a press notice and legal directions to support the changes.
13. A roundtable on the management of the deceased was held with key stakeholders on the 19 July. The intelligence we gained from this event and our data collection exercise has led to further regulatory activity in Q3, with the issuing of legal directions and a webinar with license holders in the postmortem sector.
14. The communications team have also been supporting the delivery of core business, issuing four Regulatory Updates in Q2 and one Regulatory Alert. We continue to engage regularly on social media on core HTA business, sustaining good levels of engagement. Internally the team support engagement through the weekly exchange call for staff, Ask the CEO sessions, Q&A sessions with internal staff, and shared regular news roundups.

## **Policy**

15. Throughout Q2, and into Q3, over a 5-month period the work on "assessing our impact" has been progressing. This assessment is the first structured and collective assessment of the HTA's impact as a regulator. The findings, which are discussed in a separate paper are overall very positive regarding the impact and the value added by the HTA as the regulator for human tissue. The work also identified opportunities for improvement which will need to be considered and elements agreed can then be prioritised through our planning framework.
16. Work has also been progressed to prepare for a review of the HTA's guidance on the handling of pregnancy remains. This review follows a recommendation, from an independent study on pregnancy loss published in July 2023, which proposed a strengthening of guidance in relation to pregnancy loss. Despite a limited regulatory remit for the HTA in relation to pregnancy loss, we will be reviewing our guidance on the handling of pregnancy loss remains by the end of March 2024.
17. Over the remainder of the year, the Policy function will be primarily focussed on the delivery of emerging areas of activity such as the Duty to Report and Xenotransplantation, as well as, progressing the reprioritised business plan

activity. This includes the establishment of the Insight Network which has been deferred to Quarter 4.

## **Information Technology (including data and digital)**

18. Over the last quarter, IT activity has been focused on day-to-day operations and maintenance of the existing infrastructure. In early October, ARAC received its regular report on Cyber Security and system resilience. The report summarised a position of good performance across our processes and systems and in responding to any actual or potential threats. Internal performance indicators for the period have remained at 100% with no unplanned downtime and in full compliance with Response to any NHS cyber alerts (RTANCA).
19. Progress has also been made in the development of the Regulatory Insight Model & Index (RIMI) with the identification of an emerging set of tiered indicators based on significance and their insight to risk inherent in performance, establishments, and sectors. We are continuing to refine these indicators and a supporting intelligence model, in advance of contracting external support to progress the RIMI project from Q4.
20. The new Head of IT joined the HTA on 1 November 2023. This appointment provides important and much needed capacity to the function.

## **Corporate Services**

21. During Q2, the HTA received 11 Freedom of Information (FOI) requests. All the FOI requests received, except one, were dealt with in line with the statutory timeframe. We received a complex request which required legal advice and additional time to apply the relevant exemptions. We maintained open communication with the requester who was understanding and appreciative of the updates.
22. In Q2, no complaints were received by the HTA.

## **Finance**

23. The table below is the summary position as at the 30 September 2023 (Q2 of the 2023/24 business year). Year to date, we have a surplus against budget of £434k. This is largely affected by the phasing of the budget for our Grant in aid and Non-cash income. The budget will be re-profiled at the end of Q3.

### **Table 1: Summary income and Expenditure: year to date**

|                                    | Actuals<br>£000s | Budget<br>£000s | Variance<br>£ | Variance<br>% |
|------------------------------------|------------------|-----------------|---------------|---------------|
| <b>Income</b>                      |                  |                 |               |               |
| Grant-in-aid                       | 473              | -               | 473           | -             |
| Non-cash                           | 53               | -               | 53            | -             |
| Licence Fees                       | 4,379            | 4,436           | (57)          | (1.3)         |
| Other Income                       | 183              | 159             | 24            | 15.1          |
| <b>Total Income</b>                | <b>5,088</b>     | <b>4,595</b>    | <b>493</b>    | <b>10.7</b>   |
| <b>Expenditure</b>                 |                  |                 |               |               |
| Salaries and Wages                 | 2,015            | 2,064           | (49)          | (2.4)         |
| Travel and Subsistence             | 79               | 68              | 11            | 16.2          |
| Other staff costs <sup>1</sup>     | 53               | 83              | (30)          | (36.1)        |
| Other operating costs <sup>1</sup> | 23               | 3               | 20            | 158.3         |
| IT & Telecommunications            | 180              | 222             | (42)          | (19.3)        |
| Legal / Professional               | 70               | 69              | 1             | 0.7           |
| Accommodation                      | 99               | 49              | 50            | 102.04        |
| Project costs                      | 147              | 58              | 89            | 153.4         |
| Non-cash                           | 66               | 57              | 9             | 15.8          |
| <b>Total costs</b>                 | <b>2,731</b>     | <b>2,673</b>    | <b>58</b>     | <b>2.17</b>   |
| <b>Net income</b>                  | <b>2,357</b>     | <b>1,922</b>    | <b>434</b>    | <b>(3.7)</b>  |

## Income

24. Income is over budget by £493k (10.7%). This is due to the profile of our Grant in aid and non-cash cover. This is offset by the reduction in licence fee income (£57k) or 1.3%. The main reduction is within the Human Application sector.

25. September was the last period in which we issue licence fee invoices. The focus is now to ensure these fees are recovered by the end of the year.

## Expenditure

### 26. Explanation of significant variances (>£10k) are as follows:

- **Salaries and wages** – are under budget by £49k due to vacancies being carried for a few months and the dates of new starters being slightly different from the budget.

<sup>1</sup> These were originally reported together at Q2.

