Medicines & Healthcare products Regulatory Agency

**AGENDA FOR BOARD MEETING HELD IN PUBLIC**

09:30 am – 12:00 pm on Tuesday 21 November 2023

Chair: Professor Graham Cooke

| | **AGENDA ITEM** | **PURPOSE** | **PRESENTER** |
|---|---|---|---|
| 09:30 | INTRODUCTION | | |
| | 1. What is the purpose of this meeting, who are the Board Directors and are there any absences? | Information | Chair |
| | 2. Are there any new Declarations of Interest? | Information | All |
| | 3. What were the minutes and actions from the last meeting? | Approval | Chair |
| | AGENCY PERFORMANCE | | |
| 09:45 | 4. What are the most important current activities and priorities from the CEO's point of view? | Context | June Raine |
| 10:00 | 5. How well have the business plan targets been met and what is planned in each of the operational areas? | Assurance | Rose Braithwaite |
| 10:20 | 6. How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing? | Assurance | Marc Bailey |
| | DYNAMIC ORGANISATION | | |
| 10:50 | 7. How is the People Strategy helping the agency become a great place to work? | Strategic Direction | Liz Booth |
| 11:10 | 8. What are the key priorities for the MHRA's Health & Safety Strategy? | Strategic Direction | Marc Bailey |
| | ASSURANCE | | |
| 11:30 | 9. What assurance can be provided by the Audit and Risk Assurance Committee? | Assurance | Michael Whitehouse |

| | | | |
|---|---|---|---|
| 11:40 | 10. What assurance can be provided by the Organisational Development and Remuneration Committee?<br><br>EXTERNAL PERSPECTIVE | Assurance | Mandy Calvert |
| 11:50 | 11. What questions do members of the public have about the items on this Board Meeting Agenda? | | Chair |
| 12:00 | CLOSE OF MEETING | | |

# MHRA Board Declarations of Interest – November 2023

The MHRA Board is responsible for advising and agreeing the strategic direction of the Agency, endorsing the Agency's recommendations to Ministers on key financial and performance targets, and advising on and monitoring plans to ensure those targets are met.

The Board supports the Chief Executive Officer in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk.

**The Board and its Non-Executive Directors have no involvement in any regulatory decisions affecting medicines, medical devices or any other products or services delivered by the Agency. These decisions are the responsibility of the Chief Executive Officer, supported by the Executive Committee.**

| Name and MHRA Role | Name of Other Company or Organisation | Nature of interest | Paid | Current |
|---|---|---|---|---|
| **Professor Graham Cooke** Non-Executive Director & Interim Co-Chair | Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust | Honorary NHS Consultant | Yes | Yes |
| | NERVTAG | DHSC NERVTAG committee member | No | Yes |
| | NIHR | NIHR Research Professor | Yes | Yes |
| | NIHR | Influenza platform trial in the UK | Yes | Yes |
| | NIHR | Chair DSMB (PROTECT-V trial) | No | Yes |
| | Pfizer | Pneumonia study with Imperial College Healthcare Partners | Yes | Yes |
| | 30 Technology Ltd | Consultant/Advisor | Yes | Yes |
| | DNAnudge Ltd | Consultant/Advisor | No | Yes |
| | Seventh Sense Biosystems | Consultant/Advisor | Yes | Yes |
| | Sanofi CoV | Chair of End Point Review Committee for vaccine trial | Yes | Yes |
| | WHO | Chair of Committee for Selection and Use of Essential Medicines | No | Yes |
| **Dame June Raine** Chief Executive | World Health Organisation (WHO) Committee on Safety of Medicinal Products | Member | No | Yes |
| **Dr Marc Bailey** Chief Scientific Officer | Nokia Corporation | Ex-employee shareholder | No | Yes |
| **Dr Junaid Bajwa** Non-Executive Director | Microsoft | Employed (Chief Medical Scientist at Microsoft Research), Shareholder | Yes | Yes |

| Name and MHRA Role | Name of Other Company or Organisation | Nature of interest | Paid | Current |
|---|---|---|---|---|
| | Merck Sharp and Dohme | Ex-employee shareholder | No | Yes |
| | Ondine biomedical | Non-Executive Director | Yes | Yes |
| | Novartis Industry Council | Advisory to UK Pharma Exec | Yes | Yes |
| | UCLH | Non-Executive Director | Yes | Yes |
| | Whittington NHS Trust | Associate Non-Executive Director | Yes | Yes |
| | NHS | GP, Physician (Sessional) | Yes | Yes |
| | Nuffield Health | Governor (NED) | Yes | Yes |
| | Nahdi Medical Corporation | Non-Executive Director | Yes | Yes |
| | DIA Global | Board Member | No | Yes |
| **Julian Beach** Interim Lead, Healthcare Quality & Access | None | N/A | N/A | N/A |
| **Liz Booth** Chief People Officer | None | N/A | N/A | N/A |
| **Rose Braithwaite** Chief Finance Officer | Mental Health Foundation | Treasurer | No | No |
| **Amanda Calvert** Non-Executive Director & Interim Co-Chair | Astrazeneca | Ex-employee shareholder<br>Immediate family member | No | Yes |
| | Quince Consultancy Ltd | Provides consultancy services including companies in the healthcare sector. | Yes | Yes |
| | Athenex Pharma | Quince Consultancy providing strategic consultancy on oral oncology chemotherapy platform. ILAP applicant and Marketing Authorisation applicant. | No | No |
| | Cambridge Judge Business School | Member of Advisory Board | No | Yes |
| | Duke Street Bio | Advisory / Consultant | Yes | Yes |
| | Fennix Pharmaceuticals | Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading. | No | No |
| | High Value Manufacturing Catapult | Non-Executive Director | Yes | Yes |
| **Dr Alison Cave** Chief Safety Officer | None | N/A | N/A | N/A |
| **Dr Paul Goldsmith** Non-Executive Director | Closed Loop Medicine Ltd | Shareholder, director & employee; MA submission | Yes | Yes |
| | Summit Inc | Shareholder | No | Yes |
| | Ieso Digital Health | Shareholder | No | Yes |
| | Institute of Global Health Innovation (IGHI), Imperial College, London | Visiting Professor | No | Yes |
| | MDU Ltd | Director | Yes | No |

| Name and MHRA Role | Name of Other Company or Organisation | Nature of interest | Paid | Current |
|---|---|---|---|---|
| | MDU Investments Ltd | Director | Yes | No |
| | NHS | Consultant Neurologist | Yes | Yes |
| | NHS | Clinical Senate Member | No | Yes |
| | Radix Big Tent Foundation | Trustee | No | Yes |
| | Sleepstation | Co-founder of original programme, 2012-2014 | No | No |
| **Claire Harrison** Chief Digital & Technology Officer | None | N/A | N/A | N/A |
| **Haider Husain** Non-Executive Director | Healthinnova Limited | Chief Operating Officer | Yes | Yes |
| | Milton Keynes University Hospital NHS Foundation Trust | Non-Executive Director | Yes | Yes |
| | British Standards Institute | Panel Chair BS30440 – Use of AI within Healthcare | No | Yes |
| | Dementia Carers Count | Trustee | No | Yes |
| | World Wars Muslim Memorial Trust | Trustee | No | Yes |
| | Microsoft Corp | Ex-employee shareholder | No | No |
| | BBC | Family Member | No | Yes |
| | NHS Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board | Associate Non-Executive Director | Yes | Yes |
| **Mercy Jeyasingham MBE** Non-Executive Director | NHS South West London Integrated Care Board | Non-Executive Member | Yes | Yes |
| **Raj Long** Non-Executive Director | Gates Foundation | Employee – Deputy Director | Yes | Yes |
| | Bristol-Myers Squibb | Ex-Employee Shareholder | Yes | Yes |
| | RESOLVE (Sustainable solutions to critical social, health, and environmental challenges) | Scientific Advisory | No | Yes |
| | Novartis | Ex-Employee Shareholder | Yes | Yes |
| | EC IMI NEURONET EC Innovative Medicines Initiative (IMI) Non-Product | Scientist Advisory Board | No | Yes |
| | Gates Venture – EC Innovative Medicines Initiative (IMI) Non-Product – IMI European platform for Neurodegenerative Disorders | Advisory | Yes | Yes |
| | HUYA Bio | Access Advisory | Yes | No |
| | PAVIA – PV Africa Board (EC Funded) | Advisory Board | No | Yes |
| | WHO – Sustainable COVAX Manufacturing Strategy for Regional Health Security | Advisory Expert | No | Yes |
| | UK Health Security Agency | Associate Non-Executive Board Member | Yes | Yes |
| | EU Innovative Health Initiatives (IHI) | Advisory Expert for this EU public-private partnership | Yes | Yes |

| Name and MHRA Role | Name of Other Company or Organisation | Nature of interest | Paid | Current |
|---|---|---|---|---|
| | | funding health research and innovation funded by European Commission | | |
| **Laura Squire OBE** Chief Healthcare Quality & Access Officer | None | N/A | N/A | N/A |
| **Michael Whitehouse OBE** Non-Executive Director & Interim Co-Chair | South East Coast Ambulance Services NHS Foundation Trust | Deputy Chair & Senior Independent Non-Executive Director<br>Chair of Audit Committee<br>Chair of Charities Committee | Yes | Yes |
| | Cruse Bereavement Charity | Trustee<br>Chair of Finance and Audit Committee | No | No |
| | Republic of Ireland Audit Office | Member of Audit Committee | No | No |
| | National Audit Office | Board Member and Chief Operating Officer until 17 April 2017 | No | No |
| **Glenn Wells** Chief Partnerships Officer | None | N/A | N/A | N/A |

# Medicines and Healthcare products Regulatory Agency

## Minutes of the Board Meeting Held in Public on 19 September 2023

(10:00am – 12:30pm)

Round Room, MHRA, 10 South Colonnade, Canary Wharf E14 4PU

**Present:**

*The Board*

| | |
|---|---|
| Professor Graham Cooke | Non-Executive Director & Interim Co-Chair |
| Dr June Raine DBE | Chief Executive |
| Dr Marc Bailey | Chief Science, Research & Innovation Officer |
| Julian Beach | Interim Executive Director, Healthcare Quality & Access |
| Rose Braithwaite | Chief Finance Officer |
| Dr Alison Cave | Chief Safety Officer |
| Amanda Calvert | Non-Executive Director & Interim Co-Chair |
| Dr Paul Goldsmith | Non-Executive Director |
| Claire Harrison | Chief Digital & Technology Officer |
| Haider Husain | Non-Executive Director |
| Raj Long | Non-Executive Director |
| Dr Glenn Wells | Chief Partnerships Officer |
| Michael Whitehouse OBE | Non-Executive Director |

*Others in attendance*

| | |
|---|---|
| Rachel Bosworth | Director of Communications and Engagement, MHRA |
| Carly McGurry | Director of Governance, MHRA |
| Natalie Richards | Head of the Executive Office, MHRA |
| Penny Carter | Deputy Director, Infrastructure and Laboratory Services, MHRA (for item 6) |
| Kerry McEyeson | Deputy Director, Human Resources, MHRA |
| James Pound | Deputy Director, Standards & Compliance, MHRA (for item 6) |
| Malgosia Malach | Head of Organisational Development, MHRA (for item 7) |
| Kathryn Glover | Deputy Director, Medicines Regulation and Prescribing, DHSC |

### INTRODUCTION

### Item 1: What is the purpose of this meeting and who are the Board Directors?

1.1 Professor Graham Cooke opened the meeting as Chair. Since the previous MHRA Chair Stephen Lightfoot stepped down, Professor Graham Cooke, Amanda Calvert, and Michael Whitehouse will be undertaking interim Co-Chair roles for the MHRA until a new Chair has been appointed.

1.2 The Chair set out his expectations and priorities for this Board meeting held in public which was being live streamed to the registered audience and recorded. The Chair welcomed everyone to the meeting, including a broad range of observers including patients and members of the public, representatives of patient groups, healthcare professionals, government officials, industry, media and MHRA staff.

**Item 2: Are there any Apologies or Declarations of Interest?**

2.1 Apologies were received from Mercy Jeyasingham, Non-Executive Director; Junaid Bajwa, Non-Executive Director; Alison Strath, Chief Pharmaceutical Officer for Scotland; Greig Chalmers, Head of Chief Medical Officer's Policy Division in the Scottish Government; and Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland.

2.2 The Board reviewed the Declarations of Interest (DOIs) for all MHRA Board members. Graham Cooke declared that he has joined the DHSC NERVTAG committee; and Paul Goldsmith declared that he has been appointed as visiting Professor at the Institute of Global Health Innovation at Imperial College. The Chair reviewed the DOIs and was satisfied that there were no conflicts of interest preventing any Board Member from participating in the full agenda of this meeting.

**Item 3: What were the minutes and actions from the last meeting?**

3.1 The Board reviewed the minutes and actions from the last meeting and updates were provided**.**

**AGENCY PERFORMANCE**

**Item 4: What are the most important current activities and priorities from the CEO's point of view?**

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered the following:

**(i) Dynamic Organisation –** including an update on the Business Plan 2023-24;

**(ii) Scientific Research and Innovation** – including latest updates on Clinical Trials; the Innovative Devices Access Pathway (IDAP); Control testing; Microbiome; Bacteriophages; and Communications for standards sales;

**(iii) Healthcare Access** – including updates on COVID-19 vaccines; UK plasma; established medicines; and designation of three new Approved Bodies;

**(iv) Partnerships – national and international** – including updates on the Windsor framework; the International Recognition Framework; the Access Partnership; and Devolved Administrations;

**(v) Patient Safety** – including updates on Clinical Practice Research Datalink; Valproate; codeine linctus; safety of breast implants; bed rails; variant COVID-19 tests; the launch of a new Yellow Card Centre in Northern Ireland; the British Pharmacopoeia; and the Criminal Enforcement Unit; and

**(vi) Digital & Technology** – including updates on the Regulatory Management System (RMS); SafetyConnect; Intellicase system replacement; the laptop refresh; and freeze dryers.

4.2 The Board thanked Dr Raine for her report and provided comments relating to clinical trials; development of a business plan with clear resource needs underpinning IDAP; medtech regulatory reform which is being led by Dr Laura Squire; ensuring lessons learnt from the RMS programme are incorporated, noting the first public facing release of RMS is due in March 2024 which brings in the principles of self service; the value that the regional Yellow Card Centres bring in promoting reporting; the benefits of a Scientific Advisory Group for CPRD to use this unique real world data asset; and understanding how CPRD can be further promoted globally. The Board noted Dr Raine's report with thanks.

**Item 5: What was the operational performance of the MHRA for Quarter 1, 2023/24?**

5.1 The Board considered a report describing the Agency's operational performance for quarter 1 of 2023/24. The Board noted that Corporate Plan was published on 4th July; the first year Business Plan was then published on 7th September due to the need to review the deadlines for deliverables to ensure that these are realistic and achievable. The Board noted that most of the 43 objectives are on track, however 12 are showing at risk. The Board provided comments relating to recruitment and retention and actions begin taken to recruit specialist staff in a timely manner; understanding lessons learnt from clinical trials; taking maximum advantage of pay frameworks; working with other Arms Length Bodies to build career pathways; working with the Faculty of Pharmaceutical Medicine to develop educational pathways to build the pipeline of specialists; and bringing secondees in through fellowships.

5.2 The Board provided further comments relating to income growth in relation to CPRD and working to remove any barriers to this; established medicines performance; defining performance metrics across the Agency to enable accurate performance monitoring; contributing to the government's response to the O'Shaughnessy review; the increase in the number of PQs and how these are being addressed; an action was taken to provide the Board with a breakdown of the type of PQs being received.

5.3 The Board provided further comments relating to development of a reputation strategy; how complaint handling is managed in the Agency and the work ongoing to develop a single complaint management system cross-Agency; and developing a report of metrics which can be published regularly. The Board noted the report with thanks.

***Action 103: Provide the Board with a breakdown of PQs received in the last quarter.*** ***Glenn Wells***

***Action 104: Develop a reputation strategy for the Agency with reputation index measures.*** ***Rachel Bosworth***

**Item 6: How effectively is the MHRA maintaining performance on clinical trials and how has a sustainable clinical trial function been established from 1 September?**

6.1 The Board considered a paper describing the actions taken to restore performance on clinical trials, and how a sustainable clinical trial function has been established from 1 September 2023. James Pound and Penny Carter joined for this discussion. The Board noted that there have been delays in clinical trial assessment by the MHRA since September 2022 which increased over time despite efforts to reduce and eliminate these delays. The main causal factor was the loss of a significant number of experienced staff in the Clinical Investigations and Trials team and this was associated with difficulties in recruiting new staff with relevant skills.

6.2 As a result of the increasing scale of this assessment backlog a crisis response was initiated in July 2023 to rapidly address these delays. The aim of this response was to ensure the elimination of the backlog and that all newly received compliant applications from 1 September 2023 were approved within statutory timeframes. All newly received compliant clinical trial applications received from 1 September 2023 are being processed within statutory timeframes.

6.3 The Board reviewed how the cross-agency crisis response has addressed the backlog, presents the ongoing measures to ensure continued clinical trial approval performance and outlines the foundations of a new clinical trial process based on the public consultation outcome announced in March 2023. This is aligned with the UK Government ambitions as set out in the Life Sciences Vision and O'Shaughnessy Review to ensure that the UK is an attractive location for clinical trials and the benefits this brings to UK patients and the healthcare system.

6.4 The Board discussed the lessons learned exercise which is now being undertaken. There are 3 key areas under review: (i) implementing an early warning system to identify where backlogs are building up within the Agency to quickly identify any issues to mobilise on; (ii) taking a more proactive approach with regards to communications, to increase transparency around any issues; and (iii) building a flexible agile workforce, ensuring key staff who leave are swiftly replaced, and implementing a robust training mechanism for new and existing staff.

6.5 The Board noted the report with thanks and provided comments relating to the importance of implementing robust recruitment and training processes in place; the flexibility and willingness of MHRA staff who rapidly upskill and support other areas of the Agency to address this backlog; using other opportunities such as implementing apprenticeships, formal training systems and rotations to upskill staff; building horizon scanning capability in the Agency to predict the pipeline of work coming in; developing

the capacity and capability of the innovation accelerator function, and utilising the O'Shaughnessy review recommendations to drive this work.

6.6 The Board provided further comments relating to utilising digital and technological solutions to underpin this work; utilising resources such as the government skills campus; focusing on the key functions of signal detection, new technologies, established medicines, compliance and clinical trials, and ensuring these are underpinned by robust implementation plans; implementing robust performance management and measurable targets throughout the Agency. The Board noted that prior to launching the pilot, advice was sought from the CHM and from external reference groups including trade associations. The Board acknowledged the hard work of all staff involved in addressing this backlog and development of a new process; it will be vital to ensure data is readily available and transparent; it will be vital to focus on horizon scanning to predict the pipeline of work coming in to the Agency.

***Addition to action 101: Provide an update to the Board in November 2023 on the progress of the new clinical trial process pilot. Prepare a plan for training and upskilling of staff to increase resilience across the Agency. Marc Bailey***

**DYNAMIC ORGANISATION**

**Item 7: What is the progress in delivering an excellent culture with strong leadership at the MHRA?**

7.1 The Board considered a paper providing to assurance to the Board the agency is making progress towards delivering an excellent culture with strong leadership. The recommended approach should be to view culture as a dynamic process to work with, rather than a static object that can be easily measured and “fixed”. Recognising the significance of leadership in creating cultures, the MHRA’s leadership influence culture and should emphasise expected leadership behaviours of the agency’s leaders. The Board reviewed the leadership development offer in 2022/23 to build leadership capability and continued plans to keep investing in this. The Board noted that to create an excellent culture with strong leadership, it is on the leaders to take responsibility, set the leadership standard consistently and role modelling behaviours, assessing leadership capability, prioritising leadership development, and ensuring accountability.

7.2 The Board noted the update and provided comments relating to utilising the staff survey results to inform culture and leadership work; the impact of the transformation; involving staff in change to increase engagement and build a strong culture; identifying themes from staff exit interviews to inform culture and leadership work; utilising the Organisational Development and Remuneration Committee to undertake deep dives in to this area of work; increased focus on staff development such as through the lessons learnt exercise on clinical trials; and actions that can be taken to ensure staff feel supported. The Board noted the update for assurance.

## ASSURANCE

### Item 8: What assurance can be provided by the Patient Safety and Engagement Committee?

8.1 The Board considered an assurance report from the Patient Safety and Engagement Committee (PSEC). The PSEC met on 9th August 2023 and discussed the review of the safety of fluroquinolones; the Patient engagement plan for the Agency's review into rectopexy mesh; and the Yellow Card Biobank consent process. The Board provided comments relating to fluroquinolones and the DHSC suicide strategy. The Board noted the report for assurance.

### Item 9: What assurance can be provided by the Organisational Development and Remuneration Committee?

9.1 The Board considered an assurance report from the Organisational Development and Remuneration Committee (ODRC). The ODRC met on 10th July and 28th July 2023 and discussed the progress on the delivery of the RMS programme; Executive Team Remuneration; the progress on the development of leadership, values and culture across the Agency; and feedback from the leadership team to agree the forward workplan for 2023/24. The Board provided comments relating to the work of the One Agency Leadership Team and feedback to the ODRC; listening and addressing concerns; and ensuring all staff have a common purpose. The Board noted the report for assurance.

## EXTERNAL PERSPECTIVE

### Item 10: What questions do members of the public have for the MHRA Board?

10.1 The Board answered a range of questions which had been submitted by members of the public before and during the meeting. These questions concerned the work to address the clinical trials backlog and maintaining regular communication on clinical trial application status.

## ANY OTHER BUSINESS

11.1 No items of other business were raised and the Chair closed the meeting.

**ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 19 September 2023**

*The actions highlighted in red are due this month*

| Action Number | Action | Owner | Date | Status |
|---|---|---|---|---|
| **Carried Forward from previous meetings** | | | | |
| 29 | 16/03/21: Present an Agency Science Strategy to the Board. 15/11/22: Revise the Science Strategy to include clear prioritisation; and greater inclusion of in-house expertise on behavioural science with a complementary expert group. Include vaccines work as a specific area of expertise, alongside biologics and the UK Stem Cell Bank, to create a distinctive offering to make the UK an internationally recognised centre of excellence in this field. A review of scientific committees should also be undertaken. Present a further update to the Board in March 2023.<br><br>21/03/2023: Science Strategy to be presented to the Board in July.<br><br>11/07/23: Present an update to the Board on progress against each of the themes in the Science Strategy at the end of 2023. | Marc Bailey | ~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ ~~11/07/23~~ 12/12/23 | |
| 70 | 18/01/22: Develop and present a Data Strategy to the Board. | Alison Cave & Claire Harrison | ~~17/05/22~~ ~~18/10/22~~ ~~15/11/22~~ ~~18/04/23~~ 12/12/23 | |
| 73 | 15/02/22: Develop a Sustainability Strategy. | Glenn Wells | ~~17/01/23~~ 16/01/24 | |
| 97 | 16/05/23: ARAC will undertake a deep dive on RMS; all Board members will be invited to attend. | Michael Whitehouse | 19/09/23 | Completed |
| 99 | 11/07/23: Patient involvement in internal audit should be reviewed by the Patient Safety and Engagement Committee. | Carly McGurry | 21/11/23 | |
| 100 | 11/07/23: The Board endorsed the Annual Report and | June Raine | 19/09/23 | Completed |

| | | | | |
|---|---|---|---|---|
| | Accounts; these should now be signed and submitted to the NAO for certification. | | | |
| 101 | 11/07/23: Action: Present an update to the Board on the performance and proactive communications and engagement activities related to clinical trials which will maintain trust in the Agency from industry and research customers.<br><br>19/09/23: Provide an update to the Board in November 2023 on the progress of the new clinical trial process pilot. Prepare a plan for training and upskilling of staff to increase resilience across the Agency. | Marc Bailey | 21/11/23 | On agenda |
| 102 | 11/07/23: Invite the Patient Safety Commissioner to a future Board meeting. | Alison Cave | 21/11/23 | |
| **New Actions** | | | | |
| 103 | 19/09/23: Provide the Board with a breakdown of PQs received in the last quarter. | Glenn Wells | 21/11/23 | |
| 104 | 19/09/23: Develop a reputation strategy for the Agency with reputation index measures. | Rachel Bosworth | 21/11/23 | |

Medicines & Healthcare products Regulatory Agency

**BOARD MEETING HELD IN PUBLIC**

**21 November 2023**

| | |
|---|---|
| **Title** | **What are the most important current activities and priorities from the CEO's point of view?** |
| **Board Sponsor** | June Raine |
| **Purpose of Paper** | Context |

# What are the most important current activities and priorities from the CEO's point of view?

## 'TOP 10' HEADLINES

- A new Clinical Trials Notification Scheme for low-risk trials which meet certain criteria ensures that these will be authorised within 14 days, further enabling medicines research
- The UK Stem Cell Bank, the largest provider of embryonic stem cells globally, celebrated its 20th Anniversary with a scientific symposium including a look to future clinical uses
- Tirzepatide (Mounjaro), a GLP-1 agonist diabetic medicine as a pre-filled injection pen was authorised for weight loss together with a reduced calorie diet and increased activity
- A gene therapy for sickle cell disease and transfusion-dependent β-thalassemia (Casgevy) was approved, the first medicine that uses innovative gene-editing or 'CRISPR'
- Dostarlimab (Jemperli) was authorised via the US FDA initiative Project Orbis to treat advanced endometrial cancer in combination with chemotherapy
- New Key Performance Indicators in Healthcare Quality and Access Group support the aim to process national applications from 1 January 2924 within statutory timeframes
- Preparations continue at pace for the new International Recognition Framework, which is due to be implemented in January 2024, including new digital technology support
- We ran a public and patient information session for the Innovative Devices Access Pathway, providing an overview of the new process and opportunities for involvement
- The MHRA's Criminal Enforcement Unit contributed to the world-wide Operation Pangea which resulted in the seizure of approximately 600,000 doses of unlicensed medicines
- The Civil Service People Survey closed in October, with a 72% response rate which is a 2% increase on last year, and results will be shared with staff in the new year.

## SCIENCE, RESEARCH, AND INNOVATION

### Clinical trials notification scheme

1.1 In October we published guidance on the new Clinical Trial Notification scheme. Initial applications for the lowest-risk Phase 3 and 4 trials will be processed within 14 days instead of the statutory 30 days, provided the sponsor can demonstrate the trial meets the MHRA's criteria, including by confirming there are no known safety issues with the medicine being investigated. About 20% of UK initial clinical trial applications are expected to be eligible for the scheme, speeding up approval times to enable clinical research.

**UK Stem Cell Bank 20th anniversary**

1.2 The UK Stem Cell Bank (UKSCB) celebrated its 20th anniversary with a scientific symposium featuring talks from colleagues past and present, and some of the UK's top stem cell scientists. This coincided with a range of activities across media platforms highlighting the work of the bank to ensure high quality, ethically derived, human embryonic stem cells are available as starting materials for future cell therapies. Globally, the UKSCB has supplied stem cells to 25 different countries for research and clinical applications, with 54% of the stem cell lines requested in 2022 being of clinical grade, which has risen year on year. The symposium included discussion on the future potential for more therapeutic uses.

**Innovative Devices Access Pathway**

1.3 We ran an Innovative Devices Access Pathway (IDAP) public and patient information session on 2 October, providing an overview of IDAP and opportunities for patient involvement, which 132 people attended. We also completed a recruitment process for patient experts to support the selection panel to decide which 8 applications will enter the IDAP pilot.

**NHS Diagnostics**

1.4 The Deputy Chief Scientific Officer for the NHS, Dr Vicki Chalker, visited the MHRA laboratories. Dr Chalker met a number of scientists who introduced their area of work. Topics of discussion included potential collaborations on cancer genomics, point of care testing and moving testing to surgeries and hospitals, which is an expanding area to support rapid patient diagnosis and to triage and treat patients more rapidly. Further, there are opportunities to forge stronger links with the NHS pathology network to support future diagnostics.

**Novel vaccines platform**

1.5 Scientists in the Immunotherapy team in Biotherapeutics and Advanced Therapies group hosted a visiting scientist from University of Santiago del Compostela, Spain, to complete a collaborative research project on exploration of microspheres as a novel vaccine platform. Good progress was made, and the data will form part of a future scientific publication.

**Chikungunya vaccine development**

1.6 Two scientists from Diagnostics attended the Annual Conference of the International Society of Vaccines, held in Lausanne. At the meeting a presentation was made of the work performed partly in collaboration with the Paul Ehrlich Institute, Germany, International Vaccine Institute, South Korea and Bharat Biotech International, India to establish a serological mechanism of protection against Chikungunya virus. The presentation made by a postdoctoral scientist in the team, won the second place award amongst presentations made by early career researchers at the meeting. These data will help establish the scientific framework for regulatory decision making regarding the likely efficacy of candidate vaccines that are in development and seeking regulatory approval globally.

**Antimicrobial resistance**

1.7 The MHRA Microbiome lead attended a 3-day workshop at the University of Ghana organised by the National Biofilms Innovation Centre (NBIC) and the West African Centre for Cell Biology of Infectious Pathogens (WACCBIP). Faculty, researchers, and industry leaders from both countries came together to exchange knowledge and find areas of synergy in biofilm-related research: Breaking Barriers in Antimicrobial Discovery, UK and Ghana Forge Future Collaborations, and the West African Centre for Cell Biology of Infectious Pathogens. Participation has helped cement links with the National Biofilm Consortium which is an aspect of our antimicrobial resistance work.

**Biological product safety**

1.8 A scientist from the Viral Vaccines group (SRI-R&D) attended the biannual International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) meeting in Prague as a member of the Expert Working Group (EWG) for revision of ICH Guideline "Q5A: Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin". The EWG concluded a four-year work programme to revise the guideline to reflect advances in technology (e.g. next-generation sequencing, viral clearance) and continuing efforts to reduce animal use. The revisions were adopted by the ICH Assembly and will shortly be published and subsequently incorporated into regional guidelines by ICH members, with the aim of harmonising regulatory guidelines globally.

**Polio vaccine quality control**

1.9 The Head of Polio Laboratory attended the WHO workshop on the "Implementation of International Standards for Quality Control of Polio Vaccines including oral polio vaccine and inactivated polio vaccine" in Indonesia. A Principal Scientist from the group was invited by the WHO to be the meeting Rapporteur. Our experts presented two talks during the event: "Ongoing effort towards High Throughput Sequencing standardization for Quality Control of polio vaccines" and "Standardization of the potency test for Oral Polio Vaccine". Our participation highlights our expertise in this field and the requirement for us to aid in capacity building in global laboratories.

**Influenza vaccines**

1.10 The WHO-Industry Cross Functional Working Group on Influenza, co-Chaired by the Head of Pandemic Influenza, has been working to troubleshoot challenges in the global influenza vaccine response. Working together with stakeholders, we are investigating ways of facilitating the global availability of critical materials, including candidate vaccine viruses, in the event of an influenza pandemic. These activities are aimed at ensuring timely delivery of effective influenza vaccines to the UK public and for the global public health response.

**WHO Expert Committee on Biological Standardization**

1.11 Experts from Science, Research and Innovation Group presented the outcome of their work to the WHO Expert Committee on Biological Standardization (ECBS) during October. Members of the expert committee, which meets once or twice per year, were favourably impressed by the quality of the work presented and recommended that WHO accepts our proposals to adopt a number of new and replacement WHO International Standards and Reference Reagents. The newly adopted standards included: new antibody standards for Nipah virus and Q-fever, a new standard for thrombin activatable fibrinolysis inhibitor and a new reference reagent for gut microbiome DNA extraction; and replacement standards for alpha-fetoprotein, thyroid stimulating hormone, follicle-stimulating hormone / luteinizing hormone, protein S plasma and an RNA standard for SARS-CoV-2 molecular diagnostics.

**Pandemic preparedness**

1.12 As a WHO Essential Regulatory Laboratory, the Pandemic Influenza team is currently generating candidate vaccine viruses (CVVs) in response to recent human cases of swine influenza cases. Developing pre-pandemic CVVs is a key preparedness activity. Should a related influenza pandemic strike, these CVVs would be available to influenza vaccine manufacturers to enable the development and supply of vaccines to the public.

1.13 A scientist in the Diagnostics team was invited by the UK National Measurement Laboratory (LGC-NML) to attend and speak at an event at the Houses of Parliament on 18th October, chaired by Stephen Metcalf MP and entitled, “Are diagnostics the key to pandemic preparedness”. At this event scientists from LGC-NML, the UK Health Security Agency, FIND (a nonprofit organisation) as well as MHRA laboratories at South Mimms spoke about the contribution of each organisation to science that underpinned the development and use of diagnostic tests to an audience drawn from NHS, academics, assay developers and regulators. The importance of the work of the laboratories at South Mimms to develop and supply appropriate reference materials in an outbreak of a novel pathogen was promoted, as they saw that it enabled assay performance and data to be compared in a meaningful manner.

**Stability of biologics**

1.14 Two scientists from the Research and Development team were invited speakers at the Festival of Biologics in Basel, Switzerland. The Head of Formulation Science delivered a talk, “Lyophilization to ensure we deliver stability in biologics” as did his PhD student, “High throughput screening methods to evaluate the impact of formulation on infliximab”. The Head of Biosomilars delivered a presentation, ‘Biosimilars: an update from UK’, giving an overview of biosimilar approvals in the UK and the new international recognition procedure (IRP) for medicines effective from 1 January 2024, using approvals from 7 reference states. She explained the role and use of WHO International Standards for biosimilars and provided an update on established standards and the pipeline including clinical standards in development. Streamlined clinical evaluation of biosimilars is being discussed globally in view of the progressive regulatory practice adopted by the MHRA and the World Health Organization in their biosimilar guidance.

**Quality assurance**

1.15 The Science, Research and Innovation Group underwent a successful audit for its activities carried out under ISO17025. The standard covers the general requirements for the competence of testing and calibration laboratories, and the audit therefore covered the Control Testing activities along with the more general quality management requirements. This is the second assessment in a 4-year cycle and the recommendation was for the accreditation to be maintained. The four auditors attending the site recognised the many changes that the organisation has undergone and noted the significant improvement from last year. The auditors made 16 mandatory findings and three recommendations, with a deadline of 3rd December 2023 for completion. A recommendation was made to suspend one of the infrequent tests from the scope of accreditation and it was agreed that this should be removed. This will now undergo the change control process to ensure all aspects of the removal are considered and completed.

**Grant award from DHSC and the Engineering and Physical Sciences Research Council**

1.16 A 4.5-year grant was launched, the Future Vaccines Manufacturing Hub led by Imperial College London with MHRA among the partners, which also include CPI, Universities of Strathclyde and Bristol and vaccine manufacturers. We are contributing our expertise in the stabilisation of novel vaccine formats, including mRNA, and has the potential to improve the availability of thermostable vaccines and also new vaccine modalities to low-and-middle income countries. This continues the valuable collaboration between R&D scientists and Professor Robin Shattock’s lab which started with the first Vaccine Manufacturing Hub (2009-2023).

## HEALTHCARE ACCESS

### National new drug authorisations

2.1 A number of significant approvals have been given via the national route of authorisation. The 4 authorisations below were announced by the MHRA on the day of grant as part of the Year 1 corporate plan commitment to publish a public statement following approval of all new chemical entities within one week.

- **Tirzepatide**
  Tirzepatide was authorised for a new indication of weight loss, for adult patients with a BMI of 30kg/m or more (obesity), as well as those with a BMI between 27-30kg/m² (overweight) who also have weight-related health problems such as prediabetes, high blood pressure, high cholesterol, or heart problems. It is to be used together with a reduced-calorie diet and increased physical activity. Tirzepatide, a GLP-1 agonist for diabetes, works by regulating a patient's appetite making them feel less hungry. The authorisation of tirzepatide will contribute to the Life Science Vision mission of tackling obesity, one of the biggest public health problems that the UK faces.

- **Epcoritamab**
  The new active substance epcoritamab (Tepkinly) was authorised for the treatment of diffuse large B-cell lymphoma in adults. This bispecific antibody attaches to immune cells and cancer cells resulting in the killing of cancer cells.

- **Ritlecitinib**
  The new active substance ritlecitinib (Litfulo) was authorised to treat severe alopecia areata (patchy hair loss) in adults and adolescents 12 years of age and older. Ritlecitinib works by reducing the activity of JAK3 and TEC kinases, which are involved in inflammation at the hair follicle.

- **Dostarlimab**
  Dostarlimab (Jemperli) was approved for a new indication via FDA's Project Orbis, to treat advanced endometrial cancer in combination with chemotherapy. This monoclonal antibody is a checkpoint inhibitor and stimulates the immune system to kill tumour cells.

### Gene therapy for sickle cell disease

2.2 The MHRA gave a conditional approval to the first gene therapy for sickle cell disease and transfusion-dependent β-thalassemia (Casgevy). This is the first medicine to be authorised that uses innovative gene-editing or 'CRISPR' technology. Casgevy is a genetically modified autologous CD34+ cell enriched population that contains human hematopoietic stem and progenitor cells edited *ex vivo* by CRISPR/Cas9 at the erythroid-specific enhancer region of the *BCL11A* gene. Sickle cell disease is an inherited blood disorder that affects the red blood cells, causing severe pain, organ damage and shortened life span due to misshapen or "sickled" blood cells.

### Reliance route

2.3 An additional 5 new active substances were authorised via the EC Decision Reliance Procedure (ECDRP). This includes glofitamab (Columvi) which was designated an orphan drug for diffuse large B cell lymphoma. Five innovative medicine products progressed to 'request for information' after seeking advice from the Commission on Human Medicines. The percentage of new active substances assessed via the national route within 210 days was 50% in October. This is an improvement compared to 20% for April to October.

**COVID-19 vaccine**

2.4 A new version of the Comirnaty (Pfizer) COVID-19 vaccine was authorised via the EC Decision Reliance Procedure (ECDRP) on 4 October. This is adapted to the XBB.1.5 variant. Unlike last year's version, it is monovalent and does not include ancestral strain mRNA. This vaccine, along with the Spikevax (Moderna) XBB.1.5 vaccine, is being rolled out this Autumn to at risk groups.

**National applications performance**

2.5 New Key Performance Indicators (KPIs) are being developed and introduced in Healthcare Quality and Access Group in a further effort to meet the Agency's commitment to process all national applications which are compliant according to statutory timelines by January 2024. National Applications and Type 2 variations were affected by the redeployment of clinicians and scientific assessors to the clinical trials backlog.

**Software as a Medical Device change programme**

2.6 Significant steps forward have been made with the delivery of the Software and AI as a Medical Device Change Programme Roadmap. When a registered medical device is significantly changed, the manufacturer must notify their conformity assessment body and this may lead a re-assessment. Medical devices using Artificial Intelligence and machine-learning can require more frequent updates than other types of devices. Building on the principles of Good Machine Learning Practice, published in 2021, we have continued to work in partnership with Health Canada and FDA on this issue. On 24 October, we published further guiding principles with the FDA and Health Canada covering the development of Predetermined Change Control Plans, enabling a more proportionate approach to lifecycle management of these products.

**Artificial Intelligence Airlock**

2.7 On 30 October MHRA announced that we will be taking forward the development of the MHRA 'Regulatory Sandbox', the AI Airlock, focused on addressing some of the challenges that medical devices incorporating AI meet with evidence generation using traditional trial techniques. New funding from the Department of Science, Innovation and Technology and the Department of Health and Social Care will enable MHRA to build the team developing the service, so that it will be ready for launch in April 2024.

**Electronic patient information**

2.8 The UK ePI (electronic patient information) Task Force is a group of UK medicines manufacturers, NHS organisations and the MHRA working together to explore how medicines information can be improved using a range of digital solutions. The aim is to deliver patient-centred electronic patient information in the UK, putting patients at the centre of design and including the needs of those that are digitally excluded. The MHRA provided an update on the ongoing work at the November meeting of the Management committee (MC) of the International Pharmaceutical Regulators Programme (IPRP).

**International recognition team**

2.9 Funding has been used to create a new multidisciplinary international recognition team consisting of a Head of International Recognition (SCS1), 2 medical assessors, 2 pharmaceutical assessors, one quality assessor and one non-clinical assessor. Initial offers have now been made for 4 of the 7 roles.

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## PATIENT SAFETY

### New isotretinoin prescribing advice

3.1 The report of Isotretinoin Implementation Expert Advisory Working Group of the Commission on Human Medicines, comprising experts from a range of fields including dermatology, general practice, and psychiatry, was published on 31 October 2023. The group advised on the development of new guidance on the prescribing of isotretinoin, including information about the healthcare professionals who are able to prescribe and treat patients who require isotretinoin treatment. The guidance was in response to the recommendations of the Isotretinoin Expert Working Group that was published in April 2023. The British Association of Dermatologists, the British Dermatological Nursing Group, and other stakeholders have produced supplementary documents to assist clinicians in adhering to the new guidelines.

### Valproate dispensing in original packs

3.2 We published guidance to support the dispensing of valproate-containing medicines in the manufacturer's original full pack, when the new legislation came into force in England, Scotland, and Wales from 11th October 2023. Earlier this year, together with the DHSC we consulted on proposals to enable original pack dispensing and whole pack dispensing of medicines containing sodium valproate in community pharmacies across the UK. The new guidance outlines what pharmacists need to do differently when dispensing valproate-containing medicines and provides information on the reasons for the change. This measure is to ensure that patients always receive the manufacturers' specific warning and pictograms, including a patient card and the statutory patient information leaflet, which alert patients to the risks in pregnancy. From now on there are expected to be very few instances in which a patient will be dispensed valproate containing medicines without receiving a full pack with its warnings. If any other packaging is used, the reason for its use should be explained to the patient by the pharmacist and they should receive the patent information leaflet.

### Operation Pangea

3.3 The Criminal Enforcement Unit (CEU) contributed to Operation Pangea, an international initiative coordinated annually by Interpol with the purpose of combatting trade in the online sale and supply of illicit medicines and medical devices. During the intensified week of action, CEU staff worked collaboratively with Border Force at international parcel hubs in the UK, which resulted in the seizure of approximately 600,000 doses of unlicensed medicines. In addition, inspections undertaken at three premises resulted in the seizure of over 55,000 doses of unlicensed medicines. The removal of these products from the unregulated supply chain has prevented them from reaching the UK public. A lengthy investigation into the supply of falsified information to the MHRA for the purpose of obtaining a marketing authorisation to trade in medicines concluded last month when the defendants pleaded guilty at Crown Court. They will be sentenced in the new year.

### CPRD's patient engagement event

3.4 The CPRD's annual patient engagement event was held on 30 October 2023. This is an annual virtual event that is held for patients. Invitations were sent to practice patient groups in CPRD contributing practices, the CPRD Lay Advisor and partner organisation patient forums. Patients were updated on CPRD activities and developments, including the transition to a trusted research environment (TRE) model of data access. Proposals for output checking to meet the national 'safe outputs' requirements were shared with patients and views were sought on various options. The overall consensus of patient partners was that automated checks based on validated objective criteria set by experts with manual checking of a sample of outputs would be acceptable.

### Education series for medical students

3.5 Work is under way to develop an educational series for medical students with the aim of raising awareness and improving understanding of the Yellow Card scheme and the wider regulatory role of MHRA in patient safety. Following the pilot of the e-learning modules with medical students at Kings College London and Nottingham University (2022/23), discussions have now begun with the Medical Schools Council to consider future applications of the resource. Moving forward, we will be working with the Medical Schools Council to further refine the resource and develop a bank of exam questions for the 2024/25 academic year.

## DIGITAL AND TECHNOLOGY

### SafetyConnect

5.1 Further improvements are ongoing with SafetyConnect, the new vigilance data capture and signal detection system for adverse events associated with medicines and medical devices. The go-live is now planned for 27 November 2023. Case migration testing commenced on 25 October. Testing has identified issues with the reporting functionality, for example relating to data fields and formats. The project is looking at options to address this including the potential upgrade and further investigations are being progressed.

### Intellicase replacement

5.2 The Criminal Enforcement Unit (CEU) and Devices Compliance team currently use a combination of disparate IT systems, spreadsheets, and databases to deliver a range of critical services. Because these various systems are not integrated this can lead to a lack of timely, accurate and complete information, resulting in decisions based on subjective opinions and assessments of risks and threats. One of the key systems currently being used, 'Intellicase' is no longer believed to be fit for purpose. We now plan to replace it with a single, more efficient, fit for purpose 'software as a service' solution which should result in improved operational efficiency, decision-making, and performance, through improved analysis of intelligence data and collaboration between teams. The aim is to have the new solution in place by the end of March 2024.

### International Recognition

5.3 The International Recognition Procedure digital infrastructure project is progressing to plan and is being jointly delivered by Digital & Technology Group and an IT supplier. The online form for applicants has been developed and tested. An update on progress was presented to the One Agency Leadership Group on 24 October with go-live planned for January 2024.

### Regulatory Management System

5.4 Following presentation of the revised delivery plan to the Regulatory Management System (RMS) Programme Board, work continues to deliver against the key milestones for RMS Release 1:

- RMS self service portal
- eCTD Case Management
- UK-SRS
- Legacy archive reporting
- Legacy archive search
- Inspections universe reporting

5.5 The work is broadly on track although changes to Legacy Archive and reporting approaches have been requested. Work has commenced to develop the next iteration of the RMS Business Case to review options and associated costs. This is to be presented to the Agency ExCo mid November 2023**.** Following advice from the Agency Board, an external independent validation review of the RMS programme is to be undertaken.

**Service desk maturity project**

5.6 Our Service Desk providers have introduced a call monitoring system called NFON on their laptops. This enables Service Management to monitor call answering times as well as seeing how many calls are received and dropped. The target is to answer all calls within 30 seconds. Initiatives to free up the Service Desk analysts to enable them to concentrate on the user experience are currently being assessed. A new survey tool for helpdesk calls is currently being tested. It will allow us to ask for feedback on performance on completion of helpdesk calls. The question will change after a period of time and will be measured against an XLA (eXperience Level Agreement) so service improvements can be made.

## DYNAMIC ORGANISATION

**Civil Service People Survey**

6.1 The Civil Service People Survey closed on 23rd October, with a response rate from the MHRA of 72% or 923 respondents. This represents a 2% increase on last year. The results will be processed and shared with staff in the new year.

## AGENCY PRIORITIES

In summary, the current priorities for the Agency are to:

i. Maintain the Agency's focus on delivering its core business functions, meeting assessment targets for all key services and eliminating any backlogs

ii. Embed the Clinical Trials Notification scheme taking a risk-proportionate approach to the approval of clinical trials and deliver the recommendations of the O'Shaughnessy report

iii. Operationalise the new international recognition framework which allows the Agency to streamline approvals for safe and effective medicines, and progress plans for international recognition for medical devices

iv. Deliver a new AI airlock to provide innovators with a space to test new technologies with the potential to have significant public health benefits in a safe way that enables the regulator to further understand the impact of these technologies.

v. Refocus the Regulatory Management System programme replacing legacy IT systems, taking account of Agency priorities and the need to integrate transformed business processes.

**Dr June Raine, CEO**

**November 2023**

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING - HELD IN PUBLIC

**21 November 2023**

| | |
|---|---|
| **Title** | How well have the Business Plan targets been met and what is planned in each of the operational areas? |
| **Board Sponsor** | Rose Braithwaite |
| **Purpose of Paper** | Assurance |

# How well have the Business Plan targets been met and what is planned in each of the operational areas?

## 1. Executive Summary

1.1 Overall the Agency is on track to deliver its Business Plan objectives for 2023/24 with areas that are at risk of slippage having sound mitigations in place to bring them back on track.

1.2 The Key Performance Indicators (KPIs) have been expanded to show new areas of operational delivery and will continue to be developed over the remainder of the year. They show a number of areas of successful delivery but do flag areas where the Agency needs to continue to work to improve its performance.

## 2. Introduction

2.1 The quarterly performance pack provides information to the Board on the progress the Agency is making towards its annual Business Plan objectives and how it is performing against its key performance indicators.

2.2 The Delivery & Performance Committee (DPC) which is responsible for monitoring the Agency's performance reviewed the status of activities and proposed mitigations for off-track items. It has sessions with leads to review the mitigations to test their effectiveness. There is good evidence that leads are prioritising their business plan objectives and working on sound mitigation plans.

2.3 Items where there are concerns regarding underperformance are escalated to the Executive Committee for decisions on mitigations plans and further actions.

2.4 Work has begun on updating our performance metrics and a new draft report will be tabled for Q3. Finance has begun engaging teams to discuss improvement. Part of this change will include better integration of the clinical trials and Parliamentary Questions (PQs) data.

## 3. Proposal

### Business Plan Objectives

3.1 Overall, the Agency is on track to deliver its Business Plan within this reporting year. However, there are some emerging risks of slippage and these are being carefully monitored.

3.2 The main areas of note are (see slides 7-9):

- The successful launch of a **new graduate scheme** and new and **improved financial reporting,** both of which feature under the fourth strategic priority, an Agency where people flourish alongside a responsive customer service.

- Work addressing **backlogs** is in hand but given the scale of the task and the need to embed a cross-Agency process, the Delivery and Performance Committee (DPC) flagged the risk that it cannot guarantee that all backlogs will be cleared by the end of 2023/24. The DPC is compiling a list of those most at risk for the ExCo and will be prioritising backlogs with statutory deadlines. It should be noted that progress is being made but some areas are more complex to resolve.

- Work addressing **backlogs** is in hand but given the scale of the task and need to embed a cross-Agency process, the DPC flagged the risk that it cannot guarantee that all backlogs will be cleared by the end of 2023/24.

- While mitigations are live, the two legislative items (**Clinical Trials** and **Point of Care Manufacturing**) are at risk with regard to their Q4 deadlines. This is largely due to the need to reconsider the regulatory framework in light of lessons from the clinical trials process review and the potential risk that this will require a new public consultation; and delays from the need to seek approval and secure additional technical expertise, respectively.

- There are two items that will miss their in-year due dates but are still deliverable within the Business Plan's overall lifetime. The work to "better define healthcare system supply priorities for medicines and devices in terms of patient need and proactive supply chain management and to inform our priorities" has been delayed by ongoing major supply incidents impacting both the Agency and wider involved stakeholders. The work to improve our standards distribution approach has been delayed due to an increase in the amount of sales orders-on-hand and the need to prioritise service delivery for existing customers.

**Operational Performance of the Agency**

3.3 The performance pack provides the details of the Q2 performance up to the end of September. Additional slides have been added on standards portfolios (slide 19), Clinical Trials (slides 41-43) and Parliamentary Questions (PQs) (appendix A).

3.4 The current report shows good performance within:

- **Clinical trials** - slides 18-20. The backlogs have been substantially reduced during Q2 as shown in the August and September columns in slide 19.

- **Grant applications** – slide 23. As well as grant income being £110k higher than budget, the current success rate of decided applications stands at 77% for 2023/24, up from 43% last year. This has resulted in the number of grants being approved increasing by 25% to 10.

- **CPRD income** – Slide 34. The target to grow income by 9% has been achieved YTD and in every month other than May.

- **Staff Turnover** – Slide 36. Turnover rate of 9% is excellent and below expected levels. Especially satisfying considering 2022/23 saw turnover rates of between 14%-23%.

- **Debt –** Slide 39. Debt over 60 days has reduced by 60% (£5.2m) since last year, significantly reducing the risk of lost revenue through bad debt.