- **Travel and Subsistence** – is over budget by £11k. The majority of the overspend relates to home to office travel, spend year to date is £28k versus budget of £18k.
- **Other staff costs** – are underspent by £30k which is represented by underspends within; recruitment (£25k), staff training £15k which is offset by overspends within conference attendance, staff benefits, staff welfare and subscriptions totalling (£10k).
- **Other operating costs** – are over budget (£20k) represented by overspend within consultancy (Fuller costs) and printing costs which were high due to changes made within the annual accounts production.
- **IT & Telecommunications** – an underspend of £42k represented by underspends within consumables costs of £4k and IT consultancy £32k. However, we expect there to be spend against IT consultancy towards the end of Q3. The remaining variances relate to maintenance costs (3k) and Telephone costs of £3k.
- **Accommodation** – is overspending against budget (£50k) due to increased building and service charges being passed on by DHSC as part of our lease.

27. The above costs will continue to be closely monitored throughout the year.

## Forecast outturn

28. Below is a summary of our forecast outturn for the year.

|                        | Forecast<br>£000s | Budget<br>£000s | Variance<br>£ | Variance<br>% |
|------------------------|-------------------|-----------------|---------------|---------------|
| <b>Income</b>          |                   |                 |               |               |
| Grant-in-aid           | 752               | 763             | (11)          | (1.4)         |
| Non-cash               | 107               | 107             | -             | -             |
| Licence Fees           | 4,420             | 4,481           | (61)          | (1.4)         |
| Other Income           | 209               | 185             | 24            | 12.9          |
| <b>Total Income</b>    | <b>5,488</b>      | <b>5,536</b>    | <b>(48)</b>   | <b>0.9</b>    |
| <b>Expenditure</b>     |                   |                 |               |               |
| Salaries and Wages     | 4,023             | 4,144           | (121)         | (2.9)         |
| Travel and Subsistence | 153               | 136             | 17            | (13.0)        |
| Other staff costs      | 110               | 141             | (31)          | (22.1)        |
| Other operating costs  | 35                | 8               | 27            | 341.6         |
| IT Telecommunications  | 402               | 406             | (4)           | (0.9)         |
| Legal / Professional   | 147               | 138             | 11            | 7.9           |
| Accommodation          | 152               | 171             | (19)          | (11.1)        |

|                        |              |              |            |            |
|------------------------|--------------|--------------|------------|------------|
| Non-cash               | 136          | 113          | 23         | 20.4       |
| Project costs          | 339          | 285          | 54         | 18.9       |
| <b>Total costs</b>     | <b>5,497</b> | <b>5,542</b> | <b>45</b>  | <b>0.8</b> |
| <b>Net expenditure</b> | <b>(9)</b>   | <b>(6)</b>   | <b>(3)</b> |            |

29. The above forecast reflects the deferment of some projects to the new year. The Project Costs line includes pieces of work on our website including accessibility, work on the Regulatory Insight Model and Index (RIMI) which is expected to commence early Q4 subject to business case approval, and 'Assessing Our Impact', the final report of which has been received. In addition, projects relating to the review of inspections costing of £180k in total, has been reduced to £90k with phase 2 (£90k) being deferred to 2024/25.

30. We monitor our spend each month and seek to defer activities to maintain a balanced position at year end.

## Other key performance indicators

### Debtors

31. Outstanding debt from licensing activities as at end of September is £2,872k represented by 700 establishments. This is slightly above the same period last year (£2,606k). Below is a breakdown of debtors by sector.

| Sector                | No. establishments | of | Value of debt £   | Percentage % |
|-----------------------|--------------------|----|-------------------|--------------|
| NHS                   | 219                |    | £1,605,297        | 56%          |
| Government bodies     | 4                  |    | £51,343           | 2%           |
| Local Authorities     | 27                 |    | £189,068          | 7%           |
| Non-Government bodies | 249                |    | £1,0263,160       | 35%          |
| Total                 | <b>499</b>         |    | <b>£2,871,868</b> |              |

32. The NHS debtors outstanding, relate to a mixture of the April (8) and September (200) 2023 billing run. We received payment from 136 establishments since the end of the 28 days period. We expect to collect the remaining accounts by year end.

33. Within Government bodies, one relates to a Devolved Government totalling £33k, and one to an ALB £8k. Both received invoices in June and are yet to pay. The balance is for Research and Postmortem fees for two establishments.

34. The Local Authorities, 27 in total, were all billed in September. As of early November, we have received payment from 14 of them.
35. The non-government establishments are either private companies or universities. Of the 249, we have received payment from 150 establishments since the billing run.

### **Financial risks and mitigations**

36. The key financial risk is our forecast overspend against budget. Whilst we are posting a small overspend, it is possible that this will increase if we are required to fund key pieces of work such as on Fuller Inquiry related activity and Duty to Report (DTR), if the Department is unable to release further GIA. Additional mitigations to maintain our position include deferring projects to the new business year, where practicable. As the year progresses our scope for flexibility to stay within budget reduces and the position is being kept under close scrutiny.

### **Audit and Risk**

37. At the end of Q2, two audits were conducted by our internal auditors. These were Data Security Protection Toolkit the objective of which is to satisfy the annual requirement for an independent assessment of our submission. A moderate assurance and high confidence level in the veracity of our self-assessment was received.
38. The second audit was Anti-fraud controls, the objective of which was to provide assurance on the adequacy of governance, risk management, and control frameworks in place to mitigate fraud related risks. A moderate assessment was received.
39. At Annex C you will find the summary of our strategic risks. The SMT reviewed the strategic risks in November and agreed that all risk levels remain the same, with the exception of Risk 3 (There is a risk that we will fail to manage public and professional expectations of human tissue regulation stemming from limitations in current legislation, misperception of HTA regulatory reach and innovations in the use of human tissues and cells), where it was felt that this risk had increased with the imminent release of the report from the Fuller Independent Inquiry.

### **Human Resources**

40. Transition to the new CQC HR shared service is progressing well but, without an internal HR team, it is taking longer than originally envisaged. This means that our

ability to prepare and analyse Management Information is reduced until we have fully transitioned. Currently available performance information is as follows:

### ***Sickness absence***

- There have been 47 days of sickness related absence in Q2 with unspecified causes of absence. These are distributed across 10 colleagues throughout this period. Sickness absence during Q2 was higher than the reported sickness absence in Q2 2022/23 at 19 days,

### ***Attrition***

- The last time this was reported was in Q2 2022 and since then the KPIs have not been updated due to changes within the HR department. The rate has now been calculated on a yearly rolling basis; fixed term contractors employed for over 12 months are included. For context we have included figures from April 2023 to September 2023 (May 2022 to October 2022).