3.5 Meanwhile areas where the report highlights improvements are needed:

- **ILAP –** Slide 21**.** ILAP and TDP activity has ceased whilst applications remain. This is due to other priorities but a plan for resumption of activity has been developed.

- **Standards –** Slide 22. There has been a 160% increase in orders on hand since last year (worth £1.6m) highlighting the demand for this service. Extra staff have been recruited to address this with expectation that order fulfilment time will start to reduce in Q3 with a consequent reduction in orders-on-hand.

## 4. Recommendation

4.1 The Board is asked to review the report and confirm if it needs any more assurance on Agency performance.

**Rose Braithwaite**
**09 November 2023**

Medicines & Healthcare products Regulatory Agency

# MHRA Performance Report

## Business Plan Progress & Operational Performance
## Quarter 2, 2023/24

Finance Division

**November 2023**

Medicines & Healthcare products Regulatory Agency

# Part 1: Business Plan Progress

- Status of Business Plan objectives by Strategic Priority
- Status and mitigation of off-track items

| | Key action | Q2 (Jul – Sep) → | Q3 (Oct – Dec) → | Q4 (Jan – Mar) → |
|---|---|---|---|---|
| 1. Maintain public trust through transparency and proactive communication | 1.1 Embed **patient involvement across our regulatory pathways** that is meaningful, proportionate, and impactful, to help ensure medical products reach patients without delay, accompanied by efficacy and safety info that better meets the needs of all patients. | Nothing scheduled in the Business Plan, focus on core business | 1.1.1 Ensure patient involvement activities remain ethical, meaningful and impactful by embedding new tailored guidelines for priority agency functions by end Q3. | 1.1.2 Develop a new risk communication strategy to ensure more coordinated, proactive risk and safety communications to patients, the public and healthcare professionals, by end Q4. |
| | | | | 1.1.3 Design a new approach to recruit and train additional lay committee members (non-clinical, academic or scientific) to ensure our independent advisory bodies benefit from greater lay perspectives and challenge by end Q4. |
| | 1.2 **Enable diverse patient voices** to provide evidence on safety concerns on specific types of medicines and medical devices. | Nothing scheduled in the Business Plan, focus on core business | → 1.2.1 Establish a consistent, inclusive and systematic approach to ongoing patient involvement in our benefit and risk evaluation assessments by end Q3. | → 1.2.2 Complete a review of regulatory opportunities to address health inequalities by end Q4. |
| | | | 1.2.3 Identify two safety topics affecting underserved groups by end Q3 and engage with patients so they can raise concerns and to inform our approach by end Q4. | 1.2.4 Broaden our communications channels to reach under-represented and under-served populations, ensuring the contribution of more diverse voices by end Q4. |
| | 1.3 **Increase transparency of safety signals and the basis of our benefit-risk decisions** by regularly publishing the safety signals on medical products and a public statement following approval of all new chemical entities within one week, plus a summary of the evidence for the regulatory approval within one month. | ↓ 1.3.1 Make Yellow Card incident report data available in the new COVID-19 interactive format for medicines by end Q2 and devices by end Q3.<br><br>*(N.B., due date replanned to Q4 given dependency with, and delays to, wider SafetyConnect rollout.)* | Nothing scheduled in the Business Plan, focus on core business | ↑ 1.3.2 Pilot publication of safety signals assessed by our Pharmacovigilance Expert Advisory Group on our Yellow Card website and the publication of accessible lay summaries of our benefit and risk evaluation assessments by end Q4. |
| | | | | 1.3.3 By end Q4, establish the governance of the Yellow Card Biobank and successfully demonstrate procedures in action for participant recruitment, sample collection and sample storage. |
| | | | | ↑ 1.3.4 By end Q4, regularly publish a public statement following approval of all new chemical entities within one week and provide a summary to provide the evidence for the regulatory approval within one month. |

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

| | Key action | Q2 (Jul – Sep) → | Q3 (Oct – Dec) → | Q4 (Jan – Mar) → |
|---|---|---|---|---|
| 2. Enable healthcare access to new, safe and effective medical products | 2.1 Deliver **predictable and reliable operational performance** having defined our priority improvements for our core services to ensure swift and robust decisions on medical products, safety signals and compliance. | Nothing scheduled in the Business Plan, focus on core business | Nothing scheduled in the Business Plan, focus on core business | 2.1.1 Identify service improvements across all priority areas with robust plans for implementation and effective change management to be in place by end Q4.<br>→ 2.1.2 Eliminate current service backlogs by end of 2023/24.<br>↑ 2.1.3 Deliver phase one of our innovation-enabling and risk-proportionate medicines compliance strategy including the development of a pilot project for an outcome-based model by end Q4.<br>2.1.4 Fully embed our new SafetyConnect vigilance system and realise patient and operational benefits by end Q4. |
| | 2.2 Develop and embed **system cooperation with UK partner organisations, including the NHS**, to ensure the gap continues to be narrowed between regulatory and health ILAP technology approval with a clear path to patient deployment. | Nothing scheduled in the Business Plan, focus on core business | ↓ 2.2.1 By end Q3, work with stakeholders to lay the foundation for electronic Patient Information (ePI) by 2026 to ensure more accessible information for patients.<br>↓ 2.2.2 Establish the UK healthcare systems priorities for medicines and medical devices in terms of patient need and proactive supply chain management and to inform our priorities by end Q3. | ↑ 2.2.3a Establish the ILAP by delivering a partnership governance that delivers ILAP activities by end Q4.<br>↑ 2.2.3b Establish the IDAP by delivering a partnership governance that delivers the IDAP pilot project by end Q4.<br>2.2.4 Work with the HRA to implement the 60-day review period of clinical trial applications in line with the recommendation of the O'Shaughnessy. |
| | 2.3 Launch the improved **regulatory management system** to make our services more streamlined, as the first phase of the replacement of legacy IT systems, enabling all new product licences, variations, inspections, and process licences to be efficiently handled, maximising the use of self-service for low-risk decisions. | Nothing scheduled in the Business Plan, focus on core business | Nothing scheduled in the Business Plan, focus on core business | 2.3.1 Launch the first release of our new regulatory management system by end Q4. |

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

| | Key action | Q2 (Jul – Sep) → | Q3 (Oct – Dec) → | Q4 (Jan – Mar) → |
|---|---|---|---|---|
| 3. Deliver scientific and regulatory excellence through strategic partnerships | 3.1 Introduce the **MHRA Science Strategy**, establish and build on partnerships in key priority areas with national and international partners with measurable benefits that support prompt and robust regulatory decision-making | Nothing scheduled in the Business Plan, focus on core business | 3.1.1 Publish a Data Quality Strategy, including proposals for revised and extended data quality checks, for our Clinical Practice Research Datalink services and refresh our data quality webpage by end Q3. | 3.1.2 Launch our MHRA Science Strategy, including engagement with key stakeholders, and delivery of key themes by Q4. |
| | | | | ↑ 3.1.3 Establish processes to identify future areas of innovation, working with national and international partners to align priorities with patient need by end Q4. |
| | 3.2 **Re-prioritise standards, control testing and underpinning research** to ensure support for priority areas of our MHRA Science Strategy and Corporate Plan. | ↓ 3.2.1 Run a trial from Q2 to end Q4 aimed at improving our distribution approach, increasing the volumes of standards we provide globally and raising awareness of our offer. | Nothing scheduled in the Business Plan, focus on core business | ↓ 3.2.2 Develop a new strategy for the BP and associated laboratory services for consultation by end Q4 including income investment plans to improve services |
| | | | | 3.2.3 Link the Innovation Accelerator activities with academia and other stakeholders by Q4 to provide support for the CERSI recommendation in the McLean Report. |
| | | | | 3.2.4 Implement a new risk-proportionate approach for the independent control testing of biological medicines to expand our ability to perform laboratory assessments by end Q4. |
| | 3.3 Legislate on **Point of Care Manufacture** and drive international regulatory progress in key scientific areas commensurate with scientific and technological advances such as mRNA technology, artificial intelligence and in silico data generation. | Nothing scheduled in the Business Plan, focus on core business | Nothing scheduled in the Business Plan, focus on core business | → 3.3.1 Deliver a new framework for UK PoCM, lay legislation before Parliament and publish guidance by end Q4. |
| | | | | 3.3.2 Establish active bilaterals and wider collaborations nationally and internationally with work programmes in place on healthcare product innovation areas of interest by end Q4. |
| | 3.4 **introduction of new guidance and legislation and work to build our status as an independent regulator** in a global environment and to ensure the UK remains a great environment to develop novel and innovative medical products. There are also some milestones for this year: | Nothing scheduled in the Business Plan, focus on core business | 3.4.1 Implement Windsor Framework for a commencement date of 1 January 2025: issue essential guidance by end Q3, place legislation before Parliament in 2024 and issue further guidance and comms as needed up to the commencement date. | → 3.4.2 Prepare legislation by Q4 to deliver reform of the UK clinical trials regulatory framework. |
| | | 3.4.3 Lay regulations for transition provisions by end Q2 to maintain the supply of devices in GB and for future regulations to strengthened PMS by end Q4 to strengthen requirements for devices on the market and increase patient safety, and clarifying plans, including consulting if needed, for international recognition of devices approved in other jurisdictions by end Q3. | | 3.4.4 Launch a new international recognition route by 1 Jan 2024 for medicines utilising pre-existing approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the US. |

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

| | Key action | Q2 (Jul – Sep) → | Q3 (Oct – Dec) → | Q4 (Jan – Mar) → |
|---|---|---|---|---|
| 4. Become an agency where people flourish alongside responsive customer service | 4.1 Deliver a range of **core and specialist learning opportunities** and implement and review the agency leadership development plan, to ensure we have the right capabilities across the organisation. | 4.1.2 Refresh our Culture Action Plan by end Q2 and deliver its actions by end Q4 to support our strategic priorities and the delivery of our redesigned services. (Q2 deadline met)<br><br>4.1.4 Update our Leadership Development Plan by end Q2 and deliver new actions to strengthen leadership capability across the agency by end Q4. ( Q2 deadline met) | 4.1.1 Introduce an MHRA-wide workforce plan by end Q3 to ensure our workforce needs are known and can be acted on. | 4.1.3 Deliver a plan for core learning and development for 2023/24 that identifies and strengthens capabilities in priority areas by end Q4. |
| | 4.2 **Attract and develop talent** by strengthening existing or creating new recruitment channels such as a graduate scheme and increasing apprenticeships. | 4.2.1 The first graduate scheme cohort to commence our new 3-year programme and complete the on-boarding of 8 new graduates by end Q2. | Nothing scheduled in the Business Plan, focus on core business | 4.2.2 Increase the number of apprenticeships towards the target of 40 by end Q4.<br><br>4.2.3 Update our talent management approach, aligning it to workforce planning and ensuring a clear link with business planning by end Q4 |
| | 4.3 Develop a **new financial plan** to ensure we continue to deliver value for money, invest in people, maintain our financial sustainability and recover the costs of all our services, with updates to our fees to be in force by 1 April 2025. | 4.3.2 Produce new improved financial management reporting using DataRails by end Q2 to ensure better data and more informed decision-making. | 4.3.1 Staff activity recording to commence in fee earning areas by end Q3 to ensure we have a greater understanding of our costs to serve. | 4.3.3 Develop new pricing for services and products by Q4 to improve cost recovery across the Agency, and consult on and deliver the next uplift in our fees by 1 April 2025. |

KEY: Red: late or not possible; Amber: at risk; Green: on-track; Blue: complete; Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

| 1. Maintain public trust through transparency and proactive communication | | | |
|---|---|---|---|
| **Q2** | **Q1** | **Off-track objective** | **Status and mitigation** |
| | | ↓ 1.3.1 Make **Yellow Card incident report data** available in the new COVID-19 interactive format for medicines by end Q2 and devices by end Q3.<br>(Alison / Phil) | This was on track but delivery has been delayed given a dependency with wider SafetyConnect rollout. The iDAP is connected to Phase II SafetyConnect delivery, which has been moved from Q2 to Q3. Go-live of the new interactive format is expected to be delivered 4-6 weeks after medicines go-live, as the data is required to be in the new systems to deliver. Device data will follow in the new format in Q4. |
| | | → 1.2.1 Establish a consistent, inclusive and systematic approach to ongoing **patient involvement in our benefit and risk evaluation assessments** by end Q3.<br>(Alison / Janine) | We have run 2 successful patient engagement exercises. One on Kaftrio, involving a partnership with the Cystic Fibrosis Trust and patients sharing their experiences via video, and a second on Montelukast, where we did a patient survey. Feedback from the Neurology, Pain and Psychiatry Expert Advisory Group on the value of patient voices in the assessment was very positive. Clinical trials redeployment had an impact on progress, and we will be 2 FTE medics down until the end of December. We are also being asked to prioritise Variations. Therefore, engagement is being deprioritised and we are working with PPSE team on guidance to ensure that engagement is utilised when it adds the most value. Given this, this remains Amber. |
| | | → 1.2.2 Complete a review of regulatory **opportunities to address health inequalities** by end Q4.<br>(Alison & Glenn / Kathryn & Emily) | The first element of the objective is the women's health review and this is now back on track for completion by end Q3 / early Q4, depending on the duration of its stakeholder engagement phase. The next stages of the objective are still being scoped across S&S and Partnerships and deliverables will be clarified for the Q3 report. This is dependent on staff resource and further work is needed to clarify assessor and partnerships staff availability. |
| | | ↑ 1.3.2 Pilot **publication of safety signals assessed by our Pharmacovigilance Expert Advisory Group** on our Yellow Card website and the publication of accessible lay summaries of our benefit and risk evaluation assessments by end Q4.<br>(Alison / Phil) | Work has begun and is slightly behind schedule given the decision to reprioritise resources to both SafetyConnect and the clinical trial redeployment exercise. Now the clinical trials deployment exercise has been successful, we are working to catch up and hope to get back on track and will keep this under review. |
| | | ↑ 1.3.4 By end Q4, regularly publish a public statement following **approval of all new chemical entities** within one week and provide a summary to provide the evidence for the regulatory approval within one month.<br>(Julian / Andrea) | This is on track but there remains one area associated with the publication requirements of UK Public Assessment Reports (UKPAR), where we have a current backlog. We are exploring a new mechanism for producing the summary of evidence and this is due to be piloted in Q3. Assuming this is successful we should be able to his the overall Q4 deadline. |

| 2. Enable healthcare access to new, safe and effective medical products | | | |
|---|---|---|---|
| **Q2** | **Q1** | **Off-track objective** | **Status and mitigation** |
| | | ↓ 2.2.2 Establish the UK healthcare systems **priorities for medicines and medical devices** in terms of patient need and proactive supply chain management and to inform our priorities by end Q3.<br>(Julian / James) | We continue to face delays given the impact of needing to resource Incident Management Teams (IMTs) for ongoing supply issues. This is diverting staff resource in both MHRA and key partner organisations (including DHSC). Given this, it will not be possible to meet the planned deadline of end of Q3. **We propose this is revised to end of Q4 and kept under review.** There are no other plan deliverables that have a dependency on this project. |
| | | → 2.1.2 Eliminate current **service backlogs** by end of 2023/24.<br>(Mick / Penny) | DPC members are working with local SMT/SLT to monitor statutory backlogs and those that affect Agency performance, and this is now moving to monthly reporting. ExCo have agreed underspend can be used to help clear backlogs. DPC are working with Finance to run a process that allows data to be interrogated more easily and a timeline for the first iteration is currently being agreed. **As this process beds in we will make progress on backlogs, but given the scale of the task and need to deliver cross-Agency process and cultural change we cannot guarantee that all backlogs will be removed by the end of 23/24.** |
| | | ↑ 2.2.3 Establish the ILAP and the IDAP by delivering a partnership governance that delivers ILAP activities and the IDAP pilot project by end of Q4.<br>**(Marc / Louise)**<br>[n.b. ILAP and IDAP objectives have been separated, the latter is on track] | ILAP activity is paused, with an increasing backlog of applications that cannot be progressed. **Resuming activity to tackle the backlog and agree plans for a refresh are contingent on all parties signing a Partnership Agreement which has been reviewed and agreed by HTA partners.** NHSE have indicated in principle agreement to formally enter into the partnership for ILAP refresh on assumption this will not include expectation to share accountability for the previous ILAP activity/backlogs. Discussions with NHS bodies in Devolved Nations at a very early stage. IA recruitment for ILAP is underway. |
| | | ↑ 2.1.3 Deliver phase one of our innovation-enabling and risk-proportionate medicines **compliance strategy** including the development of a pilot project for an outcome-based model by end Q4.<br>(Julian / James) | Remains as Amber due to impact of resource being diverted to support RMS delivery and multiple IMTs (as noted above). However, we expect to be able to return this to Green in Q4 once resource requirements are clear and if incidents abate so project activities can be prioritised. |
| | | ↓ 2.2.1 By end Q3, work with stakeholders to lay the foundation for **electronic Patient Information** (ePI) by 2026 to ensure more accessible information for patients.<br>(Julian / Andrea) | There have been delays in the ePI Task Force meeting. We are supporting progress, but it is an industry lead group. The Task Force will be updating the way ePILs are created and stored, allowing greater accessibility and improved user access. The next phase was due to start in September and run for 6 months, but the group has not met yet. We have been progressing work internally on possible legislative timeframes and requirements for proof of concept. Despite this, it is still possible to lay foundations (as determined by the Task Force) by Q3. |

| 3. Deliver scientific and regulatory excellence through strategic partnerships | | | |
|---|---|---|---|
| **Q2** | **Q1** | **Off-track objective** | **Status and mitigation** |
| | | ↓ 3.2.1 Run a trial from Q2 to end Q4 aimed at **improving our distribution approach,** increasing the volumes of standards we provide globally and raising awareness of our offer.<br>(Marc / Paul) | An increase in the amount of sales orders-on-hand has led to the prioritisation of our service delivery for existing customers. This has delayed the start of the distributor strategy. To address this we have recruited more staff to improve service levels. **Additionally, we are exploring the expansion of an existing role to provide dedicated support to participants in the distributor trial allowing this trial to start before year-end with the intended enhanced service level.** |
| | | → 3.3.1 Deliver a new framework for **UK PoCM**, lay legislation before Parliament and publish guidance by end Q4.<br>(Glenn / Cathy) | **Project is Amber tracking Red with regard to the original deadline given the availability of technical expertise and the impact of the situation with the NI assembly.** Ministerial clearance has now been received to recruit an expert to progress the framework. This should remain marked as at risk given the delay, but it may still be possible to deliver by end Q4. |
| | | → 3.4.2 Prepare legislation by Q4 to deliver reform of the **UK clinical trials** regulatory framework.<br>(Glenn / Cathy) | **Project is Amber tracking Red with regard to the original deadline given the need to reconsider the regulatory framework in light of lessons from the redeployment exercise.** If lessons are sufficiently different from the proposals in the original public consultation for the legislative reform this might result in the need to reconsult. A workshop with external experts is planned in November. We are working with lawyers to clarify requirements and should it be necessary will consider splitting the SI to enable us to take key changes forward first to a faster timeline. |
| | | ↓ 3.2.2 Develop a new **strategy for the British Pharmacopoeia** and associated laboratory services for consultation by end Q4 including income investment plans to improve services<br>(Marc / James) | Planned delay to activity due to need to manage with other high priority activities (including QMS review). Interventions planed in Q3 23/24 will ensure objective back on track by November 23 to ensure delivery in Q4 of FY 23/24. |
| | | ↑ 3.1.3 Establish processes to **identify future areas of innovation**, working with partners to align priorities with patient need by end Q4.<br>(Marc / Louise & Harriet) | This initially faced delays due to limited staff resource but funding was secured as part of the £10m from the budget. This will give the team sufficient capacity but recruitment is not yet complete so we propose to keep it on Amber. There is sufficient time return to Green when staff are in place. We are in the process of developing a specific innovation-focused work stream for systems alignment, in collaboration with national partners. |

| 4. Become an agency where people flourish alongside responsive customer service | |
|---|---|
| 4.2.1 The first **graduate scheme** cohort to commence our new 3-year programme and complete the on-boarding of 8 new graduates by end Q2.<br><br>(Kerry / Malgosia) | Completed. The programme commenced on 25 September with an induction day facilitated by the Talent and Capabilities for 8 new graduates. This is the Agency's first-ever Graduate Scheme pilot. The induction event was supported by the CEO and two Chief officers. The 8 graduates have all been assigned to their first role in the 3 main operating groups. Is a great opportunity for them to learn aspects of our regulatory business and, after three years of training, hopefully stay on to forge a meaningful career with the MHRA. |
| 4.3.2 Produce new improved **financial management** reporting using DataRails by end Q2 to ensure better data and more informed decision-making.<br><br>(Rose / Peter) | Our new Management Account separate out Resource and Capital Departmental Limit spend against funding. This means that the ExCo and budget holders have much more clarity on financial performance against those two types of funding. The new management accounts also separate Cash and Non-Cash spending, again making it much easier for budget holders to understand how much budget they have available. We have also done a roll out new dashboards to support budget holders in interrogating financial data using DataRails. |

Medicines & Healthcare products Regulatory Agency

# Part 2: Operational Performance

# Summary – Top Key Performance Indicators

| | KPI ( slide number) | | Q2 23/24 | Q1 23/24 | Q4 22/23 | Q3 22/23 |
|---|---|---|---|---|---|---|
| **Science, Research and Innovation** | IP approvals through ILAP SG (21) | | 0 | 7 | 24 | 10 |
| | IP refusals (21) | | 0 | 5 | 2 | 1 |
| | Diagnostic standards (21) | Shipped:<br>Customers: | 7488<br>149 | 4315<br>130 | 5987<br>143 | 6662<br>127 |
| | Number of TDPs requested (21) | | 0 | 8 | 5 | 4 |
| **Safety and Surveillance** | Public assessment reports (14) | | 121 | 88 | 84 | 58 |
| | Safety signals identified for further assessment (31) | | 22 | 29 | 23 | 30 |
| | Safety variations assessed (31) | | 397 | 348 | 372 | |
| | Actions taken to minimise risk to patients (31) | | 28 | 11 | 38 | 32 |
| **Healthcare, Quality and Access** | New licences (25) | | 8 | 9 | 9 | |
| | Established medicines number of abridged complex determined (25) | | 29 | 30 | 35 | |
| | CT site inspections (30) | Inspections<br>Referral for critical findings: | 11<br>2 | 13<br>2 | 10<br>2 | |
| | Supply chain site inspections (30) | Inspections<br>Referral for critical findings: | 90<br>5 | 84<br>10 | 123<br>8 | |

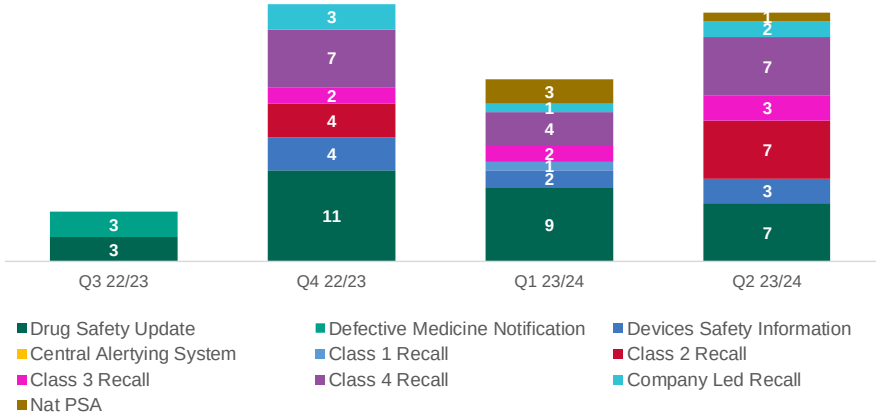
# Summary – Top Key Performance Indicators

| | KPI ( slide number) | Q2 23/24 | Q1 23/24 | Q4 22/23 | Q3 22/23 |
|---|---|---|---|---|---|
| Corporate | Forecast Income (38) | 189.5m | 184.5m | | |
| | Voluntary turnover (36) | 9% | 12% | 14% | 16% |
| | Incidents and accidents (37) | 24 | 23 | 15 | 14 |
| Enablement | CEC queries (16) | 15k | 16k | 18k | 17k |
| | Complaints (16) | 1,042 | 2,173 | | |

# Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

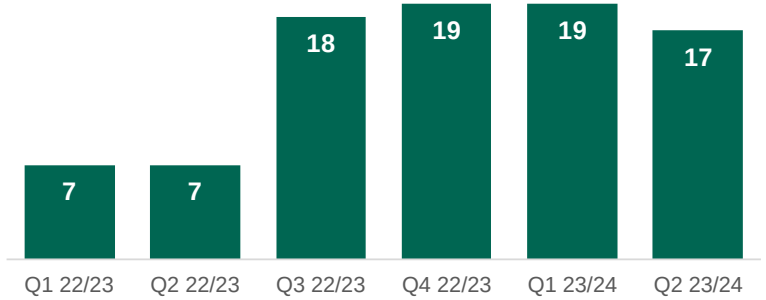
### Q2 Communication to Healthcare Professionals



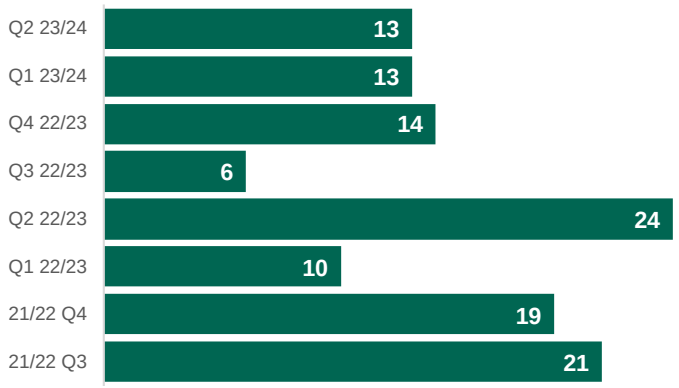

### Patient Engagement Training Completed by Staff

1154 employees registered onto the course from a workforce total of 1208. 127 have failed to either register or complete the course. That gives us 89.4% of staff who have completed the course. This score far exceeds other mandatory training run by the Agency.