- April-23 28.8%
- May-23 26.4%
- June-23 28.0%
- July-23 33.2%
- Aug-23 29.2%
- Sept-23 29.0%

- The above rates do not reflect the level of vacancies experienced during the summer of 2022/23.

### ***Training***

- The Q2 quarterly mandatory training programme which included Data Protection, Whistleblowing and Detecting and Reporting Fraud with a deadline of end of September, was completed by 80% of colleagues by the deadline. A report to SMT provides details of those yet to complete this training.

## **Quarter 3 early insights**

41. Whilst the operational KPIs in Regulation for October remain on track, licence revocations and some areas of other inactivity have reduced the number of HA establishments requiring an inspection this year. We are currently considering, based on risk, how to supplement the schedule with other proportionate inspection activity to meet our target.

42. A further two police referrals concerning ODT offences have been made in the first 6 weeks of Q3.
43. To date in Q3, the delivery of our core operations has been positive, with our Key Performance Indicators prioritised and on track for successful achievement at year end. However, a combination of our Q1 financial outturn, Q2 staffing issues in key technical positions and requests to absorb additional work in-year (such as engaging on the proposed Duty to Report) has meant that we have been unable to progress all the change activities that we had identified for delivery. The Board has been asked to agree to scaling back the proposed change activities for the remainder of the year (see the annex to the Chief Executive's Report for details).

## **Recommendation**

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

## Annex A – Quarterly Board Data Overview, 23/24 Quarter 2 Final Position

### Core Operations

| Business Plan KPIs          |   | <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid green; padding: 2px 5px; text-align: center;"><b>5</b><br/>On track</div> <div style="border: 1px solid orange; padding: 2px 5px; text-align: center;"><b>1</b><br/>Amber</div> <div style="border: 1px solid red; padding: 2px 5px; text-align: center;"><b>0</b><br/>Off track</div> </div> |              |             |              |              | 23/24 YTD     |
|-----------------------------|---|--|--------------|-------------|--------------|--------------|---------------|
|                             |   | May  | Jun          | Jul         | Aug          | Sep          |               |
| <b>Operational Delivery</b> |   |  |              |             |              |              |               |
| R<br>e<br>g                 | 222 inspections covering all sectors [measured quarterly against projection for the quarter]                  | 19   | 20           | 22          | 20           | 24           | 124           |
|                             | 100% of panel cases actioned within 10 working days   | 100% (12/12)   | 100% (39/39) | 96% (22/23) | 100% (27/27) | 100% (34/34) | 99% (149/150) |
|                             | 100% of required HA inspections are undertaken during the business year                                       | N/A  | N/A          | N/A         | N/A          | N/A          | N/A           |
|                             | Median age of open Corrective and Preventative Actions (CAPAs) for major shortfalls should not exceed 90 days | 106  | 80           | 80          | 106          | 46           | N/A           |
| D<br>T<br>&<br>D            | 90% media responses provided to deadlines   | 100% (3/3)   | 100% (6/6)   | 100% (1/1)  | 100% (5/6)   | % (1)        | 95% (21/22)   |
|                             | Server downtime less than 3% (within working hours and excluding planned testing)                             | 0%   | 0%           | 0%          |              |              | 0%            |
|                             | 100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours                 | 100%   | 100%         | 100%        |              |              | 100%          |
| P<br>&<br>C<br>G            | 100% of FOIs responded to within 20 working days  | 100% (3/3)   | 100% (3/3)   | 100% (3/3)  | 100% (3/3)   | 100% (3/3)   | 100% (17/17)  |

May Jun Jul Aug Sep 23/24 YTD

People & Capability

|           |   |       |     |          |     |     |          |
|-----------|---|-------|-----|----------|-----|-----|----------|
| Resources | Surplus of income / expenditure no more than 5% of budget | N/A   | 3%  | N/A      | N/A | N/A | N/A      |
|           | Debt no more than 3% of income at year end                | N/A   | N/A | N/A      | N/A | N/A | 2%       |
|           | Unqualified external audit opinion received               | N/A   | N/A | Received | N/A | N/A | Received |
|           | Attrition rate no more than 15%                           | 0%    |     |          |     |     | 0%       |
|           | Staff sickness no more than 3%                            | 0.56% |     |          |     |     | 0.29%    |

## Change Activities

| Project    |                                 | Jul 23             | Aug 23 | Sep 23 | Commentary for Board Review |   |
|------------|---------------------------------|--------------------|--------|--------|-----------------------------|---|
| Activities | Create a new HTA strategy       | Louise Dineley     | W      | W      | G                           | The new strategy will to be delivered as a rolling 3-year plan. Year 1 will complete residuals from the 2021-2024 strategy and build the foundation for future years  |
|            | Public Bodies review            | Louise Dineley     | W      | W      | W                           | Approach to deliver and report on Project feasibility in discussion. Project anticipated start date in 24/25  |
|            | Assessment of our impact        | Louise Dineley     | G      | G      | G                           | The Project group held a kick-off meeting with Kaleidoscope (the consultancy firm that has been appointed to complete the work) and desk-based research and planning for an evaluation framework is underway. The next steps are to finalise the contract / agreement, communicate the aims and objectives with the organisation, and engage with key internal stakeholders |
|            | Establish an insight network    | Louise Dineley     | A      | A      | R                           | This Project is highly dependent on the revision of the horizon scanning process that is being completed as part of BAU activity. However, work is being done to determine the purpose and governance – and to ensure there is internal agreement on the purpose and governance of the insight network  |
|            | Data collection exercise        | Nicolette Harrison | R      | R      | A                           | A sector-focused data collection exercise to inform our assessment of risk: 95% responses received, in the process of collecting outstanding data. Reviewing options for analysis, reporting and communications with establishments.  |
|            | Review of inspections           | Nicolette Harrison | R      | R      | R                           | External consultants submitted Phase1 report. Phase 2 budget (for external contractor) not available in current business year. Reviewing recommendations delivered from Phase 1 and pathway to implementation. Considering Phase 2 specification redesign and alternative delivery options  |
|            | Independent Inquiry (Fuller)    | Nicolette Harrison | R      | R      | R                           | Continuing activity to provide evidence and input into Sir Jonathan Michael's Independent Inquiry. Considering resourcing needs/options required following release of Phase 1 report (Maxwellisation process): responding to Inquiry and coordination with DHSC   |
|            | Living Organ Donation approvals | Nicolette Harrison | R      | R      | R                           | There is insufficient capacity within the BAU LOD team to d/w this project and the significant increase in BAU work, some of which directly relates to this process (LOD approvals), other relates to the introduction of s32A HT Act offences. Approval for at least an additional 1 x FTE to increase capacity  |
|            | Retained EU Law Bill            | Louise Dineley     | W      | W      | W                           | Work may not be required – Project put back to pipeline   |
|            | Windsor Framework               | Louise Dineley     | W      | W      | W                           | Work may not be required – Project put back to pipeline   |