### Internal requests for patient engagement activities




### Scientific Papers Published




### Reputational Index

The customer insight and reputation research has been completed. Since the publication of the Corporate and Business plans, we have been reviewing the insights to identify gaps between what customers and stakeholders have reported and how our delivery plans address these needs. We have also been working to synthesise the data into components of a reputation dashboard, sought advice on this from our supplier and will seek senior input into to this in early November. In addition, we are planning the next wave of research to demonstrate any changes against our benchmarks.

### Public Assessment Reports

- 0 PARs on self-mediation reclass procedures – 0 in Q4
- 0 on safety – 0 in Q4

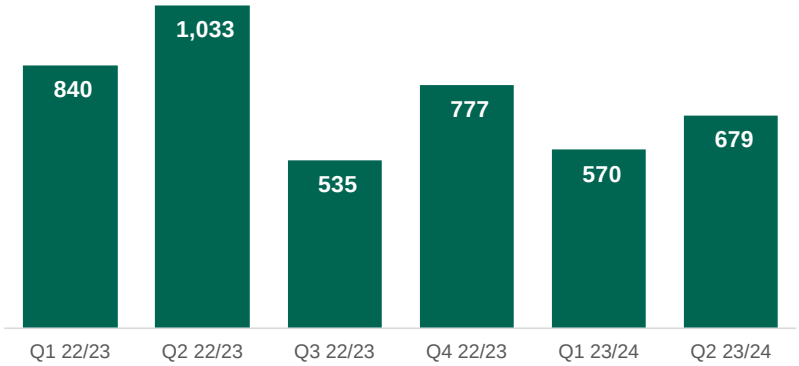
PARs published for new marketing authorisation – *(Target is 60 calendar days from licence grant, plus any clock off time)*

- Q3 - 58 (33; 57% completed on time)
- Q4 – 84 (56; 67% completed on time)
- Q1 – 88 (33; 38% completed on time)
- Q2 – 121 (45; 37% completed on time)

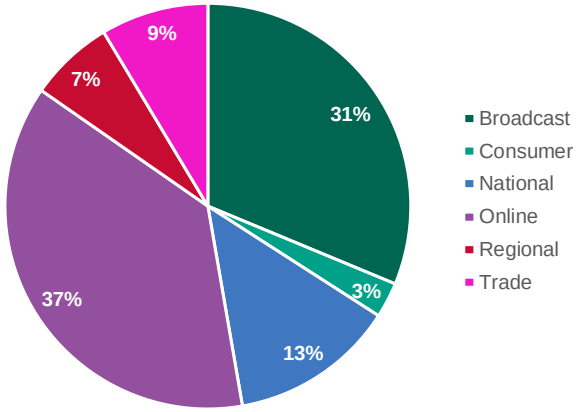
# Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

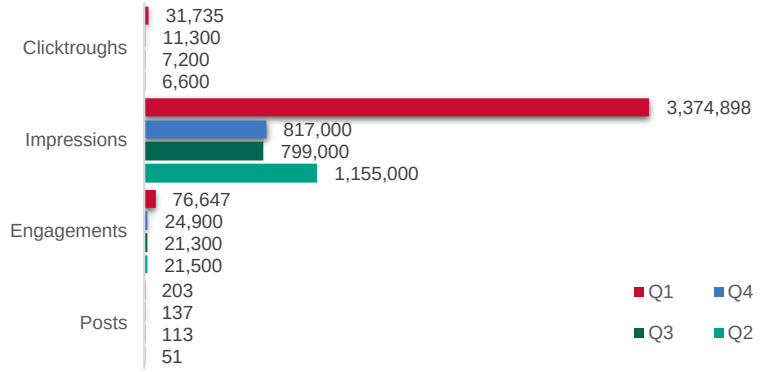
**Media Article Mentions**




**Q2 Articles by Media Type**




**Social Media Reach – by quarter**



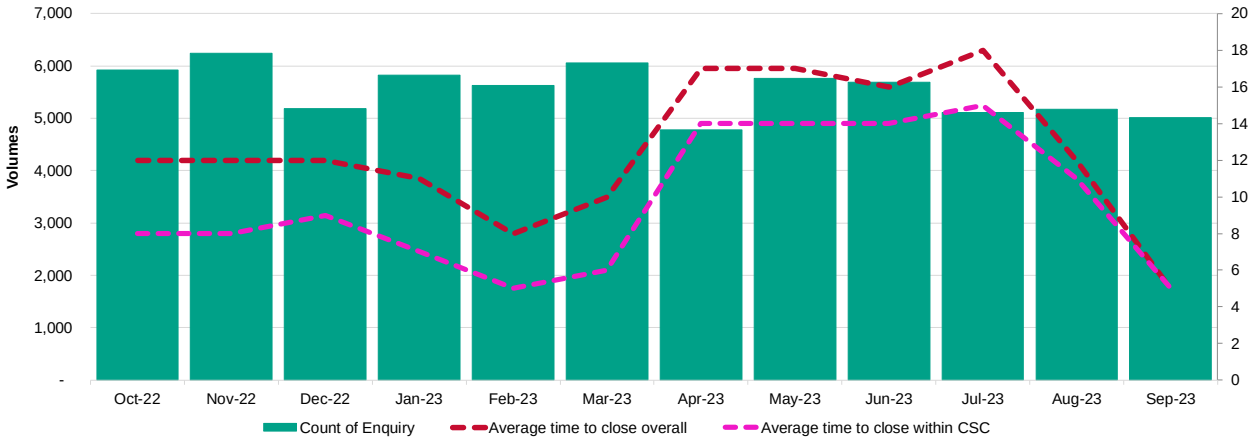

This quarter MHRA generated 671 mentions in coverage. Coverage for the reporting period was driven by reports in high-profile outlets such as *Mail Online* which highlighted the potential approvals of the new Alzheimer's drug, lecanemab, reporting that the approval *"process is currently underway in the UK, led by the Medicines and Healthcare products Regulatory Agency (MHRA)*" as the drug is set to undergo further testing to ensure it meets the regulatory bodies standards for distribution (*Sky news, The Mirror*). Elsewhere, weight loss medications emerged as a prominent driver of coverage within outlets such as *The Times* following the release of "*fake*" Ozempic on social media, reporting that "*Medicines and Healthcare Products Regulatory Agency (MHRA) sent a warning to NHS and private clinics in the UK about a national shortage of GLP-1 receptor agonists, drugs, including Ozempic*", with customers turning to less-than-reputable sources to gain access. Weight-loss medication further drove coverage in high-profile outlets such as *BBC News* and *MSN*, with reports in the former highlighting the remarks made by Chief Safety Office Alison Cave following concerns of suicidal thoughts when using the weight-loss drugs: "*As part of our close monitoring, any emerging evidence is routinely considered alongside other sources of information, including suspected adverse drug reactions. We will communicate any new advice to healthcare professionals and patients if appropriate*".

Dr Alison Cave remained the most prolific spokesperson of the quarter, appearing in 39 articles this reporting period. Notable coverage for the Chief Safety Officer surrounded remarks made regarding the weight-loss drug review, with *The Guardian* reporting on the executives' comments that "*Patient safety is our top priority. We will carefully consider all available evidence and communicate any further advice to patients and healthcare professionals as appropriate*" . Elsewhere, reports surrounded the consultation on the reclassification of cough syrup made with codeine, with *Sky News* highlighting Dr Cave's comments that "*Codeine linctus is an effective medicine, but as it is an opioid, its misuse and abuse can have major health consequences"* and that *"Every response received will help us to develop a broader view on whether codeine linctus should be restricted to prescription-only status*".

All coverage was positive in tone, with notable reports surrounding newly approved medication rollouts appearing in outlets such as *Mail Online* while *Chemist & Druggist* highlighted the announcement that "*MHRA catches Maidenhead couple in £1.6m black market medicines ploy*" as outlets highlighted the regulatory body's role in ending unlicensed medication trade.

# Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

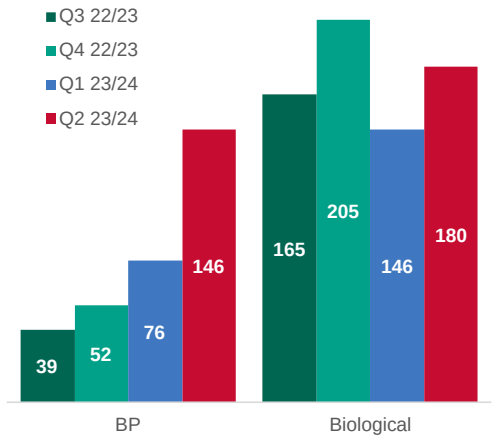



Query volumes reduced for Q2* in comparison to Q1 23/24. While the average time to close has significantly decreased this quarter, the team continues to action query backlogs from Q2 during October, which may result in an increase in the average time to close figure in Q3. Daily triaging is in place to ensure important patient and public enquiries, and high profile queries are handled promptly. Recruitment is also underway to fill vacancies within the team. Queries and complaints driven by clinical trial delays have been prioritised with no backlogs in this area. A Clinical Trial hotline was established early August to provide a more proactive and responsive service which has been well received by our customers and important stakeholders. Despite lower volumes in Q2, complexities around the handling of Freedom of Information requests continues and significant work is underway to clear all outstanding requests in this area by end of December.

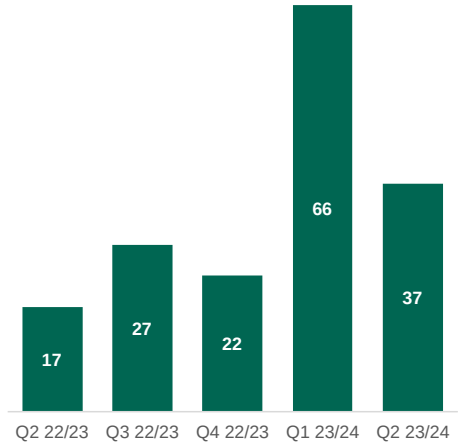
CEC is also undergoing intense training across the team and recruitment to fill vacancies continues.

In Q2: 43% queries from Industry including Academia, 17% from Patients and members of the Public, 7% Healthcare providers, the rest split between Government, Suppliers, Campaign groups

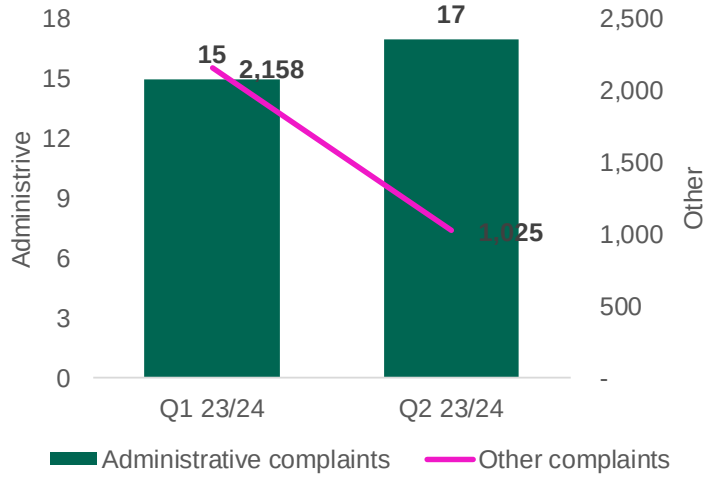
**New Customers - Standards**




**Parliamentary Questions Received**




**Complaints**

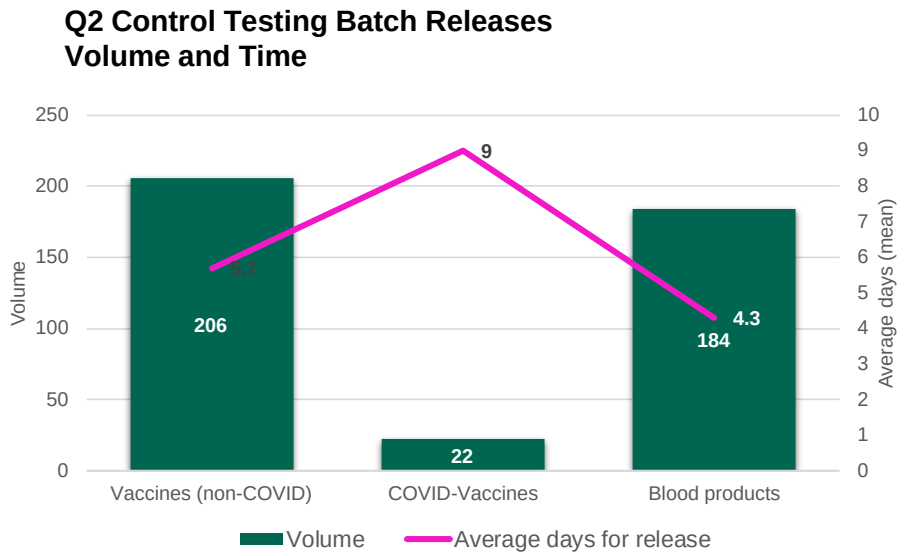



Other complaints now include data collected from CEC which is not captured within the administrative complaints process.

Details were presented to RAG in October and will be part of the feedback provided to ExCo on the 31st October.

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation




95% of vaccine batches certified within 43 days ✓

99% of blood product batches certified within 15 days ✓

**12 months rolling/moving average comparison**

The overall control testing workload across all products was steady 1443 batches from Oct '22 to Sep '23 including COVID vaccines compared to 2021/22 ( 1514 batches in 2022/23 vs. 1493 in 2021/22) and 77% increase compared to 2020/21 (893 batches).

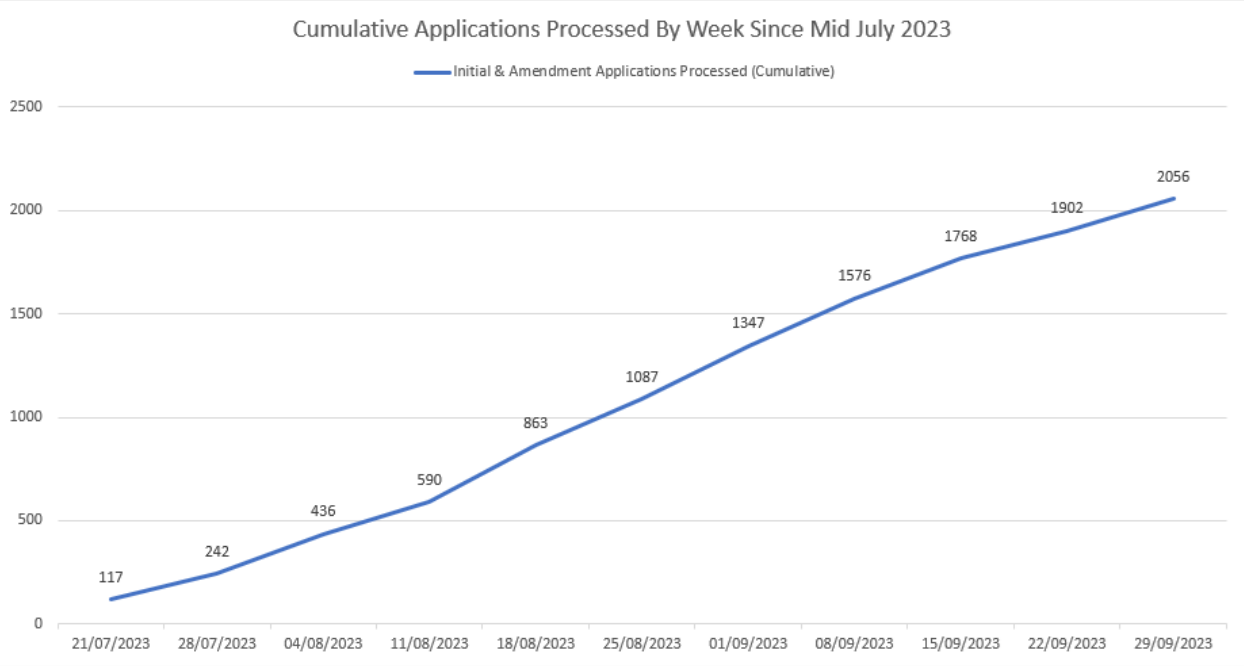
**Changes to the breadth of Control Testing**

Most of our testing is now for the UK market
Compared to pre-EU exit, we are testing a wider range of different products
We are evolving from a specialised, high throughput laboratory to one with a wider scope that better reflects the variety of biological medicines on the UK market
In 2022/23, 49% of batches for the UK (743) underwent lab-testing compared to <35% in 2019 and <15% in 2020, when NIBSC testing still included batches for the non-UK/EU market)
We are aiming to further reduce the proportion of batches that are released in the UK based on certificates issued by EU control testing laboratories
All plasma pools that are used to manufacture UK blood products underwent testing for adventitious blood viruses (2843 In 2022/23 – up 2% on 21/22 [2798] and up 123% on 20/21 [1254])

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

## Clinical Trials performance



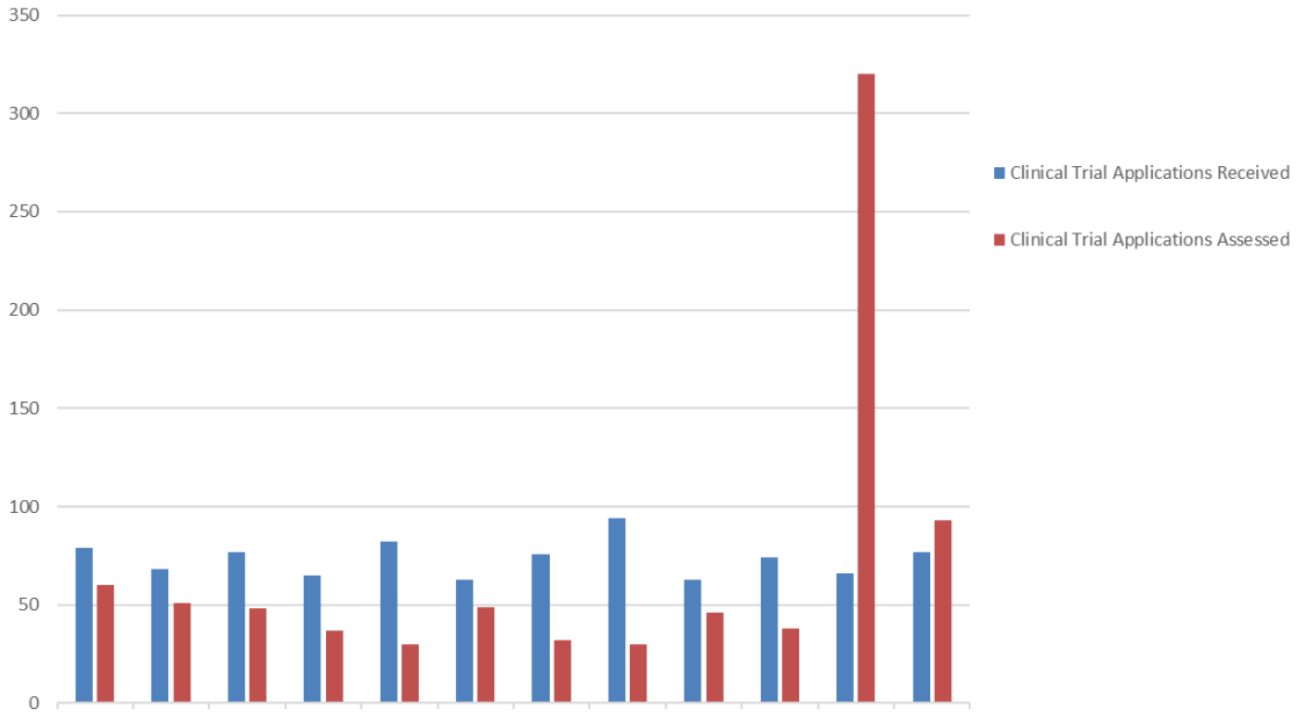

The graph opposite sets out the cumulative number of assessments completed, for both initials and amendments over the course of the last 2.5 months and that number now totals 2,426. This includes the complete elimination of the backlog that existed in mid-July 2023, processing of applications received over July-September and from September ensuring we meet our commitment to assessing all newly received compliant applications within statutory timeframes.

This represents a very significant increase over our normal level of throughput for CT assessment and reflects the Agency taking urgent, concerted and targeted action to address delays in CT assessment and the significant impact this was having on the delivery of clinical trials in the UK. I have included the link to our regularly published performance metrics however I wanted to present the data in this way to better illustrate the enormous cross Agency effort that has gone into addressing this issue.

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

**Number of Clinical Trial Authorisations applications received and assessed**

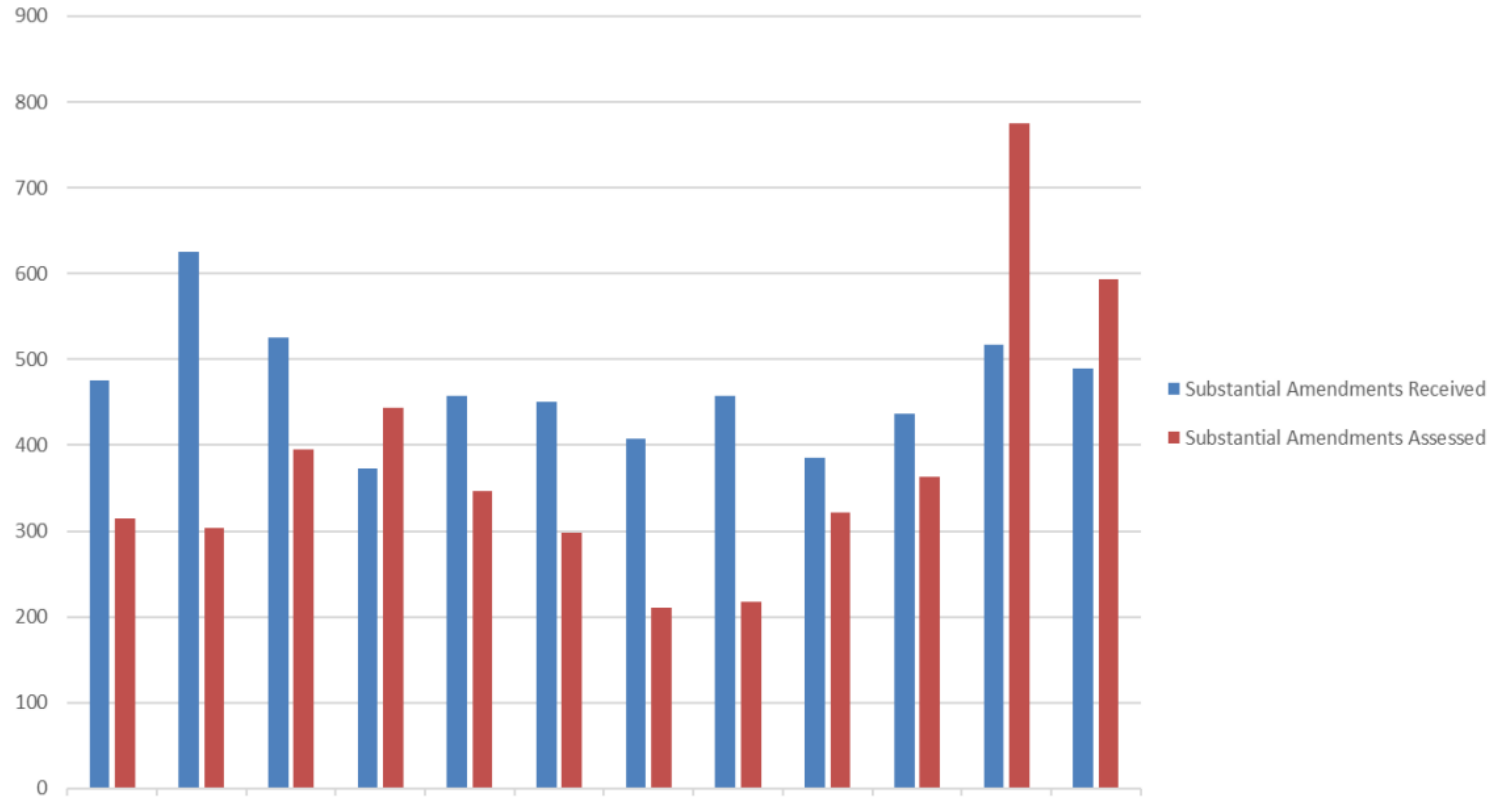



| | Oct-22 | Nov-22 | Dec-22 | Jan-23 | Feb-23 | Mar-23 | Apr-23 | May-23 | Jun-23 | Jul-23 | Aug-23 | Sep-23 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Trial Applications Received | 79 | 68 | 77 | 65 | 82 | 63 | 76 | 94 | 63 | 74 | 66 | 77 |
| Clinical Trial Applications Assessed | 60 | 51 | 48 | 37 | 30 | 49 | 32 | 30 | 46 | 38 | 320 | 93 |

The graph opposite shows the number of valid clinical trial authorisation applications(CTA) received and the number of CTA applications assessed in any given month. The number of applications assessed for any given month is the number of applications for which the first opinion letter was issued in that month (i.e. first review)

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation



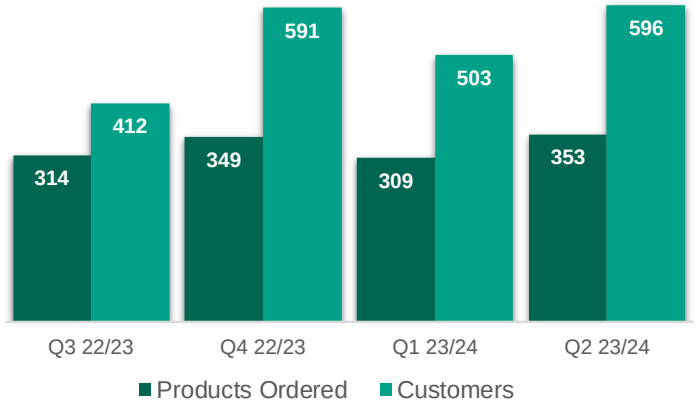

| | Oct-22 | Nov-22 | Dec-22 | Jan-23 | Feb-23 | Mar-23 | Apr-23 | May-23 | Jun-23 | Jul-23 | Aug-23 | Sep-23 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Substantial Amendments Received | 476 | 625 | 525 | 373 | 458 | 451 | 407 | 458 | 385 | 436 | 517 | 490 |
| Substantial Amendments Assessed | 314 | 304 | 395 | 443 | 346 | 298 | 210 | 218 | 321 | 363 | 775 | 593 |

The graph opposite shows the number of substantial amendments received and the number assessed in any given month. The number of amendment assessed for any given month is the number for which an opinion letter was issued in that month.