| Project    |  | Sponsor        | Jul 23 | Aug 23 | Sep 23 | Commentary for Board Review  |
|------------|--|----------------|--------|--------|--------|--|
| Activities | Guidance on pregnancy loss                       | Louise Dineley | W      | W      | W      | Work may not be required – Project put back to pipeline  |
|            | Respond to external reviews                      | Louise Dineley | W      | W      | W      | Work may not be required – Project put back to pipeline  |
|            | Duty to report (concerning transplants overseas) | Louise Dineley | W      | W      | W      | Project not yet started – anticipated start date TBC   |
|            | IT strategy requirements                         | Louise Dineley | W      | W      | W      | Project not yet started – anticipated start date January 24'   |
|            | Records management review                        | Louise Dineley | W      | W      | W      | Project not yet started – anticipated start date December 23'  |
|            | Finance system review                            | Tom Skrinar    | W      | W      | W      | Work may not be required until 24/25 – Project put back to pipeline  |
|            | People strategy development                      | Tom Skrinar    | W      | W      | W      | Project not yet started – anticipated start date January 24'   |
|            | Performance management review                    | Tom Skrinar    | W      | W      | W      | Project not yet started – anticipated start date January 24'   |
|            | Data & Security Protection Toolkit               | Louise Dineley | G      | G      | C      | Project delivered and approved by Portfolio SMT  |
|            | Develop RIMI (Regulatory Insight Model & Index)  | Louise Dineley | W      | W      | A      | Draft DHSC BC shared with Finance to provide procurement and financial rigor ahead of CEO approval and submission to DHSC and Lord Markham. Meeting held with Director of Resources to review the DHSC Business Case                           |
|            | Start the outsource of IT                        | Louise Dineley | W      | W      | W      | Work cannot be progressed due to costs – Project put back to pipeline  |
|            | Outsource HR                                     | Tom Skrinar    | W      | W      | A      | Data transfer of HTA employee file complete. Not all services expected to be live are up and running Review recruitment service to identify what processes are not 'live'; awaiting 'process map' from CQC to share; review onboarding process |
|            | All Portfolio                                    | All SMT        | A      | A      | A      | Overall RAG status remains at Amber. However, work will need to be undertaken with more Projects subjected to Change Control with anticipated start dates pushed further back  |

HTA meeting papers are not policy documents.  
 Draft policies may be subject to revision following the HTA Board meeting

## Annex B – Quarterly Board Data Overview, 23/24 Quarter 3 Latest Position

### Core Operations

#### Business Plan KPIs

|                      |                   |                       |
|----------------------|-------------------|-----------------------|
| <b>8</b><br>On track | <b>1</b><br>Amber | <b>1</b><br>Off track |
|----------------------|-------------------|-----------------------|

|                             | Jun   | Jul          | Aug         | Sep          | Oct          | 23/24 YTD    |               |
|-----------------------------|---|--------------|-------------|--------------|--------------|--------------|---------------|
| <b>Operational Delivery</b> |   |              |             |              |              |              |               |
| R<br>e<br>g                 | 222 inspections covering all sectors [measured quarterly against projection for the quarter]                  | 20           | 22          | 20           | 24           | 19           | 146           |
|                             | 100% of panel cases actioned within 10 working days   | 100% (39/39) | 96% (22/23) | 100% (27/27) | 100% (34/34) | 100% (27/27) | 99% (176/177) |
|                             | 100% of required HA inspections are undertaken during the business year                                       | N/A          | N/A         | N/A          | N/A          | N/A          | N/A           |
|                             | Median age of open Corrective and Preventative Actions (CAPAs) for major shortfalls should not exceed 90 days | 80           | 80          | 106          | 46           | 76           | N/A           |
| D<br>T<br>&<br>D            | 90% media responses provided to deadlines   | 100% (6/6)   | 100% (1/1)  | 83% (5/6)    | 100% (4/4)   | 100% (5/5)   | 95% (21/22)   |
|                             | Server downtime less than 3% (within working hours and excluding planned testing)                             | 0%           | 0%          | 0%           | 0%           | 0%           | 0%            |
|                             | 100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours                 | 100%         | 100%        | 100%         | 100%         | 100%         | 100%          |
| P<br>&<br>C<br>G            | 100% of FOIs responded to within 20 working days  | 100% (3/3)   | 100% (3/3)  | 100% (3/3)   | 100% (3/3)   | 100% (3/3)   | 100% (20/20)  |