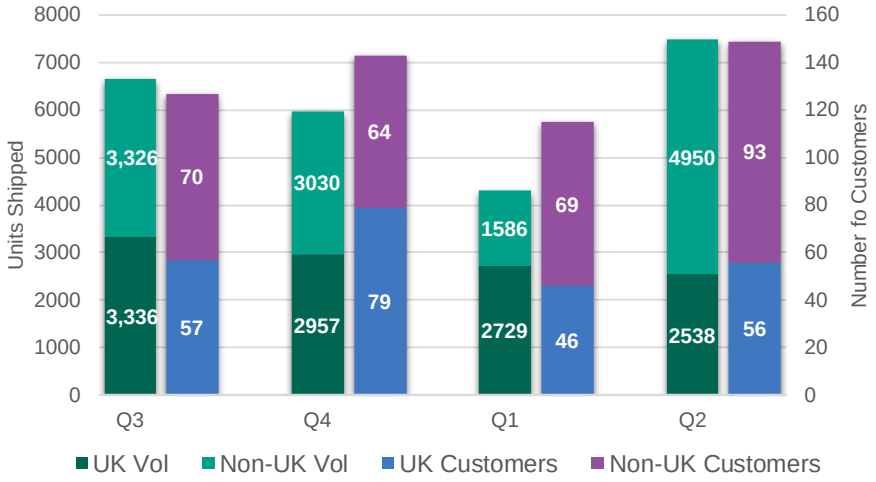
# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

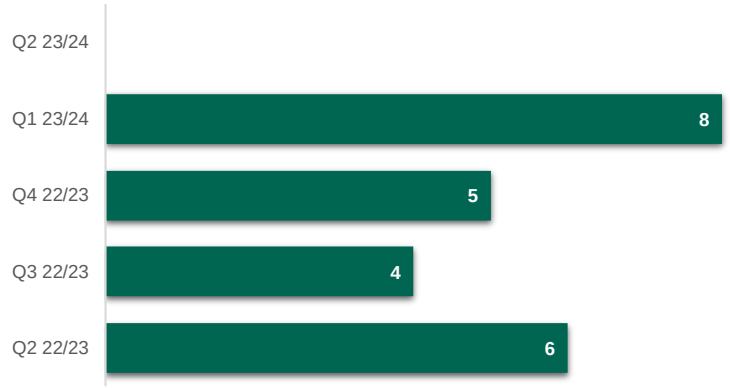
**International Standards – Different Products and Customers**




**Diagnostic Standards – Volume Shipped and Customers**




**TDP Requests**




**ILAP**

Q2 IP applications – **11** (14 in Q1)

Q2 IP MHRA review meetings – **2** (16 in Q1)

Q2 IP approvals through the ILAP steering group – **0** (7 in Q1)

Q2 IP refusals - **0** (5 in Q1)

**International Standards**

There continues to be little change in the numbers but this might be reflective of the capacity within the sales team to process orders through to logistics.

In the reporting period the number of pending orders (majority within sales before despatch) increase from 997 to 1039. This is a lesser increase in the backlog and suggests close to steady state in the period. However, with monthly orders fulfilment at 500 the trending we are conducting is ca. 2 months out of date. Orders are slightly down compared to 1 –year ago

**ILAP**

The activities for ILAP have been slowed as a result of reallocation of resource to clinical trials response and due to the absence of a quorate steering group. MHRA-led initial meetings have resumed in the latter part of Q2 as clinical trials has resolved. Expectation is activity will resume in Q3.

Options for adjusting the process to tackle the backlog rapidly are being developed.

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

**All Standards Portfolios (excluding contract fills)**

| | Units shipped | Number of different products ordered | Number of different users | Cost recovered (M) | Orders on hand (end of quarter) |
|---|---|---|---|---|---|
| **Q2 23/24** | 32,557 | 800 | 740 | 3 | £2,558,053 |
| **Q1 23/24** | 40,117 | 799 | 636 | 4.3 | £2,275,652 |
| **Q4 22/23** | 39,007 | 852 | 759 | 3.7 | £2,103,743 |
| **Q3 22/23** | 31,377 | 799 | 569 | 2.7 | £1,832,498 |
| **Q2 22/23** | 27,236 | 781 | 678 | 2.4 | £1,018,599 |
| **Q1 22/23** | 65,471 | 847 | 844 | 4.8 | £945,990 |

There is a seasonal surge around Q4 and Q1 that is due to our 'flu reagent distribution activities. Cost recovery YTD is £7.3M compared to £7.2M in 22/23. Backlog in sales team has grown by 450K over Q1 and Q2 and £1.6m in 12 months. Countered by an exceptional flu order of 800K – this is expected to be a one-off due to manufacturing issues with usual supplier.

Orders on hand expected to start decreasing in Q3 due to temporary resource being onboarded, long-term expectation for efficiency improvements to deliver increased BAU capacity.

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

## (1) SRI (South Mimms Site) Grants and Contracts
In this quarter, 5 grants were awarded.

| Report period | Title | | Funder | Duration / months | Value |
|---|---|---|---|---|---|
| 23/24 Q2 | Vaccine development for potential epidemic diseases stage 1 | Outbreak preparedness. Collaboration with Dstl, UKHSA, Institute of Madagascar | SRBI-InnovateUK | 24 | 1,996,230 |
| | In vitro safety and immunogenicity characterisation of SimCell vaccines | Development of assays | InnovateUK A4I | 6 | £28,708 |
| | Mutated human oncogene recombinant nucleosomes as reference materials for liquid | Development of reference material | InnovateUK A4I | 6 | 34,021 |
| | Identification and impact of leechables on stem cell products in an automated biomanufacturing | Assays to assess in-process quality | InnovateUK A4I | 6 | £19,244 |
| | Metrology for genomic profiling to support early cancer detection and precision medicine - Genome Met | development of suitable reference materials | InnovateUK | 36 | £118,709 |

## (2) Grant application and success rate (from Research Grants office):
Success rate is comparable to previous quarters

| | 2022 | | | | | 2023 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Q1 Apr-Jun | Q2 Jul-Sep | Q3 Oct-Dec | Q4 Jan-Mar | Q1-Q4 Total | Q1 Apr-Jun | Q2 Jul-Sep | Q3 Oct-Dec | Q4 Jan-Mar | Q1-Q4 Total |
| Grants applied for | | | | | | | | | | |
| Successful | 4 | 4 | 5 | 2 | 15 | 5 | 5 | | | |
| Pending - ongoing | 1 | 0 | 4 | 1 | 6 | 17 | 8 | | | |
| Unsuccessful | 5 | 3 | 3 | 1 | 12 | 1 | 2 | | | |
| Closed as not going ahead | 0 | 2 | 0 | 0 | 2 | 0 | 0 | | | |
| Win rate (%) | | | | | 42.86 | | | | | |

## (3) Grant forecast secured income at each Quarter (from Research Grants office):

-Trends will be available in future reports
-Forecasts reflect multi-year, phased funding nature of research grants

| Financial Year | 22/23 | 23/24 | 24/25 | 25/26 | 26/27 | 27/28 |
|---|---|---|---|---|---|---|
| Secured grant income / £m: Q1 | 4.1 | 5.7 | 2.8 | 1.5 | 1.3 | 1.2 |
| Secured grant income / £m: Q2 | | 5.1 | 4.2 | 1.6 | 1.4 | 1.3 |
| Secured grant income / £m: Q3 | | | | | | |
| Secured grant income / £m: Q4 | | | | | | |

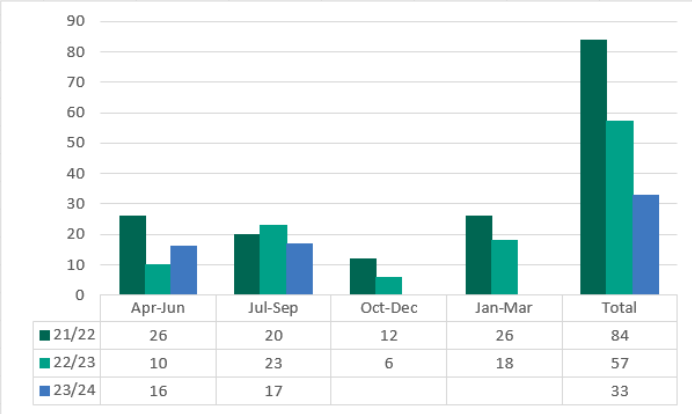
## (4) Grant and research contract utilisation in 23/24 Q1 (from Finance):

| | 2023 | | | | |
|---|---|---|---|---|---|
| | Q1 Apr-Jun | Q2 Jul-Sep | Q3 Oct-Dec | Q4 Jan-Mar | Q1-Q4 Total |
| YTD actual | 1,262,671 | 2,571,417 | | | |
| YTD budget | 1,279,811 | 2,444,356 | | | |
| YTD variance | (17,140) | 127,061 | | | |

# Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

**Communicating our science and its impact: Scientific publications**




Target of 90 scientific publications per year.

**Scientific Publications from SRI-SMS**

The number of publications in peer-reviewed scientific journals is presented. Historically, we have reported by calendar year, in line with journal publication years, with an anticipated 90 publications pa. The figures are presented in FY format hereon in.

The total number for the FY to date is the same to the same period in 2022/3 and less than for 2021/2. This is not unexpected given the staffing changes experienced across the teams. Such changes have been noted historically during periods of significant change to the former NIBSC. Staff continue to be encouraged to submit data for publication through their line management.

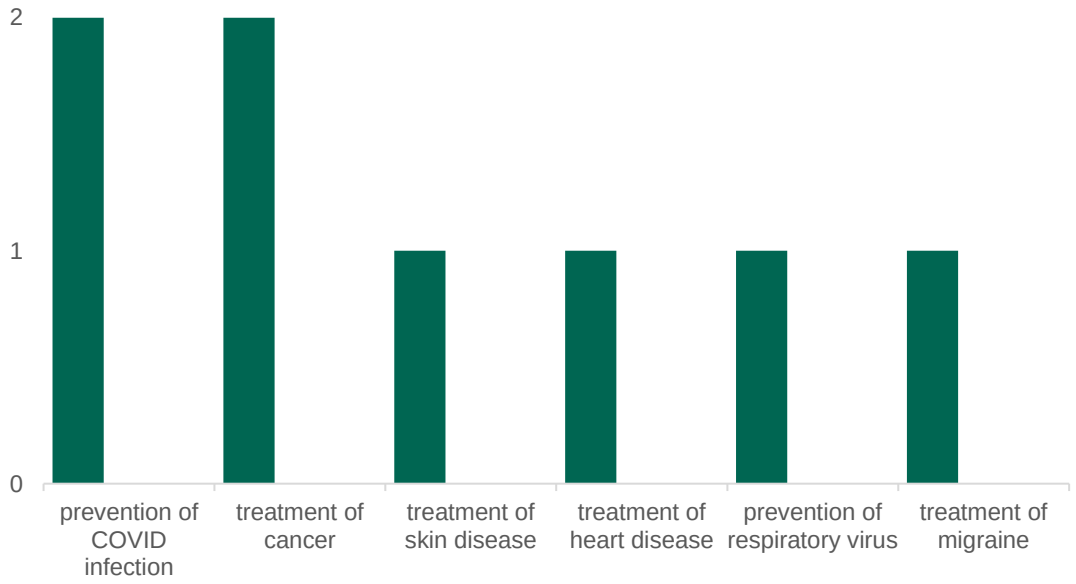
**The scientific impact of some of the publications is presented.**

| Title | Journal | Scientific Impact |
|---|---|---|
| Sensitive poliovirus detection using nested PCR and nanopore sequencing: a prospective validation study | *Nature Microbiology* | Proves that using DDNS to detect polio outbreaks can save public health authorities crucial time and money |
| Development of a monoclonal antibody sandwich ELISA for the determination of antigen content and quality in diphtheria vaccines | *ALTEX* | The assay is ideally suited for incorporation into a consistency approach for routine diphtheria vaccine quality control testing and may be suitable to serve as the stability indicating test in replacement of the current in vivo potency test |
| Variability of in vivo potency assays of whole-cell pertussis, inactivated polio, and meningococcal B vaccines | *Vaccine* | Data support the idea that it is preferred to move to in vitro assays for batch to batch consistency monitoring |
| DNA and histones impair the mechanical stability and lytic susceptibility of fibrin formed by staphylocoagulase | *Front Immunol* | Assessing the role of the complex of staphylocoagulase and prothrombin in *S. aureus*-associated endocarditis |
| Vaccine-induced neutralizing antibody responses to seasonal influenza virus H1N1 strains are not enhanced during subsequent pandemic H1N1 infection | *Front Immunol* | Greater insight into the role of previous exposure to H1N1 strains in generating cross-recognition of H1N1pdm09 |
| Recommendations for Setting a Criterion for Assessing Commutability of Secondary Calibrator Certified Reference Materials | *Clin Chem* | Important considerations since a secondary higher-order calibrator is required to be commutable with clinical samples to be suitable for use in the calibration hierarchy of an end-user clinical laboratory in vitro diagnostic medical device (IVD-MD). |
| Collaborative study for the calibration of a replacement International Standard for tetanus toxoid for use in flocculation test | *Biologicals* | Use of the 3rd WHO IS for tetanus toxoid provided an opportunity to assess the use of alternative methods for measuring flocculation units: the results intimate that these alternative methods could be useful for monitoring consistency of production at different stages of vaccine manufacturing. |
| Insights into product and process related challenges of lentiviral vector bioprocessing | *Biotechnol Bioeng* | Lentiviral vectors (LVs) are commonly used to deliver and stably integrate genetic information to recipient cell chromosomes for the treatment of numerous disorders. Study highlights the prospects of improving lentiviral vector recovery by evaluating manufacturing conditions that contribute to vector losses for specific production systems. |
| Development of a thermochromic lateral flow assay to improve sensitivity for dengue virus serotype 2 NS1 detection | *Nanoscale* | Results from this study may expand the utility of the LFA for early diagnostics. |
| 3Rs implementation in veterinary vaccine batch-release testing: Current state-of-the-art and future opportunities. A webinar and workshop report | *Biologicals* | Outcome of a report from the working group that included SRI colleague. The workshop focussed on challenges to be addressed, future goals. An example from the UK included the ELISA developed at the SRI laboratories to provide better discrimination between tetanus toxoid lots than achieved by animal testing. |
| Scalable manufacturing of gene-modified human mesenchymal stromal cells with microcarriers in spinner flasks | *Appl Microbiol Biotechnol* | Due to their immunomodulatory properties and in vitro differentiation ability, human mesenchymal stromal cells (hMSCs) have been investigated in more than 1000 clinical trials over the last decade. This study investigated how to address the challenge of scale-up in manufacturing to provide sufficient doses for clinical applications. |
| Reproducibility and Harmonization in Research using Biological Standards: The Example of Platelet Agonist Collagen-Related Peptide | *J Vis Exp* | A case study-led demonstrating the value of biological standardisation. |
| White papers x 3 | *Bioanalysis* | Recommendations on recent issues in bioanalysis across different biological product areas and assays. |

# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

**New Licences – Q2 2023 New Active Substances (NAS)**



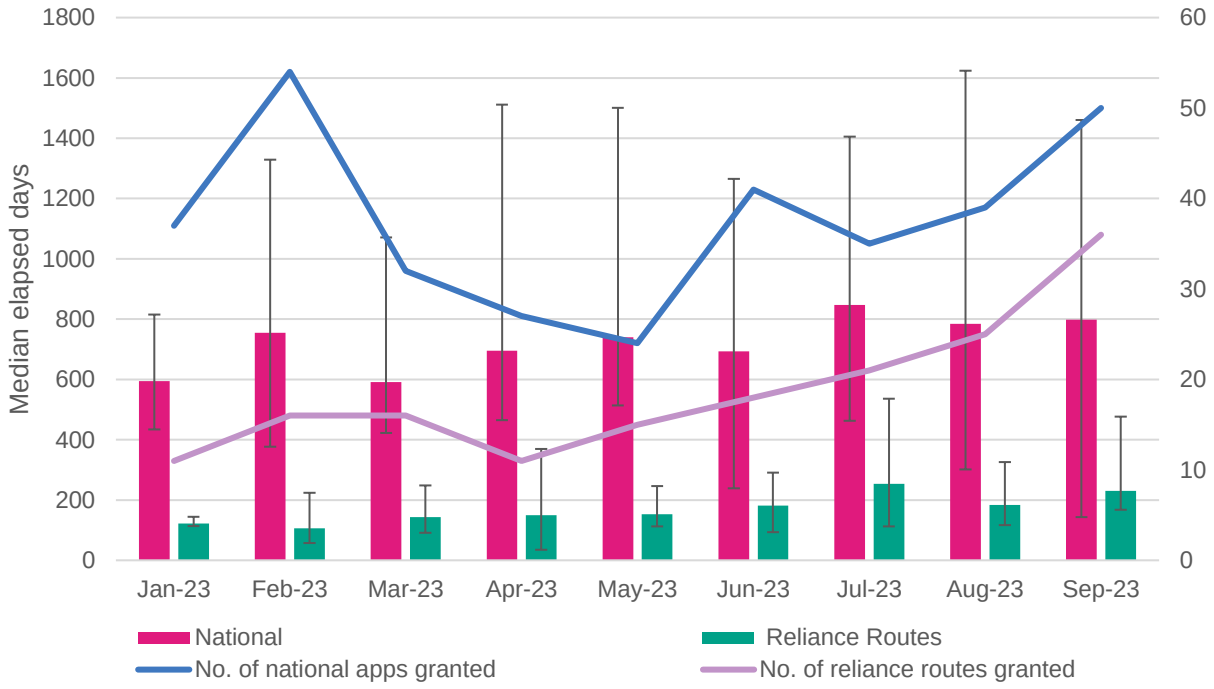

**NAS resulting from Project Orbis & The ACCESS Consortium (none in Q2 2023)**

A total of 8 new licences were granted in Quarter 2 2023, 7 via the reliance route and one (treatment of migraine) via the national route. Currently 11 new active substance applications are under assessment.

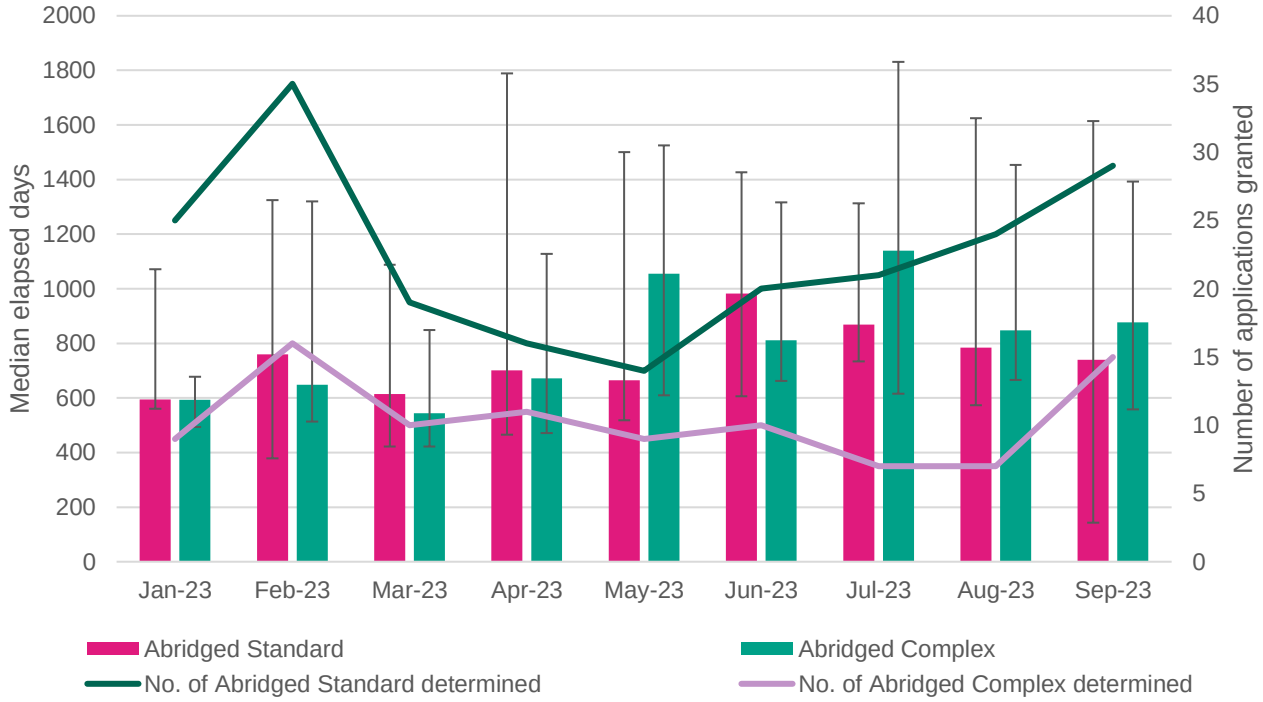
# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

**Established Medicine Initials – Median days elapsed to determination with 10% to 90% interpercentile range includes number of applications determined (Jan - Sept 23)**




**Established Medicine – Standard/Complex initial national applications – median days elapsed to determination with 10% to 90% interpercentile range and number of applications determined (Jan - Sept 23)**



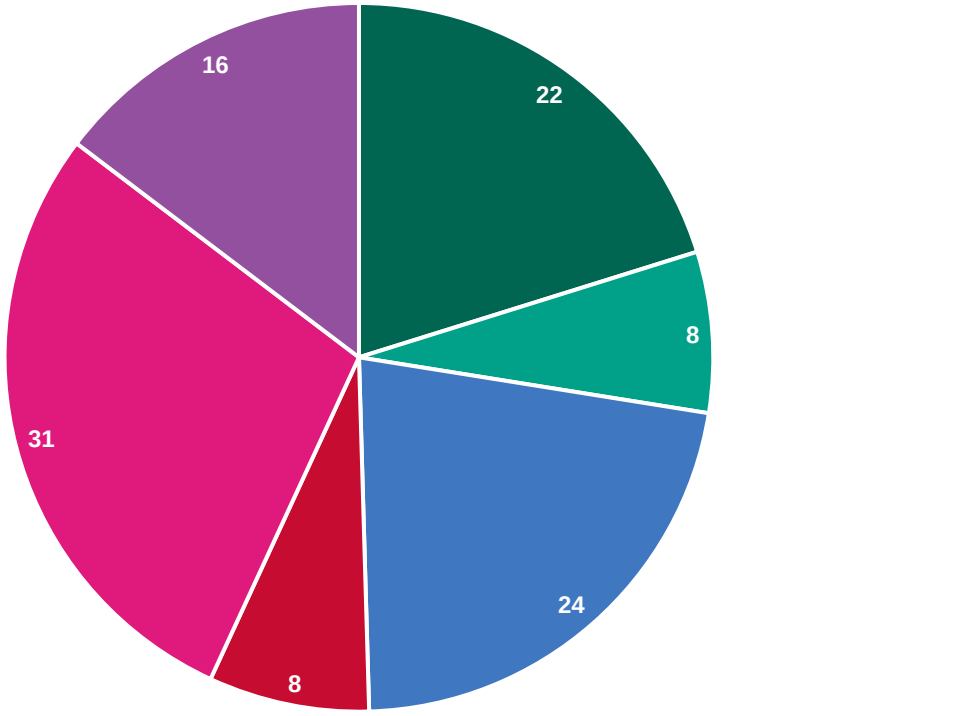

Focus on clearing applications through activities generated in the Task and Finish Group. First actions which are driving change over the period agreed with ExCo at the end of the period.

Processing times will vary and not follow trend lines for 2023 as older applications are processed, giving the broad ranges between 10-90% percentiles

# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

**Established Medicine – Standard/Complex initial national applications number of applications determined July to September 2023 (Q2)**



# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

| Measure | July 2023 | August 2023 | September 2023 |
|---|---|---|---|
| Initial Parallel Import Applications received | 67 | 69 | 98 |
| Initial Parallel Import Licences granted | 45 | 92 | 53 |
| Minimum time to grant (months) | 2.8 | 5.0 | 8.7 |
| Median time to grant (months) | 12.5 | 11.9 | 11.8 |
| Time to start assessment (months) | 9.9 | 10.2 | 10.3 |
| | | | |
| Variations received | 896 | 1040 | 955 |
| Variations granted | 1069 | 684 | 897 |
| Time to grant leaflets (months) | 3.1 | 3.2 | 2.9 |
| Time to grant pharmaceuticals (months) | 3.3 | 3.0 | 3.2 |

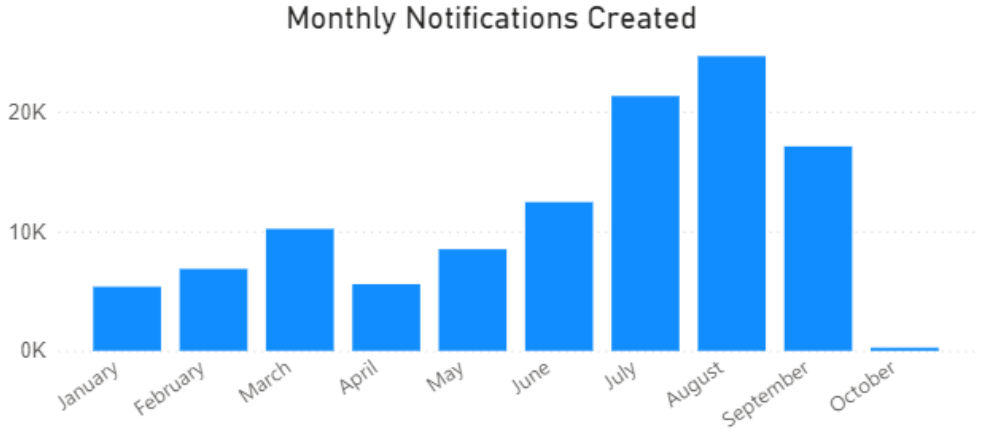
- Time taken to grant initials (median time) and variations in March remains stable and consistent with previous months.
- The overall upward trend for the numbers of initial applications and variations granted has continued in Q2 2023 and will continue to be monitored as part of the ongoing initiatives to streamline and improve the efficiency of the different review processes.

# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

## Import Notification System

01/07/2023 - 30/09/2023




| | |
|---|---|
| Total number of notifications created | 63087 |
| of which are urgent notifications* | 22.40K |

*Urgent notifications are prioritised and involve additional Pharmaceutical Assessor resources than standard notifications

| | |
|---|---|
| Total number of different products processed* | 1607 |
| of which are urgent notifications | 382 |

*Each product requires an individualised assessment by the Pharmaceutical Assessor

| | |
|---|---|
| Total number of notifications acknowledged | 60193 |
| Total number of notifications assessed | 49.60K |
| No Objection | 2337 |
| No Objection With Reason [1] | 42.86K |
| Objection With Reason | 1168 |
| Further Information Requested | 3239 |

1. The Pharmaceutical assessor has imposed conditions on the importation

**CBPMs* - cannabis-based products for medicinal use in humans**

| | |
|---|---|
| Total number of notifications | 3006 |
| Total number of different products processed | 70 |

*The assessment of CBPMs is the most resource intensive type of product INS currently experiences

- Unlicensed medicines may be supplied for patients with unmet clinical needs or when the licensed equivalents face supply disruptions.
- Cannabis Based Medicinal Products for Use in Humans in the UK are mostly supplied via INS.

# Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

## Standards and Compliance

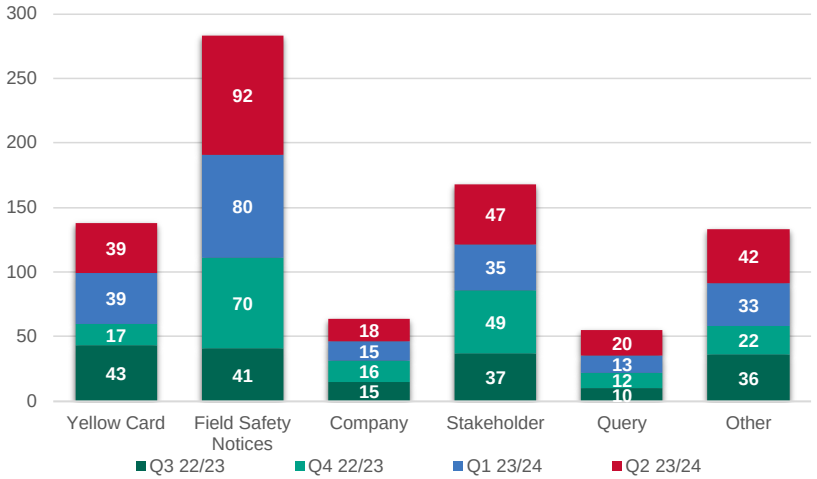
| Nature of activity | How does this improve compliance? | Q 2 Performance |
|---|---|---|
| **Initial reviews of new Approved Bodies.** | Ensures bodies approved to undertake assessments of conformity against regulations for Medical Devices used in the UK meet required standards | 1 new applications received in Q2 (received on last day of Q2 so not yet reviewed)<br>0 initial reviews undertaken since Q1 (1st application received in last week of Q1), Target is to completed 90% within 2 weeks |
| **Designation of new approved bodies.** | | 3 new Approved Bodies designated in Q2<br>6 open applications for designation, each at varying stages in the process |
| **Inspectorate Blogs** | Keeps industry up to date with latest standards and best practice, and lessons learned from inspections, ensuring they are aware of requirements. | Unique Visitors 18,645 (Q1 25,419)<br>Unique Page Views 25,359 (Q1 33,821) |
| **GXP Guide Sales** | | Orange Guide – Q2 23/24 £16,951, of which £5,933 royalty received from Pharmaceutical Press (PP)<br>Green Guide –Q2 23/24 £14,150, of which £4,953 royalty received from PP<br>[Δ 54% from Q2 22/23, 22/23 was updated, from 2017] |
| **Site Inspections** | Inspections can be desk based (remote), hybrid (assisted by remote technology) or full physical inspections. Inspections detect system problems which could put patients at risk. | 11 (Q1 13) Clinical Trial sites inspected. 2 (Q1 2) referral for critical findings.<br><br>12 (Q1 13) Laboratories (GLP/GCP/GMPQC) Inspected, 1 (Q1, 0) referrals for critical findings.<br><br>2 (Q1 5 Pharmacovigilance (safety monitoring) systems inspected. 0 (Q1 2) referral for critical findings.<br><br>54 (Q1 57) Manufacturers Premises Inspected, 2 (Q1 1) referrals for critical findings.<br><br>90 (Q1 84) Supply Chain sites inspected. 5 (Q1 8) referrals for critical findings. |
| **British Pharmacopoeia Total Sales (Publication plus Reference Standards)** | Combined sales revenue from the BP publication and sales of British Pharmacopoeias Reference Substances (BPCRS) gives an indication of our product reach and customer demand | Total Revenue (Q2) = £2,814.769 [Δ 1.5% vs same period last year]<br><br>Total revenue (YTD) = £4,245,849.4 [Δ 3.6 % on same period last year] |

# Performance – Safety & Surveillance

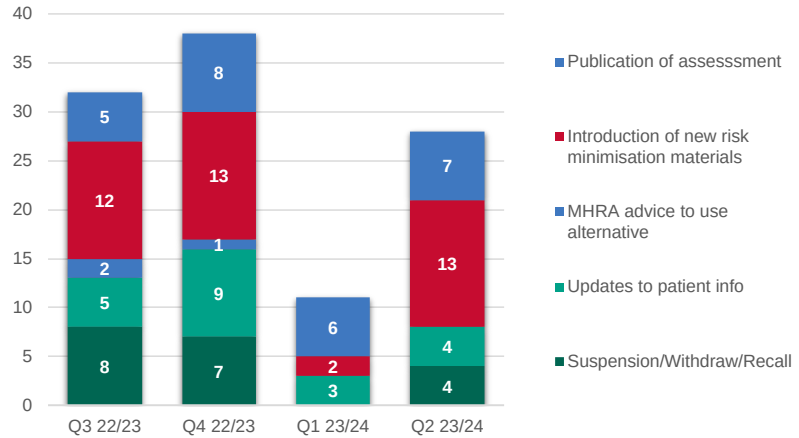
Delivery Plan Priority – Patient Safety

## Yellow Card – Q2 reports


## Benefit Risk Evaluation




## Actions Taken to Minimise Risk to Patients*




## Safety Signals

For medicines

The total number of drug -event combinations:

- Black Triangle/Additional Monitoring substances: **19,222** – 22,786 in Q1.
- Established substances**: 27,925** – 41,236 in Q1

<u>The total number of new safety signals identified for further assessment **22 – 29** in Q1</u>

| Variations Q2 | National | Reliance | CMS |
|---|---|---|---|
| Received | 172 | 139 | 104 |
| Assessed | 155 | 143 | 99 |
| Completed | 163 | 154 | 199 |

Current total backlog = 1,450 (down from 1,671 in Q1)

# Performance – Safety & Surveillance

Delivery Plan Priority – Patient Safety

| Assessed threat reduction impact | Q2 22/23 | Q3 22/23 | Q4 22/23 | Q1 23/24 | Q2 23/24 |
|---|---|---|---|---|---|
| MAJOR | 0 | 0 | 1 | 0 | 3 |
| MODERATE | 6 | 2 | 6 | 4 | 10 |
| MINOR | 280 | 250 | 257 | 491 | 206 |
| TOTAL | 286 | 252 | 264 | 495 | 229 |

**Accompanying narrative**

There has been a notable increase in the number of interventions assessed as having had a major or moderate impact during Q2. With the CEU at close to full staffing and with individuals now fully integrated into their new roles, there are more opportunities to commit resources to more impactful interventions. The number of minor interventions fell since last quarter, which is likely to reflect the shift towards more impactful threat reduction activity

**Interventions completed in quarter assessed as having a major threat reduction impact include:**

- Five subjects suspected of involvement in medicines crime were charged with serious offences, including conspiracy to supply controlled drugs, and unlicensed and prescription-only medicines.
- A CEU intelligence package disseminated to Great Manchester Police contributed to a series of arrests for conspiracy to supply Class A, B and C controlled drugs, and financial asset denial amounting to almost £230,000.

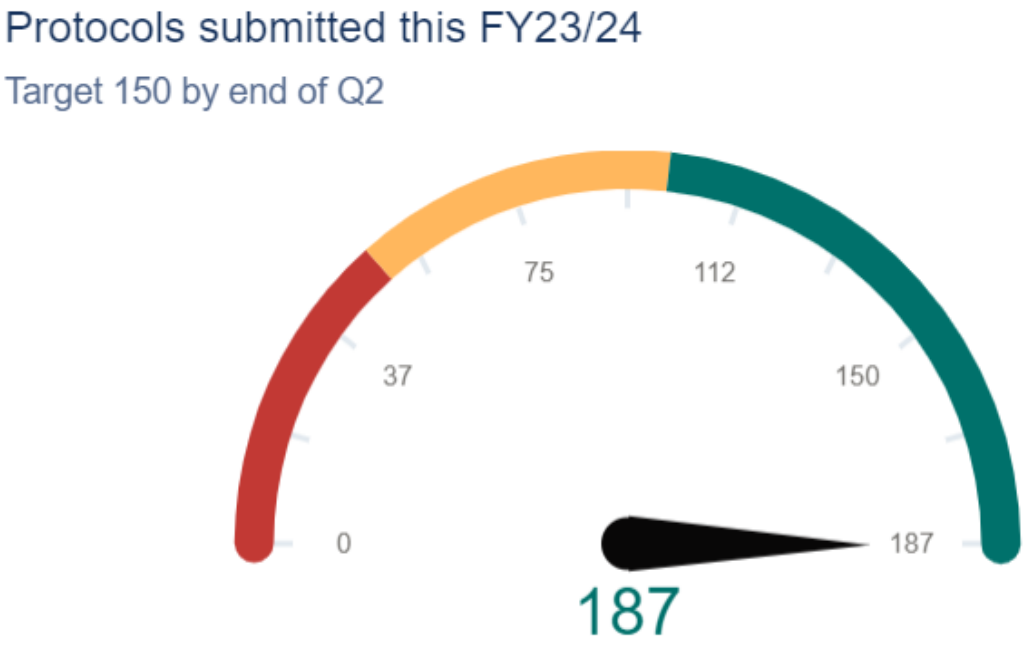
**Interventions completed in quarter assessed as having a moderate threat reduction impact include:**

- The arrest of two subjects involved in the illegal sale of POMs and unlicensed medicines, with large quantities of illegally traded Botox, approximately £50,000 in cash and other luxury items being seized. Follow-up to this has resulted in the identification, seizure and closure of several bank accounts linked to the subjects.
- Confiscation orders totalling of £330k granted against two subjects involved in the unlawful supply of Class C POMs and unlicensed medicines.
- A delivery driver for a medicines distributor was sentenced to three years for the theft of medicines and their subsequent illegal sale/supply
- A two-day enforcement operation alongside UK Border Force staff at Coventry International Postal Hub resulted in the seizure of 800,000 doses of medicine.

**Interventions completed in quarter assessed as having a minor threat reduction impact:**

- This included multiple takedowns of illegally trading webpages, social media listings and marketplace listings, bank account closures, account freezing orders and warning letters sent to low-level first-time offenders.

# Total number of new Research Data Governance (RDG) applications submitted in 2023/24



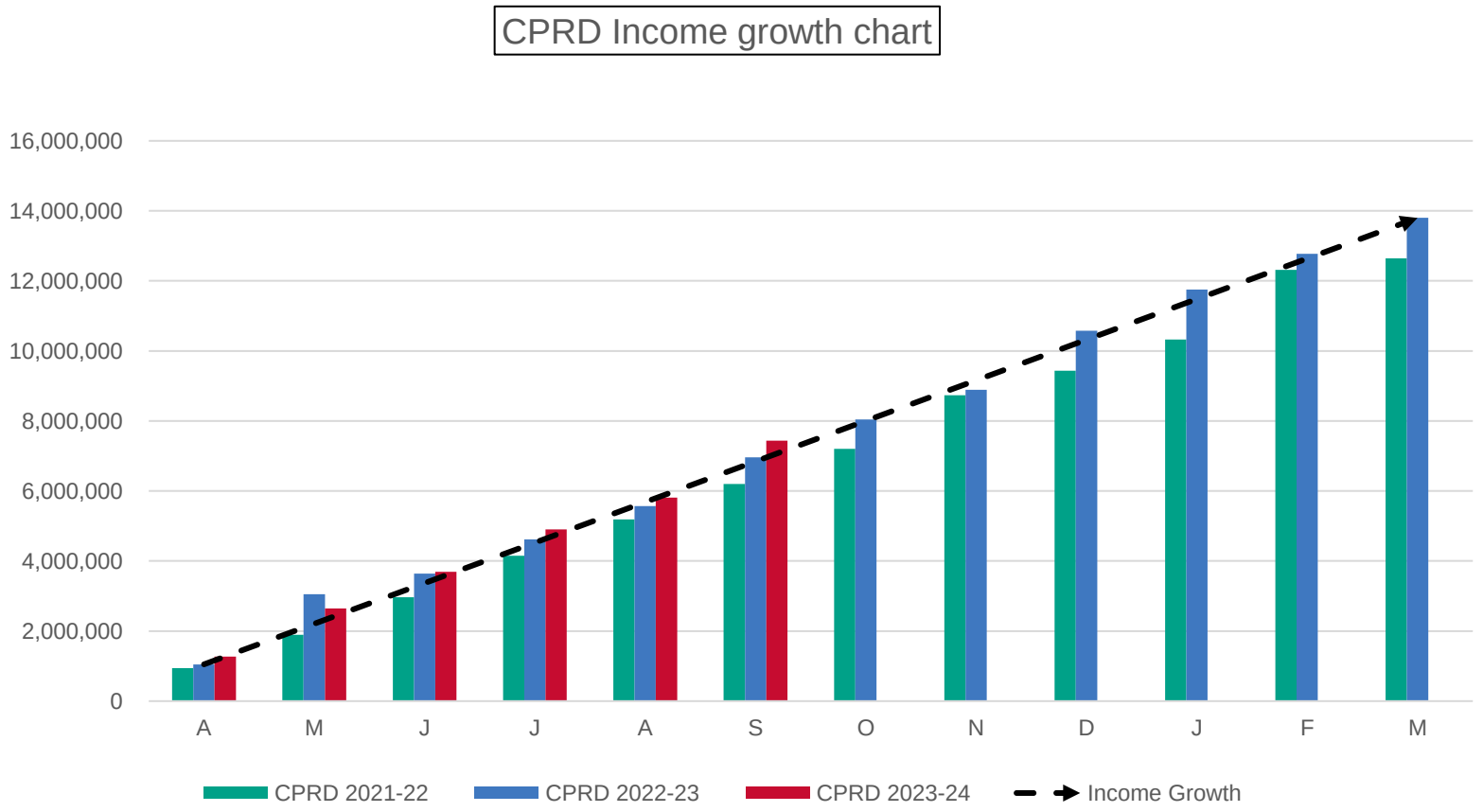

| Target by end of quarter | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Protocols target | 75 | 150 | 225 | 300 |
| Protocols submitted this FY | 92 | 187 | | |

This indicator could provide an early signal of waning interest in CPRD data which in turn could impact income from data licence fees.

To consider:

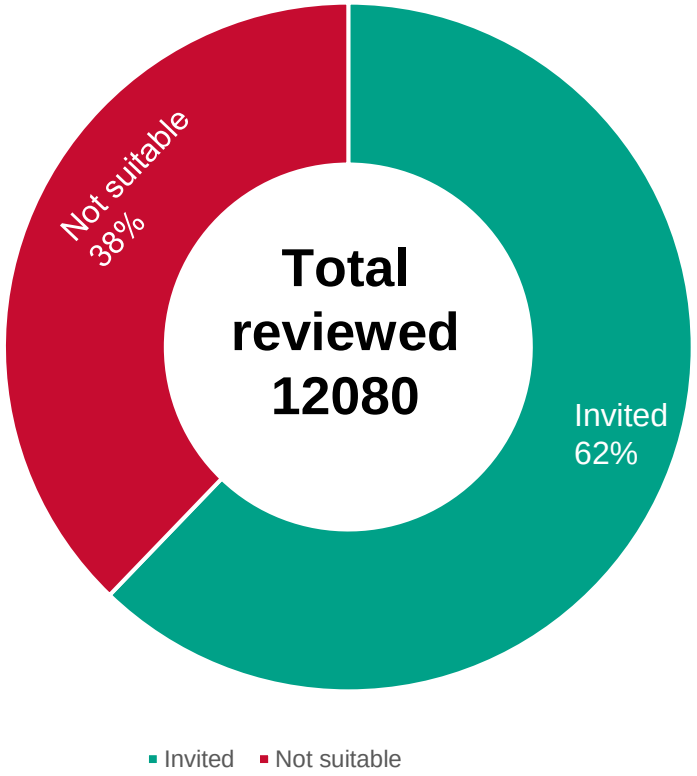
Needs careful interpretation as we routinely receive amendment requests to expand the scope of approved studies and recent applications related to machine learning typically have a much broader scope of use.

# CPRD Income growth




- This chart represents the CPRD income growth target in 23/24 and comparisons with 2021/22 and 2022/23, and the bars represent cumulative income across any given financial year.
- The dotted line represents the target income phased across 12 months and incorporates a 9% income growth as compared to 22/23

# Interventional Research Metric



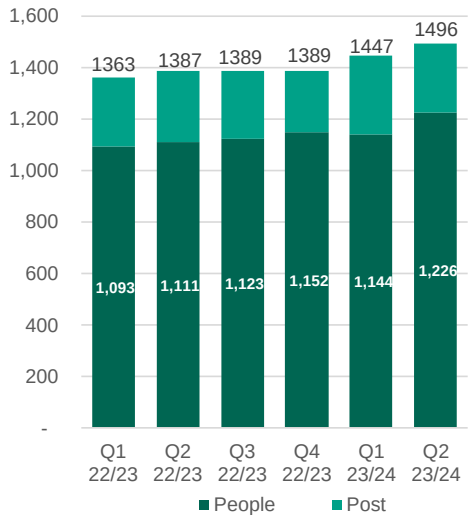

Proportion of GP reviews resulting in patient invitation to participate in a clinical study for all recruitment activities for CPRD Interventional Research services (Target 75%)

| Target | Q1 | Q2 |
|---|---|---|
| 75% | 70% | 62% |

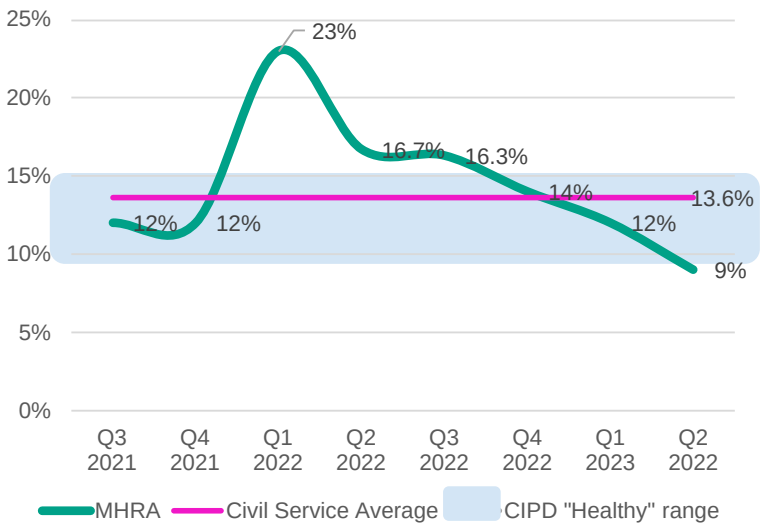
# People

Delivery Plan Priority – Dynamic Organisation

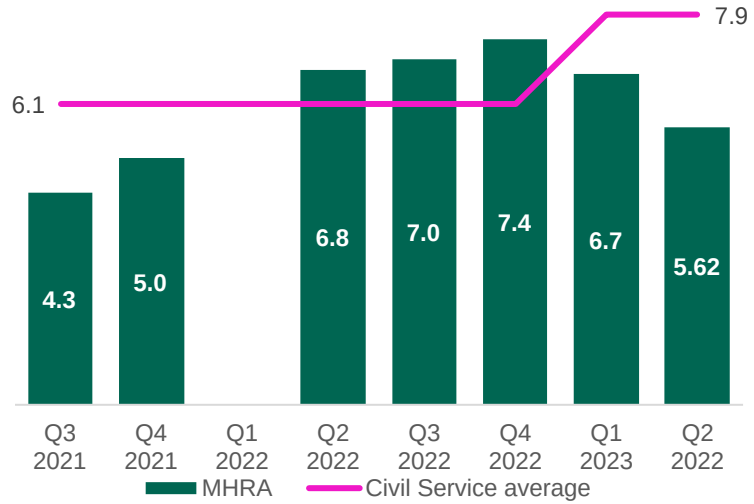
**Recruitment**
**Posts filled v structure**




**Voluntary Turnover – Annualised**




**Sickness Absence Days – Annualised**




We had 1,226.3 people in post at the end of Q2  2023 (FTE, permanent, fixed term and Phd students covering established posts).

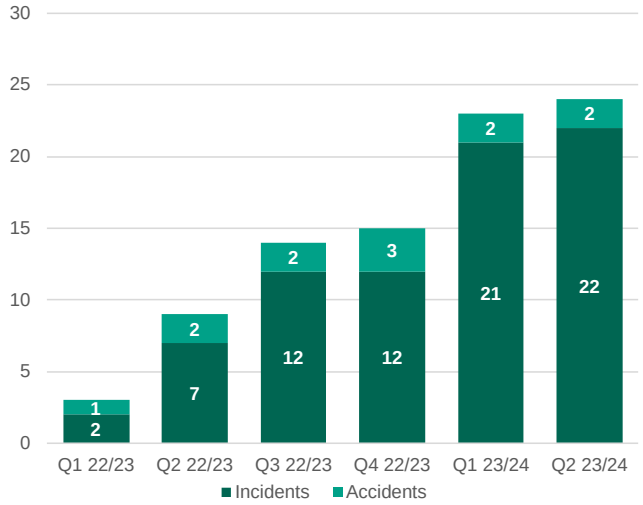
There has been a further reduction in our turnover of staff to 9% bringing turnover under the levels considered ‘healthy’ by the CIPD (10-15%) but reflective of Agency turnover pre pandemic and pre transformation.  Despite a challenging employment market for all sectors, we continue to see an increase in the number of joiners versus leavers, reflected in our steadily decreasing turnover.  We welcomed 76 new starters to the Agency in Q2 versus 26 voluntary leavers, with our largest cohort of new joiners (41) in September alone.

This continued peak in recruitment puts significant pressure on corporate and digital teams in respect of onboarding, and on Groups in respect of induction, and the funding of additional posts, and the significant upcoming recruitment in Q3 is worth highlighting for this reason. Recruitment, whilst in itself is an investment in the Agency, is a labour intensive process somewhat hindered by an inefficient recruitment system we would hope to replace, plus Civil Service recruitment rules that can hinder flexibility. We plan to review processes and the system in so far as we can, subject to a replacement system, to benefit the agency.

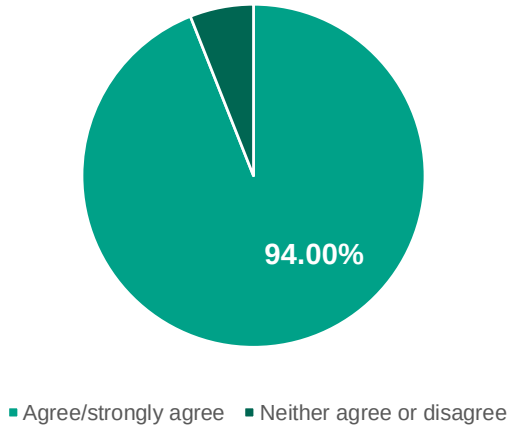
# People

Delivery Plan Priority – Dynamic Organisation

**Incidents and Accidents**




**Applicability of learning across 2023 training programme**




There were 219 training attendances (i.e. training or learning interventions developed or commissioned and delivered by the central Agency Talent and Capabilities team) by staff (some staff may have attended more than one).