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Draft policies may be subject to revision following the HTA Board meeting

|                                | Jun   | Jul    | Aug      | Sep    | Oct    | 23/24 YTD |        |
|--------------------------------|---|--------|----------|--------|--------|-----------|--------|
| <b>People &amp; Capability</b> |   |        |          |        |        |           |        |
| Resources                      | Surplus of income / expenditure no more than 5% of budget | 3%     | N/A      | N/A    | N/A    | N/A       |        |
|                                | Debt no more than 3% of income at year end                | N/A    | N/A      | N/A    | N/A    | 2%        |        |
|                                | Unqualified external audit opinion received               | N/A    | Received | N/A    | N/A    | Received  |        |
|                                | Attrition rate no more than 15%                           | 28.00% | 33.20%   | 29.20% | 29.00% | 28.90%    | 29.07% |
|                                | Staff sickness no more than 3%                            | 0.89%  | 2.04%    | 1.01%  | 0.70%  | 1.82%     | 1.41%  |

## Change Activities

| Project    |                                 | Sponsor            | Sep 23 | Oct 23 | Nov 23 | Commentary for Board Review   |
|------------|---------------------------------|--------------------|--------|--------|--------|---|
| Activities | Create a new HTA strategy       | Louise Dineley     | G      | A      | A      | The Project is reaching a critical stage in delivery, Key activity in November will focus on engaging with SMT and BDT to develop themed workshops to build awareness and get buy in to the New Strategy. An early draft of the new strategy will be presented to the Board in December   |
|            | Public Bodies review            | Louise Dineley     | W      | W      | W      | Confirmation of an assessment date for the public bodies review assessment is not expected until 2024-25. Preliminary work to assess HTA readiness has been paused until Q4 due to other priorities   |
|            | Assessment of our impact        | Louise Dineley     | G      | G      | G      | This Project has delivered its main deliverables and is currently winding down  |
|            | Establish an insight network    | Louise Dineley     | A      | R      | R      | Progress on this Project has ceased as the Project Manager has now left the HTA. Given the need to deliver other high-priority work (such as Duty to Report), it will not be possible to deliver horizon scanning and the Insight Network until the Policy Manager vacancy is filled. For this reason, a change request is being submitted to pause this Project until there is resource within Policy and Development to deliver |
|            | Data collection exercise        | Nicolette Harrison | R      | A      | W      | Phase 2 of the Project to progress from Nov 20. We have yet to receive confirmation that Web Curl will re-run data collection response reports to include establishment licence number  |
|            | Review of inspections           | Nicolette Harrison | R      | R      | W      | We have outlined a draft response to the supplier providing two options to close negotiations and permanently resolve the matter. We have requested legal advice (pertaining to the draft communication) to ensure we remain compliant according to contractual obligations; legal response expected 20 November. An SMT paper outlining next steps expected 30 November  |
|            | Independent Inquiry (Fuller)    | Nicolette Harrison | R      | R      | A      | We await the publication of the Inquiry's initial report, exact date unknown but expected by the end of month. A business case was submitted to DHSC to extend the specialist contractor (by 10 days to the end of the FY). The department responded with additional queries which have been answered; we await their final response  |
|            | Living Organ Donation approvals | Nicolette Harrison | R      | R      | A      | There is no resource at the moment to re-scope the Project to the initial (more limited) scope agreed for year 23/24. Internal Audit recommendations have been absorbed and 6/10 completed so far   |
|            | Retained EU Law Bill            | Louise Dineley     | W      | W      | W      | Work may not be required – Project put back to pipeline   |
|            | Windsor Framework               | Louise Dineley     | W      | W      | W      | Work may not be required – Project put back to pipeline   |

HTA meeting papers are not policy documents.  
Draft policies may be subject to revision following the HTA Board meeting

| Project    |  | Sponsor        | Sep 23  | Oct 23 | Nov 23 | Commentary for Board Review  |
|------------|--|----------------|---------|--------|--------|--|
| Activities | Guidance on pregnancy loss                       | Louise Dineley | W       | W      | W      | Scope to be determined with DHSC   |
|            | Respond to external reviews                      | Louise Dineley | W       | W      | W      | Work may not be required – Project put back to pipeline  |
|            | Duty to report (concerning transplants overseas) | Louise Dineley | W       | W      | W      | Letter issued to DHSC on 27 October outlining how HTA can manage clinician enquiries regarding overseas transplants. Discussed with DHSC on 09 November. DHSC have requested a further breakdown on IT costs. Implementation scheduled for 01 April 2024, currently being resourced through existing BAU adding to stretch on capacity |
|            | IT strategy requirements                         | Louise Dineley | W       | W      | W      | Project not yet started – anticipated start date January 24'   |
|            | Records management review                        | Louise Dineley | W       | W      | W      | Project not yet started – anticipated start date December 23'  |
|            | Finance system review                            | Tom Skrinar    | W       | W      | W      | Work may not be required until 24/25 – Project put back to pipeline  |
|            | People strategy development                      | Tom Skrinar    | W       | W      | W      | Work may not be required until 24/25 – Project put back to pipeline  |
|            | Performance management review                    | Tom Skrinar    | W       | W      | W      | Work may not be required until 24/25 – Project put back to pipeline  |
|            | Data & Security Protection Toolkit               | Louise Dineley | G       | C      | C      | Project complete   |
|            | Develop RIMI (Regulatory Insight Model & Index)  | Louise Dineley | W       | A      | R      | The draft DHSC BC is almost ready for approval. This is impacting on procurements timescales to spend up to £50K this financial year on external professional services. The ITT will need to be issued by Dec 23 to ensure bids can be reviewed and the contract is awarded by Feb 24 at the latest                                    |
|            | Start the outsource of IT                        | Louise Dineley | W       | W      | W      | Work cannot be progressed due to costs – Project put back to pipeline  |
|            | Outsource HR                                     | Tom Skrinar    | W       | A      | A      | Data transfer of HTA employee file complete. Not all services expected to be live are up and running Review recruitment service to identify what processes are not 'live'; awaiting 'process map' from CQC to share; review onboarding process   |
|            | All  | Portfolio      | All SMT | A      | A      | A  |

| Red   | Amber  | Green   | Blue  | White                            |
|---|--|---|---|----------------------------------|
| <p>There is significant risk that the overall Activity will be delivered late or will fail to deliver everything within scope against the agreed baseline plan.</p> | <p>There is a risk that one or more milestones may be late, or that the full scope will not be delivered. However, there is a good possibility of implementing mitigations to bring the plan back on track to meet the schedule and delivery as planned.</p> | <p>Overall Activity is on track to be delivered against the baseline plan and there is no or minimal risk of milestones being delivered late.</p> | <p>Activity is complete having delivered all deliverables within scope, time, quality, cost and met benefits targets.</p> | <p><i>Activity not live.</i></p> |