This data does not include the e-learning provision which is via the Government Campus (Civil Service Learning). The Government Campus provides both mandatory and a broad range of generic training, and related data is currently unavailable to MHRA for technical reasons but will be included again from Q3,

2023/24. In addition to the training reported, Agency developed training run byGroups/Functions, which has not been recorded centrally, is also not reported here.

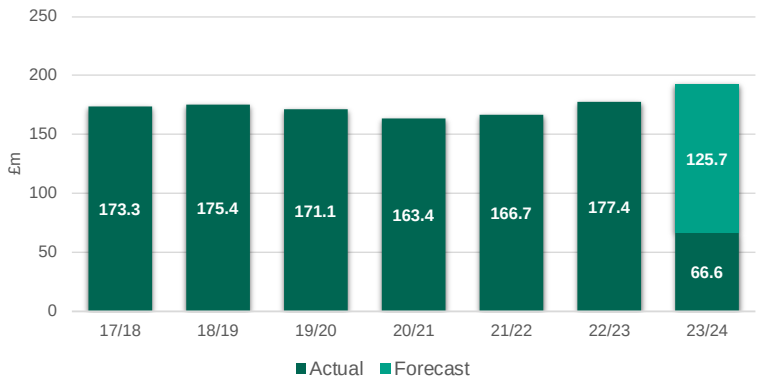
3.12 94% of corporate training participants in Q2 agree or strongly agree that the learning undertaken was applicable to their role and performance in role. Across all corporate trainings in this period, 81.8% of staff report increased confidence in the training subject matter immediately post-training.

No ‘reportable’ accidents or incidents in Q2.
Two accidents: one slip, trip, fall accident and one cut from opening an ampoule (non-hazardous).Majority of the incidents reported are facilities type issues including flooding, air handling issues, equipment failure (chillers, boiler, compressors etc). We will continue to monitor trends coming from this new data.

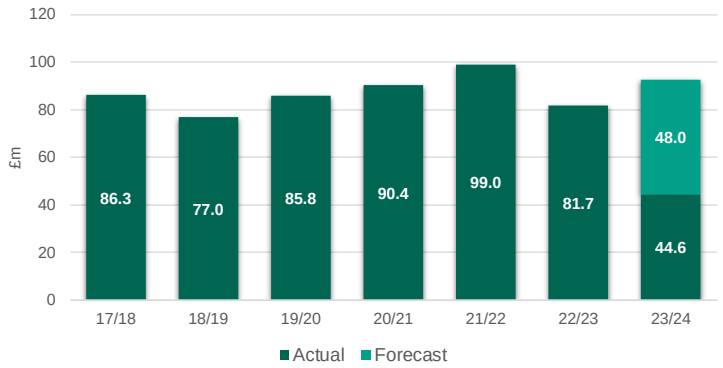
# Finance

Delivery Plan Priority – Financial Sustainability

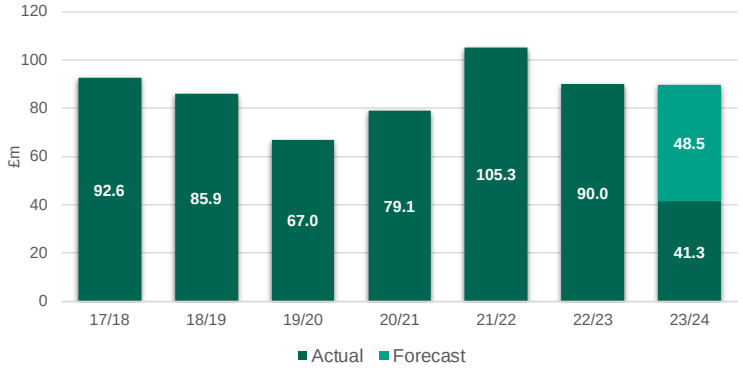
**Income** – 23/24 forecast **£192.3m** v budget £187.4m




**Pay Costs** – 23/24 forecast **£92.7** v budget £94.9m




**Non-Pay Costs** – 23/24 forecast **£89.8** v budget £93.5m

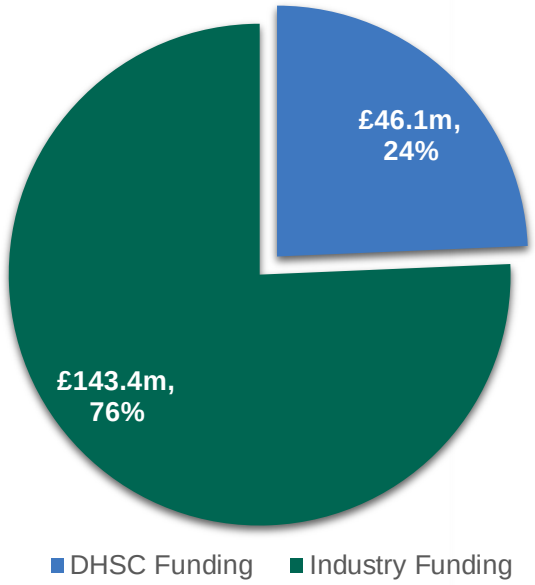



Numbers include £25.5m of DHSC capital funding.

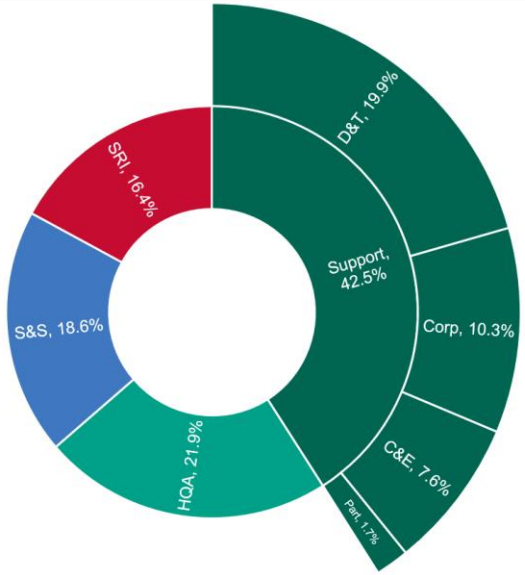
# Finance

Delivery Plan Priority – Financial Sustainability

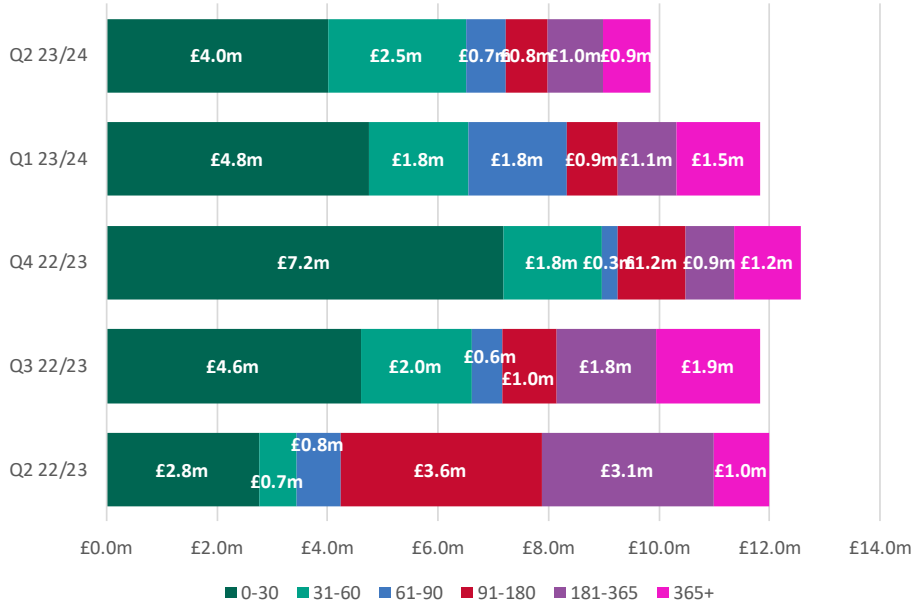
**DHSC / Industry Income Split**




**Support Expenditure %**




**Debt by Days Due exc Service Charge**




The agency has an ambitions to reduce DHSC reliance and reduce relative expenditure within the support groups.
DHSC funding for 23/24 has reduced to 24% of our total income, down from 29% last year. This is despite £15m of funding for RMS meaning we should see further decreases in future years.

Forecast support spending is down from 49.8% last year to just 42.5% this year, this is due to reduced accommodation costs as well as increased expenditure within the revenue generating areas. This shows improved efficiency within support in-line with the agency's ambitions.

Total debt has significantly reduced to £9.9m, down from an average of £12.1m in the 12 months prior. We have been especially successful at reducing debt over 60 days, reducing it to £3.4m, down from £5.3m last quarter and £8.6m last year.

# Digital & Technology

Delivery Plan Priority – Dynamic Organisation

**Service Management Highlights**

A new automated Joiners Process has been introduced. This will help streamline onboarding of new users and speed up the process. It will also ensure that when a ticket is raised it is automatically passed to teams to fulfil their role without having to be manually passed, therefore cutting out any delays.

A new helpdesk phone system (NFON) which will monitor calls to the helpdesk. This will help to lower response times and better identify busiest/quietest times in order to manage resources correctly. This is currently running on the 10SC site and will be introduced at the South Mimms site early November.

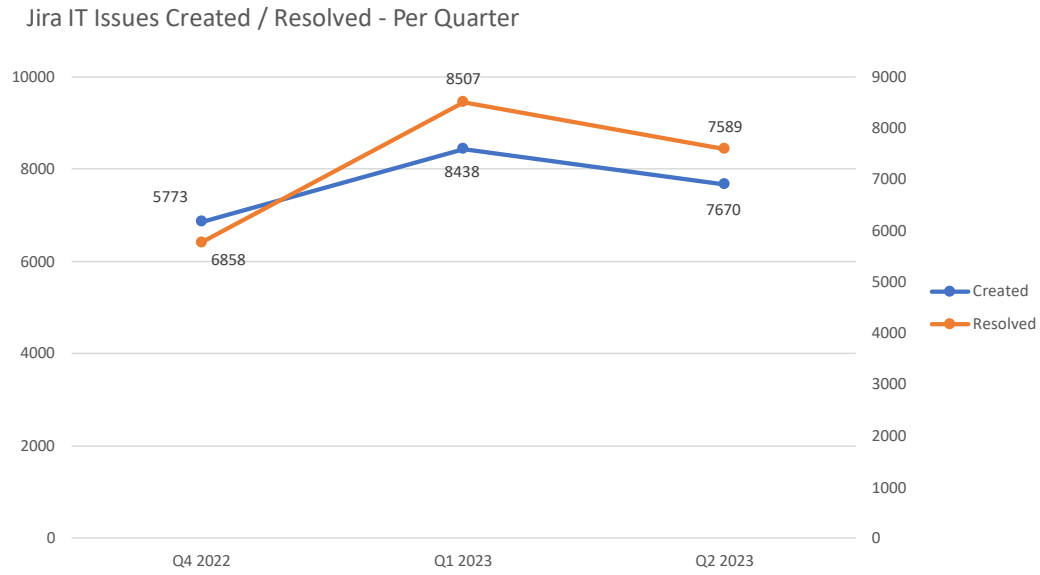
Clinical Trials (CT) helpdesk issues continue to be treated as top priority. The security critical upgrade of MoveIT, which is an essential tool to CT, was carried out over a weekend along with other activities to improve security and performance, which limited downtime.

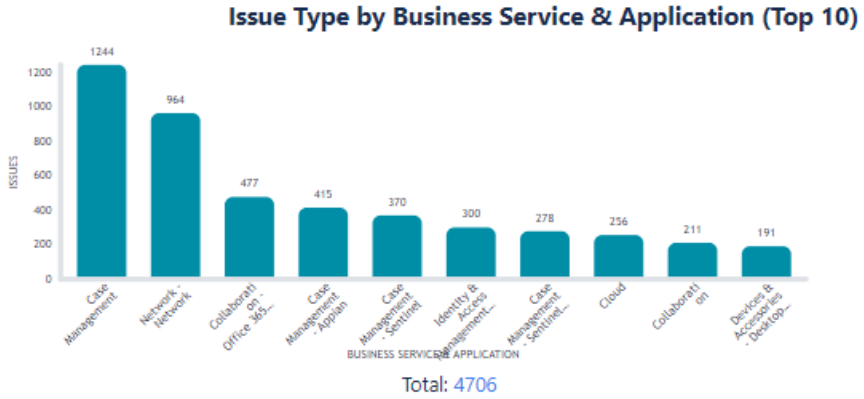
A USB request exception process was also introduced, to reduce the use of USB devices, whilst still enabling us when required for business purposes. The Service catalogue will be introduced by the end of November.

**IT Service Desk Volumetrics**

Q2 profile of raised Jira tickets

| Issue Type | No. Created | Resolved | % |
|---|---|---|---|
| Service Request | 5462 | 5417 | 99.2% |
| Incident | 1760 | 1708 | 97.1% |
| Change | 448 | 464 | 103.6% |
| Total | 7670 | 7589 | 98.9% |



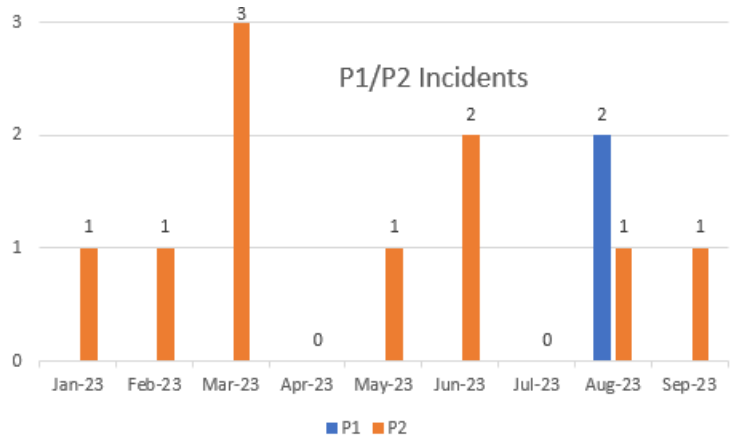
# Digital & Technology

Delivery Plan Priority – Dynamic Organisation

**P1/P2 Incidents**

In the last quarter we have had 2 P1 tickets and 2 P2.

- P1 tickets – The Sentinel containers which contain sentinel information didn't restart automatically as normal. Investigations showed that it was a process issue, and the problem was resolved by performing a restart.
- MoveIT service was down which impacted PV, Appian Fusion, and Sentinel Apps. This was due to an IP address issue which was resolved, and the application brought back online.




**Call Answering Stats**

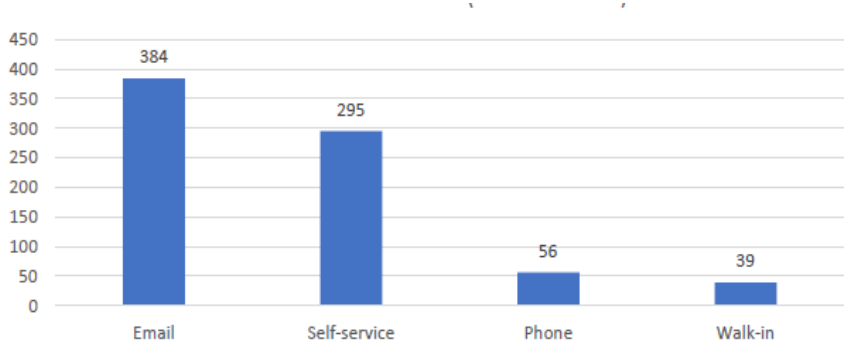
This is the first time we have been able to view the details of calls being answered, the time taken and average waiting time. We are aiming to bring the call answering time down to 30 seconds by sharing resources remotely across both 10SC and South Mimms sites.

| | August | September |
|---|---|---|
| Total Calls | 376 | 465 |
| Answered Total | 325 | 385 |
| Abandoned | 48 | 80 |
| Abandoned over 30 Sec | 16 | 20 |
| Answered within 30 Secs | 212 | 250 |
| Average wait time (secs) | 64.1 | 132 |

NB Abandoned are those calls where people cut off before the call is answered.

**Request Logging Route**

Details to the right also show how people are now interacting with the Helpdesk. Our aim is to re-launch the self-service portal by the end of 2023 and encourage more users to raise calls this way to enable automation to happen. There will of course be reasons to call the helpdesk if Passwords or hardware is broken.



Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**21st November 2023**

| | |
|---|---|
| **Title** | How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing? |
| **Board Sponsor** | Marc Bailey |
| **Purpose of Paper** | Assurance |

# How effectively is the MHRA maintaining its performance on clinical trials and how are plans for the new regulatory system progressing?

## 1. Executive Summary

1.1 This paper summarises current clinical trial assessment performance and sets out the work programme for the future sustainability of clinical trial assessment including the new clinical trial regulations.

1.2 All clinical trials applications received since 1st September 2023 have been assessed within statutory timeframes. All applications received prior to the 1st September 2023 have been assessed and there is no backlog of clinical trial applications.

## 2. Background

2.1 Clinical Trials regulation under the Medicines for Human Use (Clinical Trials) Regulations 2004 is one of 14 functions of the Medicines and Healthcare products Regulatory Agency (MHRA) as set out in the Framework Agreement between the MHRA and DHSC. It is delivered by the Science, Research and Innovation group (SRI) as a key component of the 'lifecycle' model of our "One Agency" strategy, as it integrates medical research on medicines' efficacy with innovation in treatment delivery, access and patient safety. Statutory timeframes for the assessment of clinical trials anticipate approval within 30 calendar days (initial application) and 35 calendar days (substantial amendments).

## 3. Update on performance

3.1 All applications received from 1 September for initials and amendments have been assessed within statutory timeframes, and robust reporting processes are in place to monitor performance. The most recently data for clinical trial assessment performance are summarised in Figures 1, 2, 3, 4.

**Figure 1** Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued (day 30)) and substantial amendments (day 35)


Figure 1 shows the average time taken for MHRA assessment of clinical trial applications, divided into the following categories: initial clinical trial authorisation (CTA) applications for Phase 1 healthy volunteer trials (HVT); initial CTA applications for Phase 1–4 patient trials; and substantial amendments. The monthly average for each category represents clinical trials for which were received from 1st September 2023 and the first review; from receipt of valid application to first opinion issued (day 30) for initials and substantial amendments (day 35).
Note: Second review of Phase 1-4 Initials for October cannot be provided as applications may be pending response from the applicant.

3.2 Since mid-July 2023, over 2,700 applications have been assessed by the MHRA. All backlogs have been eliminated and no clinical trial applications are overdue statutory timeframes for assessment.

3.3 The monthly performance metrics for clinical trials have been redeveloped to ensure the data is decision-relevant and accessible. The new metrics data were published on the 15th November 2023.

**Figure 2** Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application first review (from receipt of valid application to first opinion issued (statutory timeframe for first review is day 30)).

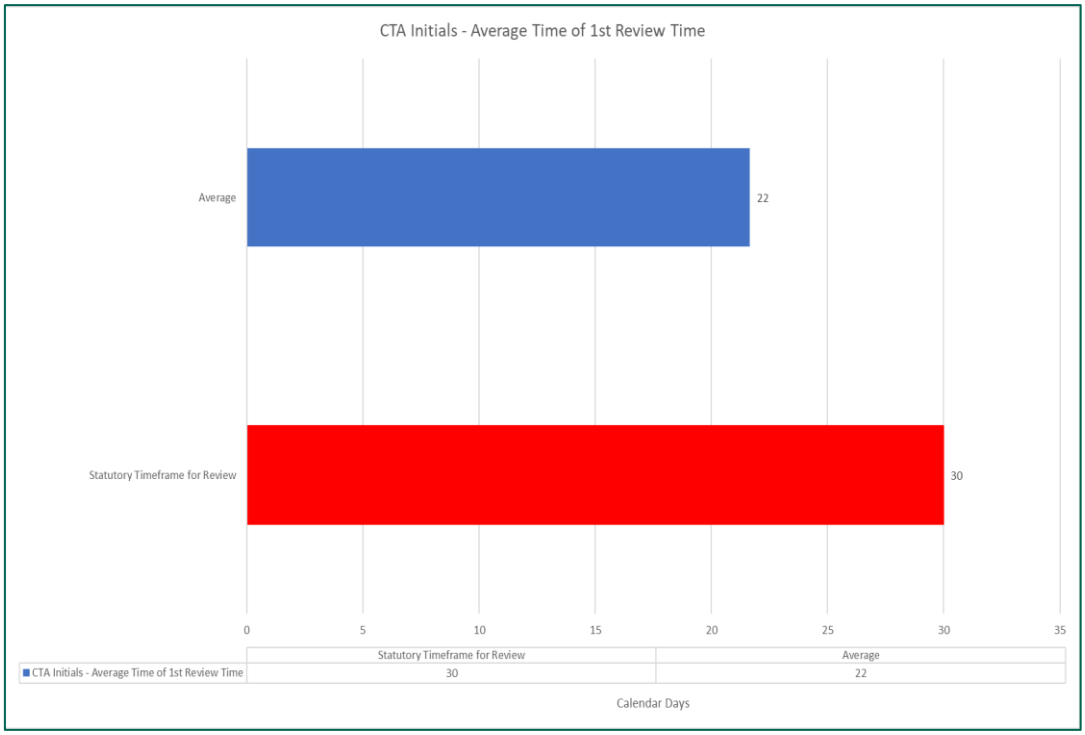



Figure 2 shows the average time taken for MHRA assessment of initial clinical trial applications. The average represents clinical trials which were received from 1st September 2023 onwards and the first review, from receipt of a valid application to first opinion issued (statutory timeframe for the first review is day 30) for initials.

**Figure 3.** Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: initial clinical trial authorisation (CTA) application second review (from receipt of applicant's response to Grounds for Non-Acceptance to outcome issued).

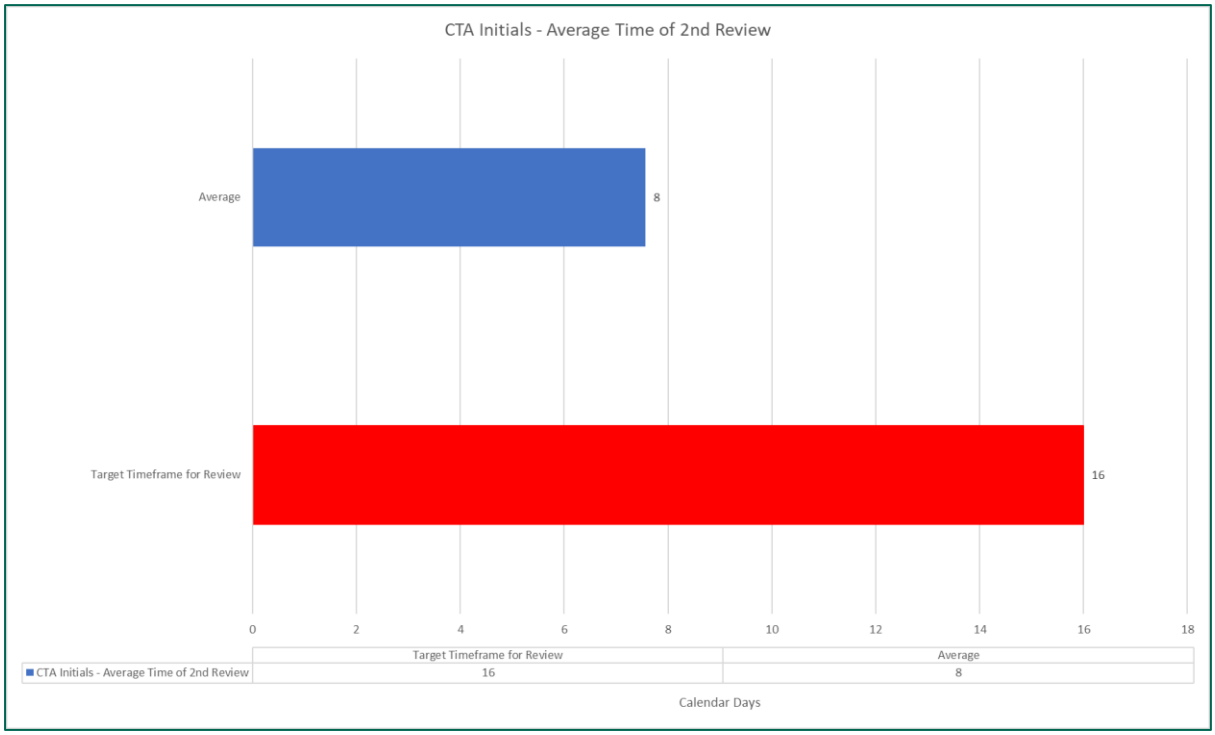



Figure 3 shows the average time taken for MHRA assessment of initial clinical trial applications. The average represents clinical trials which were received from 1st September 2023 onwards and the second review; from receipt of applicant's response to Ground for Non-Acceptance to outcome issued for initials.

**Figure 4** Average timeline (calendar days) for assessment of clinical trial applications received from 1st September 2023 onwards: amendment clinical trial authorisation (CTA) application review (from receipt of valid application to outcome issued (statutory timeframe for review day 35)).