## Annex C

### Strategic risk register 2023/24

#### 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>6 - Medium</b> | Director of Regulation                       | At tolerance    | <b>6</b>  | ↔ ↔ ↔ ↔ |
| R3: Failure to manage expectations of regulation  | Delivery e) and Development c)                      | <b>9 - Medium</b> | Director of Data, Technology & Development   | At tolerance    | <b>9</b>  | ↔ ↔ ↔ ↑ |
| R4: Failure to utilise our staff capabilities effectively   | Delivery, Development and Deployment (a, c, and d)  | <b>16 - High</b>  | Director of Resources                        | Above tolerance | <b>9</b>  | ↔ ↓ ↔ ↔ |
| R5: Insufficient or ineffective management of financial resources   | Deployment (b) objective                            | <b>9 - Medium</b> | Director of Resources                        | Above tolerance | <b>3</b>  | ↔ ↔ ↑ ↔ |
| R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure | Development (a-d) objectives                        | <b>9 - Medium</b> | Director of Data, Technology and Development | At tolerance    | <b>9</b>  | ↔ ↔ ↔ ↓ |

| Risk area  | Strategy link*  | Residual risk    | Risk owner  | Status          | Tolerance | Trend** |
|--|---|------------------|---|-----------------|-----------|---------|
| public trust and confidence is maintained  |   |                  |   |                 |           |         |
| R7 Failure to optimise the safe use of existing and emerging digital data and technology | Delivery (a-e),<br>Development (a-d)<br>Deployment (a, c and d) | <b>12 - High</b> | Director of Data, Technology and Development            | Above tolerance | <b>9</b>  | ↔↑↔↔    |
| R8: Failure to deliver the agreed Business Plan  | Delivery, Development and Deployment objectives                 | <b>12 - High</b> | Deputy Director of Performance and Corporate Governance | Above tolerance | <b>6</b>  | ↔↑↔↔    |

\* Strategic objectives 2021-2024:

\*\* This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g., ↑↔↓↔).

**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 believe we have a sound regulatory framework, which we continue to evolve in response to emerging risks and our own desire to continue to be risk-based, proportionate and data-driven.

Recent internal audits gave moderate assurance on Living Organ Donation approvals (March 2023) and the Effectiveness of the Inspection Process (April 2022).

Inspection is only part of our regulatory toolkit, and we continue to manage and respond to incident reports, whistleblowing / informant information and provide advice and guidance to our sectors and the public. We also have an active programme of engagement with our regulated sectors and other relevant stakeholders. We have also recently undertaken a risk-focused data collection exercise across all licensed establishments.

We continue to be transparent about our regulatory activities and outcomes through various means, including publication of inspection reports, performance data and other data, such as the quarterly summaries of closed incidents reported to us. These provide public assurance on our delivery of core regulatory functions. We also provide suitable public comment on matters within our remit where relevant, including on our website and through engagement with media.

We continue to support Sir Jonathan Michael's Independent Investigation into offending at a hospital mortuary and are pursuing a programme of related activity, including with wider sector stakeholders, as set out in our published advice to the Secretary of State in December 2021.

The recent sentencing of Circle Health Group to a £100,000 fine for a breach of the Human Tissue Act licensing requirements is the first such successful prosecution following an initial investigation and referral to the police by the HTA. This outcome should reassure the public and practitioners that the HTA will take strong action when made aware of potential offences.

SMT believes this risk is just below tolerance.

#### Actions to address risk:

Actions to strengthen or extend our approaches to our regulatory activity and increase transparency, to maintain public confidence in our approach to regulation, are noted below.

The HTA is continuing to evolve our approach to inspection, one of our core regulatory tools, introducing Evaluated Self-Assessments (EVAs) this year. We are on track for a further increased target for inspection coverage of 222 inspections for 2023/24 on existing licences, in addition to full assessment of all new licence applications.

The HTA has further refined its approach to living organ donation assessment in recognition of emerging risk and continues to play a significant role in multi-agency efforts to address risks related to some overseas travel for organ transplantation following the introduction of new offences under the Human Tissue Act in July 2022. An update was provided to the Board in June 2023, who approved our updated Living Organ Donation approvals policy.

During 2023/24, the HTA has extended our approach to transparency by publishing, as open data, further details about licences and regulatory activity in addition to our long-standing publication scheme, under which we publish summary details of closed incidents reported to us and all inspection reports.

Phase 2 of the Data Collection Exercise should restart during Quarter 3, through which we will aim to analyse and make use of the sector-specific risk data collected from all licensed establishments.

Following the completion of Phase 1 of the Review of Inspections in Quarter 2, the HTA will consider options for next steps during Quarter 3.

HTA's SMT continues to consider police referrals for all cases of potential offences under the Human Tissue Act and has referred a significantly increased number of cases to the police during 2023/24, principally in the Organ Donation and Transplantation (ODT) sphere.

The HTA has recognised that further revisions to its Police Referral and Warrants Policy would be beneficial, to better reflect the types of issues that arise in the ODT sphere, and that it would like to further develop a Compliance and Enforcement Strategy. These are activities to be considered for future years, given current resource constraints.

**R2: There is a risk that we will be unable to manage the lifecycle of a significant 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 | 2                    | 3      | 6 – Medium        |
| <b>Tolerance threshold:</b> |        |                |                      |        | <b>6 – Medium</b> |

### Commentary

#### At tolerance.

This risk concerns our ability to respond to and manage incidents, irrespective of their nature or cause whilst maintaining delivery of core business objectives. It is not confined to incidents relating to our regulatory remit.

In addition, those plans have also been deployed and found effective in several different circumstances over the past few years, including managing the impact of the pandemic and related restrictions, managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the trial of Fuller.

We have rewritten our Critical Incident Response Plan and tested it during 22/23 with a specialist consultant and also completed a similar exercise for our Business Continuity Plan in Q1 23/24. These have provided assurance on the effectiveness of our plans and our ability to use them.

Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial, and its potential to lead to a critical incident for the HTA, we now believe that the likelihood of this risk materialising has reduced. Sir Jonathan Michael's Independent Inquiry into the circumstances of Fuller's offending and any related wider concerns about settings in which the deceased are managed is still continuing. The Phase 1 report, focusing on how Fuller came to undertake his offending at Maidstone and Tunbridge Wells Hospital NHS Trust, apparently undetected, for many years is anticipated to be published during 2023. Phase 2, considering wider settings involved in managing the deceased, is expected to report in 2024.

Given there are currently police referrals being progressed on other unrelated matters within our broader remit, we believe there is still the potential for significant impact of an incident on our corporate objectives, either from those causes or others of which we may still be unaware.

Hence SMT considers the residual risk remains at the tolerance level.

#### Actions to address risk:

We will review both the Critical Incident Response Plan and the Business Continuity Plan annually.

We intend to undertake an annual test with all staff to ensure we are sufficiently prepared to manage incidents as they arise.

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

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

### **Commentary– to be updated based on agreement of the risk**

#### **At tolerance.**

The HTA has successfully completed year 1 of the delivery of its revised Communications & Engagement Strategy. Progress on embedding the strategy and new channels and tools that have been adopted was reported to the Board at the end of June.

The strategy is underpinned by a commitment for being more proactive and open in our communication and engagement with professionals and the public. In the last quarter we have continued to embed sector-based forums and roundtables, strengthen social media presence, and proactively respond to media enquiries. The work of the Comms & Engagement Team has contributed to the generation of positive headlines in relation to stories such as the first uterine transplant, press statements on successful prosecutions and strengthened partnerships with DHSC, ALBs and license holders.

In addition to the strategy there has been a significant focus in Q1 & 2 to ensure any published material including the experience of using the HTA website meets accessibility standards. The HTA's website has been independently audited and identified some further opportunities to improve accessibility. A revised accessibility statement has been approved and published.

The HTA remains committed to improving the accessibility of all published information.

The HTA acknowledges that to continue to regulate effectively it is important that it understand the impact of its activities whilst at the same time continuing to be responsive to innovation and growth across Life Sciences. The HTA is progressing work that seeks to assess the impact of the HTA as a regulator and its activities. This will culminate in a publication the aim of which will be to share insight and feedback on the regulated activities and sectors and promote public confidence in the safe use of tissues and cells.

Looking ahead at 2023/24 the HTA will be reviewing its Strategy. This will set the direction of travel for the next 3 years and potentially beyond as well as showcasing the ongoing importance of regulating the use of human tissues and cells.

The additional attention to which the HTA might be subject following the anticipated publication of Phase 1 of Sir Jonathan Michael's Independent Inquiry into Fuller's offending may increase the risk of misperception of the HTA's role in the public domain. The HTA Fuller Inquiry Working Group is preparing communications and media products, either for publication or to enable us to respond promptly, accurately and constructively to enquiries as well as ensuring HTA staff are suitably prepared to provide clarity on the HTA's role where required

SMT consider this risk to at 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                    | 4      | 16 - Medium       |
| <b>Tolerance threshold:</b> |        |               |                      |        | <b>9 – Medium</b> |

**Commentary**

**Above tolerance.**

As we reach the end of Q2, staff turn-over is 29.2%. This is based on a twelve-month period (Oct-Sept) using our HR system IRIS. We continue to have vacancies in key areas from time to time that can put pressure on the business, in particular in professional corporate roles with limited cover, though we do not feel that we have a significant issue with staff retention currently.

Additional work has arisen in year that has created further pressures on staff, in particular responding to the Fuller Inquiry, in Live Organ Donation work and the proposed Duty to Report. This has put significant pressure on some staff to deliver alongside BAU tasks (see also Risk 5 on resourcing), with risk of burnout and lower Health and Well-being (H&WB)

We have historic/enduring problems with recruitment, in particular to more specialist professional roles (it has taken a significant period of time to fill the Head of IT role). In some cases this is probably due to our pay offer being below market expectations.

The current transition to an HR shared service and lack of internal HR expertise within HTA means that we have not been able to fully maintain our HR offer to staff. This has put some pressure on managers to manage basic HR tasks themselves and created uncertainty around HR transactions for staff. It has also made the organisational focus on things like L&D and H&WB harder to deliver. The shared HR service has now commenced (except L&D and organisational development in April 2024), with detailed procedures in development by CQC over the coming months, meaning that it will take some time to bed in fully. Available resource for projects (e.g. the People Strategy) to be agreed and planned with CQC (see actions below).

HR policies have not been updated for some time creating risk, in particular ensuring compliance with legislation appropriate to protect staff working remotely (at home or with clients).

Actions to address risk:

- Retention. Ensure we are supporting staff, focussing on development, Health and Wellbeing (and reasonable workloads) and performance management, responding to feedback from the Staff Survey. We will restart the Staff Forum to ensure there is safe space for staff to raise and discuss issues. We will develop a People Strategy in 2024/25

working with CQC-HR (depending on HR plan/resource), ensuring our offer to staff supports resilience and a positive culture.

- Recruitment. Work with CQC to review the HTA approach. Continue flexing pay where necessary, and review HTA pay and Job Descriptions (depending on HR plan/resource).
- Review of HTA HR policies with CQC, in particular those that manage Health and Safety risks.
- Work with CQC to ensure smooth transition and HR service meets HTA needs. SLA meetings and KPIs.
- Explore further resource-sharing options with other bodies where appropriate.

**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 | 3                    | 3      | 9 – Medium     |
| <b>Tolerance threshold:</b> |        |                |                      |        | <b>3 – Low</b> |

### Commentary

#### Above tolerance.

C. 80% of our **2023/24 income** comes from fees and is variable and difficult to budget for, meaning we can be in a deficit position even when our spend is within budget. Currently (at Q2), our forecast fee income is just over 1% below budget; we are monitoring this situation closely. Our GIA and other income is generally reliable.

**2023/24 spend** is broadly as expected to deliver our agreed business plan within budget, but a number of additional pressures have arisen in year (including the one-off cost of living payment) and additional work requirements (in particular responding to the Fuller Inquiry and developing and resourcing the new DTR duties for HTA, engaging with DHSC). There is a risk of a small overspend currently and ideally, we would recruit additional staff to support extra work (as we have had to divert staff from BAU), but this would move us further into an overspend position.

Our operating **budget for 2024/25** is currently under development, looking at resource requirements for 2024/25 (in particular to absorb additional work such as DTR). DHSC has informed HTA that GIA will reduce by c. 33% in 2024/25, therefore inflation, resources for increased duties and a c. £300k reduction in GIA will need to be funded through a fee increase, which will put pressure on the sector and require careful engagement.

**HTA finance team** is currently has one internal vacancy and is covering a vacancy in HFEA. High workload increases risk in financial control and our ability to detect fraud and error, etc. It also reduces finance's ability to provide technical support for efficiencies and financial management improvement.

#### Actions to address risk:

- Engagement with Directors on budget management to ensure robust forecasting.
- Review of 23/24 business plan with SMT to identify pressures and areas that could be de-prioritised if necessary.
- Close engagement with DHSC finance around our in-year position for 2023/24.

- Close engagement with DHSC sponsor team on additional DTR resource requirements and funding, including requests for additional staff (loan) and GIA.
- Engagement on 2024/25 fees and budget with DHSC finance and sponsors as funding requirements and likely fee increase developed. To discuss with HTA Board.
- Focus on finance team capability and capacity (especially recruitment). Review of finance systems and oversight across HTA and HFEA for improvements.

**R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure public trust and confidence is maintained.**

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

### Commentary

#### At tolerance.

This risk has been updated and redefined for 2023/24 to reflect a central priority supporting efficiency and reform. As with risk 3 the HTA has progressed and delivered a number of projects in the post pandemic period reflecting changes in the way that it works and to ensure it remains responsive to opportunities for working differently. The 2023/24 Business Plan includes a number of projects that will this direction of travel. Activities under risk 3 and this risk 6 coalesce to support the HTA’s vision and mission.

It is anticipated that updates on the risk will reflect the progress of identified projects and align with updates and actions identified across other risks specifically risks 3, 4, 5 & 7. This alignment is critical as in previous years the availability of resources (people and financial) have been significant factors in setting the pace and appetite for change. A further consideration and alignment opportunity for the HTA will be with the myriad of central initiatives and programmes that see to take advantage of economies of scale and consolidation of improvement opportunities and skills.

Since the start of 2023/24 there have been a range of different activities including independent reviews such as the McLean review and the Review of Pregnancy Loss that have led us to consider and work with partners on opportunities for change and improvement in regulation.

**R7: Failure to optimise the safe use of existing and emerging 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> |

**Commentary**

**Above tolerance.**

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.

Two projects were identified in 2022/23. These were (1) the adoption of an IT Shared Services model and (2) stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 progress has not been possible due to resource constraints. The HTA's IT function has been an area of consistent pressure and over commitment of internal resource for a number of years. As part of the 2023/24 business plan there has been confirmation of a substantive Head of IT position. This post has now been successfully recruited to, with the incumbent commencing post in November

As with risk 6 the HTA's ability to optimise the use of existing and emerging data, digital and technology opportunities is largely reliant on investment and resource. There is a clear vision and confidence in what could be delivered although the reliance on single roles in this area and wider ambitions means that substantive recruited resource is at capacity.

SMT believe this risk remains above tolerance.

## R8: Failure to deliver the agreed Business Plan

| Inherent risk level:        |        |               | Residual risk level: |        |                   |
|-----------------------------|--------|---------------|----------------------|--------|-------------------|
| Likelihood                  | Impact | Inherent risk | Likelihood           | Impact | Residual risk     |
| 3                           | 4      | 12 – High     | 4                    | 3      | 12 – High         |
| <b>Tolerance threshold:</b> |        |               |                      |        | <b>6 – Medium</b> |

### Commentary

#### Above tolerance.

The 23/24 Business Plan (consisting of both core operations and change activities) has been created through a codesign process involving Board and staff such that it is intended to be both challenging but achievable.

We operate a formal Portfolio Management approach to the management of our Business Plan delivery, with explicit processes and best practice outputs tracking progress and scrutiny at Business Delivery Team (middle management) fortnightly, Portfolio SMT (senior management) monthly and Board quarterly.

Portfolio Management allows us to be flexible in-year so that as we are reviewing our performance, we can also consider additional requests and pressures as they arise, refining our Business Plan through change control and redeploying resources as needed.

To date, delivery of our core operations has been positive with both our externally reported Key Performance Indicators and internally managed Performance Indicators prioritised and on track for successful achievement at year end.

However, a combination of our Q1 financial outturn (see Risk 5), staffing issues experienced in key technical positions (see Risk 4) and requests to absorb additional work in-year (such as engaging with the Department's proposed Duty to Report) has meant that we have been unable to progress all of the change activities that we had identified for delivery. A Quarter 2 review of the change activities has been undertaken and the Board has been asked to consider scaling back the proposed change activities to reflect the current state of play (see the annex to the Chief Executive's Report for details).

As such, this risk currently remains above tolerance.

Actions to address the risk:

- Scale back ambitions for delivery of change activities during 23/24
- Be more realistic about our capacity to deliver both core operations obligations and the ability to resource ambitions change activities when drafting the 24/25 Business Plan