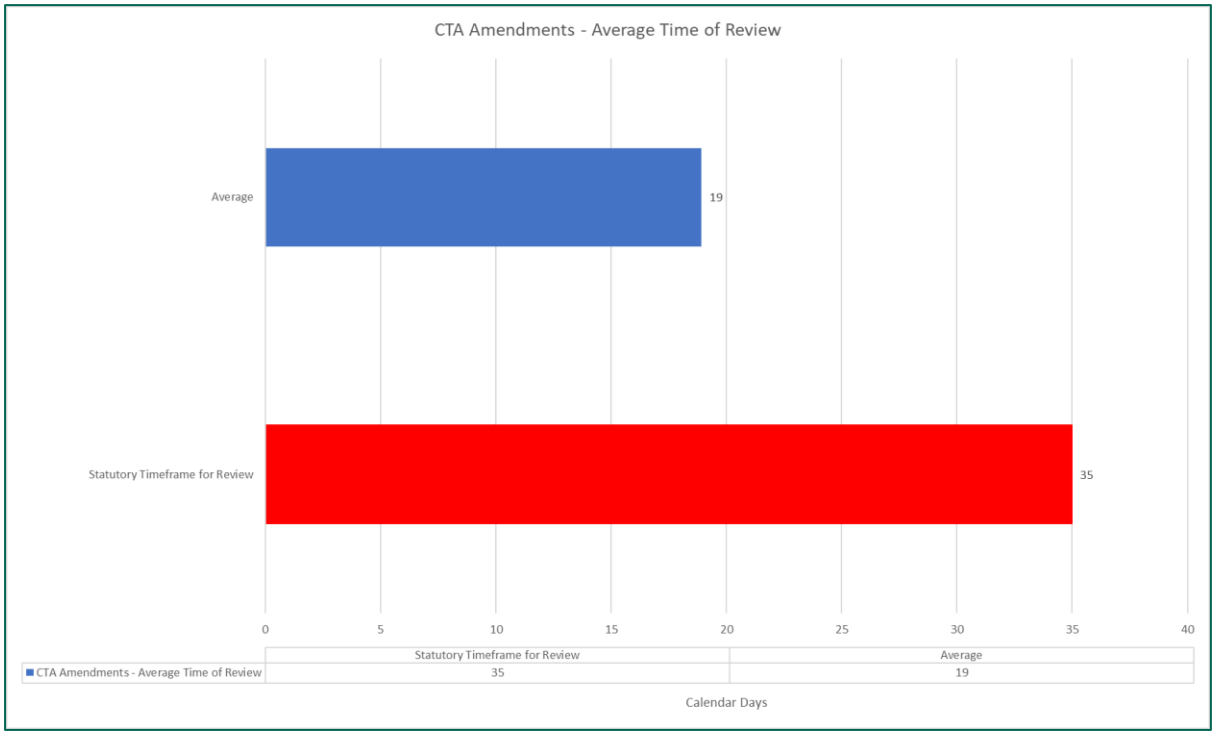



Figure 4 shows the average time taken for MHRA assessment of amendment clinical trial applications. This represents clinical trials which were received from 1st September 2023 and the outcome; from receipt of valid application of substantial amendment to outcome issued (statutory timeframe for first review day 35) for amendments.

## 4. Performance management

4.1 A number of measures put in place to resolve the backlog will be retained in the medium-term (until end Dec-23) to ensure continued performance. These include the retention of a residual number of redeployed assessment staff from within MHRA as well as the use of NIHR's clinical network and external contractors to support clinical and non-clinical assessment.

## 5. Plans for new regulatory system

5.1 New streamlined notification scheme for lowest-risk clinical trials

In the vanguard of our new regulatory system is the new clinical trial notification scheme which was launched on 12th October and aims to accelerate the approval of phase 3 and 4 clinical trials that meet the scheme's inclusion criteria. These trials are deemed to be the lowest-risk trials. Up to 20% of all trials are eligible for the scheme and it is open to all commercial and non-commercial sponsors whose trials meet the inclusion criteria.

5.2 Development of the new regulatory system

A series of internal “deep dive” sessions have been held to ensure that our proposed future regulations accommodate the learnings of the response and the international attractiveness of the UK as an environment for clinical trials and in alignment with the Life Sciences Vision, and the O’Shaughnessy review. These workshops have identified the key elements and work packages for our new regulatory system.

5.2.1 Key changes in the new clinical trials regulations

Building on the existing Government response to consultation on legislative proposals for clinical trials response this workstream will focus on the future regulatory model including risk-proportionate assessment, the appropriate use of notifications for clinical trials, maximising international interoperability and the clinical trial lifecycle model as part of the overarching work package delivering the new clinical trials regulations. These proposals are aligned around the four key themes set out in the consultation response:

- Ensure patients and their safety are at the focus of all clinical trials and bring the benefits of clinical trials to everyone
- Create a proportionate and flexible regulatory environment
- Cement the UK as the best place for conducting international trials
- Provide a framework that is streamlined, agile and responsive to innovation

5.2.2 Capacity and capability

The extensive capacity modelling developed in eliminating the backlog identified the need to increase the capacity of the CIT team for clinical, non-clinical and pharmaceutical assessment as well as for the operational support team. These recruitment campaigns are in progress, and we expect to onboard these additional staff in Q3 of FY 23/24. However, these models will be updated based on our further work to develop the regulatory system and will be updated accordingly along with the identification of key areas of technical capability. For example, additional capability in new and emerging areas of medicine and technology such as advanced therapy medicinal products (ATMPs) and the use of digital twins and synthetic data for clinical trials.

Partnering and collaborating will be key to ensure the required skills and the newly developed collaboration with the NIHR clinical network will be maintained as an important tool for specialist support from this extensive network of experts and as an element of our plans to ensure resilience for the clinical trials function.

5.2.3 Cost and fees model

The existing fees have remained unchanged for an extensive period of time and will require review to ensure they recover the cost for the new regulatory system for both assessment and upstream pre-submission scientific advice. The expected timeframe for implementing the new fee model is April 2025. Stakeholder workshops are being held during November and December 2023 on clinical trials regulation reforms in line with the O'Shaughnessy recommendations, skills and resourcing for Clinical Trials assessments and improved sponsor experience. Together with work on international alignment through the ACCESS consortium and other routes, this work will inform the new clinical trials legislation to ensure the UK is a leading host for Clinical Trials.

5.2.4 Digital and supporting infrastructure

The underpinning IT infrastructure for clinical trials requires substantial improvement and investment to ensure longer term sustainability. This also includes how we maintain the level of information and transparency with applicants on their application status.

Improvements to our existing systems have identified and, in some cases implemented, short/medium term improvements to our existing case management system to improve reporting and performance management and further work will be undertaken to improve our ability to extract and analyse real time data to improve reporting and performance.

The Agency's Digital and Technology group will utilise the outputs of the recent workshops and definition of the new regulatory system to establish future technology and user needs and planning for implementation in accordance with the legislative timetable. This work will also include working with UK regulatory partners, to identify what infrastructure is required to support an optimised approval process and one that would vastly increase transparency to applicants on progress and timings for approvals in line with recommendations of the O'Shaughnessy review.

5.2.5 Communications and customer service

One of the key points of feedback from applicants and representatives through our response to eliminate backlogs over the summer was that the lack of contact and communication they had from MHRA further compounded the problems with delays. We are therefore building our overhauled clinical trials service to be user-focused; and embedding a customer centric culture into the teams delivering. Applicants are continuing to receive proactive contact to determine their application status and reassure of our delivery within statutory timescales.

In addition, work continues to promote the messages that we are now turning round clinical trial applications in less than statutory timelines; that we have eliminated the backlog; and that we are bringing forward new measures and

regulations such as the notification scheme to further reduce application timescales.

The consolidated outcomes of these sessions will (1) define the full implementation plan and (2) inform consideration of any requirement for proportionate re-consultation. The end of Q4 FY 23/24 remains the expected timeline for the preparation of the new regulations with an appropriate period defined for implementation and to ensure the new regulatory system is in place to support the new regulations.

5.3 Engagement with external experts

A workshop with clinical trials experts from across industry, academic and the public sector was held on 3rd November 2023 to further develop and validate our new regulatory system for clinical trials. The workshop identified a number of further opportunities to ensure our regulation is risk-proportionate and enables international interoperability including (1) the adoption of a lifecycle approach for amendments to approved clinical trials that would maximise the use of notifications (2) the appropriate use of notifications and risk-proportionate assessment for initial clinical trial applications based on risk rather than the phase of the trial, with complexity a risk factor and (3) the need to develop supporting regulatory science in innovative areas of clinical trials that would in the longer term inform appropriate regulatory guidance (for example a reflection paper on the topic of decentralised trials).

The workshop also considered how our new regulatory system ensures trials are inclusive and representative where appropriate. Some trials require a narrow target population and mandating diversity could impact trials which are targeted at specific communities. The new regulatory system should include the principle of diversity so that inclusivity of trial participants is appropriately considered.

## 6. Recommendation

6.1 Is the approach adopted for maintaining ongoing sustainability of clinical trials assessment performance adequate and effective?

6.2 Further to the update provided in section 5, are there any additional key considerations for the new regulatory system for clinical trials?

**James Pound**
**November 2023**

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**21st November 2023**

| | |
|---|---|
| **Title** | How is the People Strategy helping the agency become a great place to work and a place where people can flourish? |
| **Board Sponsor** | Liz Booth |
| **Purpose of Paper** | Assurance |

# How is the People Strategy helping the agency become a great place to work and a place where people can flourish?

## 1. Executive Summary

1.1 The paper sets out an overview of the Agency's People Strategy 2023-2026, "Enabling people to flourish", which was published in July 2023. The strategy sits alongside the agency's 3-year Corporate Plan and Business Plan for 2023/24 as the extent and quality of the delivery of agency outcomes and performance goals is dependent on what all those who work at the agency do and how they do it as well as a supportive working environment and access to required information, learning and tools.

1.2 The People Strategy relies on a partnership approach between colleagues and the agency/HR with an expectation that all will take an active role to enable successful outcomes.

1.3 The paper seeks to assure the Board that the People Strategy is focused on the right priorities and welcomes reflections of Board members on its content.

## 2. Introduction

2.1 The agency launched a new People Strategy on 6th December 2022 on INsite, its internal intranet site, and the contents were discussed at the public board in January. Since then, the People Strategy has been refreshed to align with the agency's Corporate Plan 2023-26 and it is additionally now on the gov.uk. website.

2.2 The main changes to the strategy document were aligning the formatting with that of the Corporate Plan. Both documents have the same look which reinforces the close relationship between them, (both sides of a coin). The title of the People Strategy was also changed from "Putting our people first" to "Enabling people to flourish" as this really brings to the fore the connection between the People Strategy and the Corporate Plan with a strategic priority to build "an agency where people flourish, alongside a responsive customer service". So, the People Strategy can be considered as the agency's blueprint for achieving this.

2.3 The strategy is constructed on a partnership approach where all colleagues are expected to take responsibility and accountability for engaging with people policies and processes as well as living agency values and practicing required behaviours in support of these. For its part the agency (in the most cases through its Human Resources function) is committed to ensuring its policies/practices/systems and approach, enable the environment in which all colleagues can flourish while delivering required Business Plan outcomes. Ultimately success of the strategy will primarily depend on leaders and managers engaging positively with its content and playing their part in ensuring a positive experience of work for their people through ensuring meaningful work, opportunities for growth and a supportive work environment.

2.4 The People Strategy is rightly ambitious, especially given the modest size of the HR team and the high demand for "operational support" from business areas. HR

resource is limited, leaving capacity an issue to address, if we are to deliver fully on the People Strategy. To ensure clear lines of accountability for all its actions and ensure their delivery, a detailed project plan is currently being drawn up in support of the People Strategy. This will also allow proper consideration to be given to resourcing requirements and may result in some adjustments to what is possible to achieve.

2.5 The strategy prioritises five themes for action which together and with all colleagues playing their part, will make the agency a great place to work:

- Attracting and retaining the best people
- Developing exceptional people and people leaders
- Valuing diversity and promoting well-being and inclusion
- Investing in a healthy culture
- Enabling great performance and delivery

2.6 These five themes are inextricably linked and equally important, so for the strategy to succeed expectations set out for each of them need to be met to ensure the agency is a great place to work and where people flourish. For example, if the culture is perceived as unhealthy the agency will struggle to retain colleagues and this could also negatively impact future attraction.

2.7 The strategy sets out deliverables for each theme for year 1 (23/24) and will be updated annually in line with business planning arrangements. Progress on actions will be reported to People and Culture Committee. Quarterly reporting against the Agency Business Plan (23/24) goals aligned to this People Strategy provides a further opportunity for progress to be visible at senior level against the People Strategy.

2.8 Progress has been made with actions committed against each theme and the Board is asked to note a key achievement for each theme:

| **Theme** | **Highlight** |
|---|---|
| Attract and retain the best people | Introduced the first ever agency graduate scheme - 8 graduates took up their roles in September. |
| Develop exceptional people and people leaders | Updated Leadership Development Plan in place. Reward Scheme introduced to recognise examples of great leadership behaviour is open to all colleagues. |
| Value diversity and promoting well-being and inclusion | 3 ExCo diversity champions appointed. (Disability – Laura Squire, Race - Claire Harrison, Wellbeing – Alison Cave.) |
| Invest in a healthy culture. | Refreshed values launched in April and supporting Behaviour Framework in August. Behaviours were developed locally in each Group/Function. |
| Enable great performance and delivery | “Learning Library” in place – includes learning material and signposts to additional material to address capability areas. |

2.9 Success measures have been set out in the strategy itself. Progress against all measures is shown in Annex A. Some targets are already exceeded (e.g., annualised vacancy rate is currently 9%), some will not be met in this financial year (i.e. those related to culture survey responses) and some are on track to be met (number of apprentices is currently 30 but we are confident this will be 40 by

end of March) and some can only be confirmed once the Civil Service People Survey 2023 results are released.

2.10 People Survey results are a key indicator of progress across all the People Strategy themes. The 2023 People Survey results will help shape the actions for year 2 of this People Strategy, which will also be determined in partnership with colleague representatives.

## 3. Proposal

3.1 This paper seeks to provide assurance that the People Strategy is beginning to have the intended impact. Current turnover rate of 9% is at its lowest since 2021, from 17.1% at its highest. Annualised sickness absence has decreased to 5.6 days on average, including long term absence, compared to 6.8 days reported for the same period in 2022-23. Uptake in numbers of staff applying for development schemes has increased, e.g., this year 20 agency colleagues applied for the Future Leaders Scheme, one of the Civil Service's flagship schemes, with 10 recently being informed that they had reached the final interview stage. (In 2022 there were 9 applicants with 2 offered a place on the scheme and in 2021 4 applicants –but none were successful.) There is also increased awareness of what constitutes good leadership behaviours with colleagues recognising those displaying such behaviours by nominating them for an award.

3.2 The Board is asked to note that the mere existence of a strategy document will not make the agency a great place to work and a place where people can/will flourish. It is but an enabler by setting out responsibilities for all of us to ensure this will be the case and the challenge is everyone playing their part to make this happen.

## 4. Recommendation

4.1 The Board is asked to seek any further information, to provide any contributions towards future actions and confirm assurance in respect of the People Strategy.

**Liz Booth**
**21st November 2023**

Annex A People Strategy, November Board. Progress to date against success measures.

| Core Priority | Measurement | BASELINE | Year 1 target (23/24) | Year 1 Progress by end Q2 |
|---|---|---|---|---|
| **Attract and retain the best people** | Vacancy rate | 19.7% | 11% | 9% |
| | Time to hire (from the point of the advert being posted to offer accepted) | 35 days | 25 days | 59 |
| | Annualised voluntary turnover | 16.5% | 13%-15% | 8.75% |
| | Number of apprentices | 22 | 40 | 30 (w.e.f 08/11/23) |
| | Utilisation of performance reward budget (In Year and End of Year performance awards) | 76% | 90% | Delegated Grade: 17%<br>SCS: 0% *(currently collating in-year nominations)*. |
| | Utilisation of employee benefits platform (Edenred) | 76% | 85% | 76% |
| | Retention of permanent new hires | estimate 70 | 90% for first 12 months. No less than 80% by end of year 3 | 96% |
| **Develop exceptional people and people leaders** | Percentage of permanent roles filled by internal candidates | to be set in 23/24 | 30% | 38% |
| | Increase in Leadership scores in People/Pulse Survey | 28% | 40% | Awaiting Civil Service People Survey 2023 results. |

| | | | | |
|---|---|---|---|---|
| | Increase in “Leaders walking the talk” | 10% | 30% | 23% |
| **Value diversity and promote wellbeing and inclusion** | Completed rates for diversity characteristics (as an average across all characteristics) | 72% | 85% | 84% |
| | Representation rates for diversity characteristics compared to the UK working age population (UK Census 2021) | Sex (Female) 60%<br><br>Ethnicity (average across grades) 4.2%<br><br>Disability 6.4%<br><br>Sexual Orientation 2.9% | Sex (Female) 60%<br><br>Ethnicity (average across grades) 6%<br><br>Disability 9%<br><br>Sexual Orientation 4% | Sex (Female) 61%<br><br>Ethnicity (average across grades) 6%<br><br>Disability 8%<br><br>Sexual Orientation 4% |
| | Sickness absence rates ( long and short term) | 5.5 days | 4.5 days | 5.8 days |
| | Reduction in Bullying, Harassment, Discrimination scores (People Survey) | 9% | 9% | Awaiting Civil Service People Survey 2023 results. |
| | Increase in Inclusion scores ( People Survey) | 73% | 78% | Awaiting Civil Service People Survey 2023 results |
| | Increased people engagement score | 54% | 58% | 62% |

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|---|---|---|---|---|
| **Invest in a healthy culture** | Increase across all questions in Culture Survey to achieve 2021 Civil Service benchmarks or better | 2021 Civil Service Culture Survey results | Increase in positive scores across all questions | Culture Survey ran in June 2023. Increase in positive scores noted in 8 out of the 15 questions. |
| | Increase in all people survey themes to achieve Civil Service benchmarks or better | 2021 People Survey | Meet 2023 Civil Service benchmarks | Awaiting Civil Service People Survey 2023 results |
| **Enable great performance and delivery** | Agency meet its targets as set out in its performance dashboard and Corporate Plan | Not applicable | Reference Corporate Plan | Reference Corporate Plan and performance dashboard. |
| | Increase in “taking timely decisions” | 11% | 25% | 20% |
| | post-training increased confidence levels (Likert scale) | 4 | 4.5 | 4.5 |
| | Impact of training on performance, measured by feedback on applicability of new learning to role (Likert scale) | 4 | 4.5 | 4.5 |
| | Completion of performance review data on Fusion (start of year, mid-year and end year | 65% | 80% | Start of year: 80% - goals completion rate for all staff.<br><br>Mid-year reviews – currently ongoing |

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

21 November 2023

| | |
|---|---|
| **Title** | What are the key priorities for the MHRA's Health & Safety Strategy? |
| **Board Sponsor** | Marc Bailey |
| **Purpose of Paper** | Assurance |

# What are the key priorities for the MHRA's Health & Safety Strategy?

## 1. Executive Summary

1.1 The current MHRA Health, Safety and Wellbeing (HSW) Strategy runs from 2019 – 2024, and detail of the strategy is provided in this paper, along with an example of the annual action plan that sits underneath the strategy to monitor its delivery. Due to the significant changes since the HSW was written in 2019, there are plans now for developing a new, more holistic, HSW strategy to take us forward for the next 5 years.

1.2 The new strategy will run from early 2024, addressing gaps in the current strategy. The style will also be updated to provide a clearer narrative for the reader and will include the action plan that demonstrates the delivery over the 5 years to cover all the strategic objectives.

1.3 The new strategy will be for all the activities of the Agency covering a broad range of health and safety requirements including safety of staff working in the office, at home, and in high-risk activities both on site at South Mimms laboratories and in off-site locations.

1.4 The following paper outlines the key priorities to be addressed by the new strategy, and the Board is asked to consider the proposals and comment on their suitability, also identifying any additional themes that it would wish to be included in the strategy.

## 2. Introduction

2.1 The HSW Strategy for 2019-2024 (appendix 1), was developed by the Agency's Health and Safety Strategy Group (HSSG) in 2019. It has been followed by the H&S team to drive forward the strategic aims with an action plan sitting underneath each year for monitoring the key activities outlined in the strategy for that year (Appendix 2 for 2023/24 action plan Q2 update). The strategy has consisted of seven strategic themes, as follows:

1. Excellence in H&S Leadership *which ensures efficient, proactive and pragmatic ways of delivering health and safety*
2. Ensuring and maintaining an engaged, healthy and motivated workforce
3. Ensuring a safe and healthy working environment
4. Ensuring a skilled and competent workforce
5. Excellent standards and continuous improvement
6. Management of change in science and technology
7. Planning for danger

2.2 During the lifetime of the strategy, the Agency has undergone significant change, for example from external circumstances such as the COVID-19 pandemic from March 2020, and then internal changes from the Agency Transformation through 2021-22. Throughout this time the key strategic themes have mostly remained relevant to support the aims and

objectives of the Agency. Delivery against the strategic themes has not always been achieved especially as a result of changes within the organisation, but on the whole, good progress has been made.

2.3 The last few years have shown where there are possible areas to be added into the new strategy from 2024. The Agency has undergone significant change, and it has also introduced several new ways of working, with other Agency plans that need to be taken into consideration.

In the last year, the Agency developed the following:

- MHRA Corporate Plan 2023-2026
- MHRA People Strategy 2023-2026
- MHRA Culture Action Plan 2023-2026
- MHRA Science Strategy
- Revised Agency Governance and risk management processes
- Updated Management Committee Structures
- Revised Agency structure and changes in roles

2.4 The Agency has also experienced external influences, scrutiny and recommendations for change, plus learning from work with external partners.

- The COVID-19 pandemic required changes to the working practices on site and for home working, with the latter continuing for many staff as a new way of working.
- Travel during the pandemic stopped for some time but has now rapidly increased, with travel now similar to pre-pandemic levels.
- World threats have increased the number of countries designated as high-risk for travel, resulting in greater risk assessment needed before approval for travel, and additional training required for those travelling to high-risk destinations.
- The Health and Safety Executive (HSE), through its planned intervention programme has provided findings and recommendations particularly focussed on the impact of organisational change on staff activities, mental health and stress.
- Partnership working with external organisations such as UKHSA, and sharing of best practice through the UK Biosafety Leadership Group network, has provided areas of commonality and learnings that can be considered in the new strategy, including our role in significant events, e.g. pandemic preparedness.

## 3. Proposal

3.1. The current HSW strategy has provided key themes for improving health and safety within the MHRA from 2019 through to 2024. The format of the strategy however has not provided a clear programme of deliverables to be achieved within each year and key outcomes required, but these have been identified each year through the annual H&S Action Plan.

The Action Plan is monitored through the current H&S governance process with discussions held at H&S committees covering all the Agency's activities. An overview of progress has been reported to the Executive Committee and the Board through the H&S reports.

3.2 A new strategy is to be developed for 2024 – 2029, taking into account the changes outlined earlier in the paper, and addressing the recommendations related to any areas for improvement highlighted by HSE. It will also consider any recommendations received from the Agency Executive Committee (ExCo), Audit and Risk Assurance Committee (ARAC), and the Board to ensure it is able to deliver a robust H&S plan and a positive culture for the whole organisation.

3.3 The key themes that we feel are currently missing in the strategy and will be considered alongside the existing themes are:

3.3.1 Greater clarity on Leadership and Management:

- that clearly demonstrates a commitment that will be embraced by other members of staff.
- that includes a need for proactive management and ownership of health and safety to indicate a positive health and safety culture.
- that ensures an effective communication system throughout the organisation's management structure
- that formalises the role of the Wellbeing Champion.

3.3.2 A clearer focus on roles and responsibilities of staff related to health and safety requirements:

- ensuring all staff are equipped with the resources required i.e. time, skills and competence required to safely carry out their roles.
- a particular understanding of safety critical roles across the organisation, with job descriptions or goals, and training requirements for these staff clearly laid out.
- outlining the importance of accurate and current procedures and risk assessments for all activities, and maintenance of these being up to date to the targets set.
- improved integration of human factors considerations in the development of improved processes for considering human factors in all activities.

3.3.3 Building more effective and proportionate risk management for Health and Safety to ensure both legal compliance and the safety of staff:

- adopting the Agency risk management process to ensure effective use and adoption.
- ensuring that health and safety is always an integral part of planning and review processes

- understanding the risks of the organisation as a whole; to include the operation of a major hazard site; all high-risk activities carried out on and off MHRA sites; and all risks related to day-to-day activities through office and home working.

3.3.4 Safety of staff and legal compliance in relation to aging infrastructure, facilities, and equipment:

- ensuring a robust process for forward planning of replacements before becoming unsafe and/or out of life

- improved forward planning for investment decisions and effective use of capital funding

3.3.5 Collaborative working across the organisation to embed a positive H&S culture:

- developing an understanding that successful health and safety management is a collective responsibility in which all members of staff must play a part.

- establishing a clear understanding of remit within H&S and Human Resources for the wider Occupational Health, Safety and Wellbeing programme, linking with elements of the MHRA People Strategy, and taking into account the HSE priorities on wellbeing.

- develop greater streamlining of activities through identifying synergies with areas such as quality assurance.

- identifying activities within the MHRA Science Strategy that require support and advice from the H&S team to ensure safe and effective delivery of the science.

## 4. Recommendations

4.1 That the Board considers the proposed plan for a refresh of the Health, Safety and Wellbeing Strategy and provides comment on the suggested areas for inclusion in the updated strategy for 2024-2029, and any additional areas to be considered.

4.2 That NEDs, maybe from the Audit and Risk Assurance Committee, provide input to the development of the new HSW

4.3 That the Board should review and sign off the new HSW Strategy developed by the Health and Safety Strategy Group, rather than delegate this activity to one of the Executive Management Committees

4.4 That once the new HSW Strategy is issued, the Board is updated on progress against the strategy through the annual H&S reporting cycle.

**Marie Donatantonio**

**6th November 2023**

## Appendix 1

# Medicines and Healthcare products Regulatory Agency's Health, Safety and Wellbeing Strategy 2019 - 2024

**Introduction:**

The Agency's 5 -year Health, Safety and Wellbeing (HSW) Strategy has been developed to support the aims and objectives laid out in the Corporate Plan and Health and Safety Policy Statement. The HSW strategy seeks to enable and support the Agency's Public Health agenda with a focus on staff wellbeing, H&S leadership and a tailored, pragmatic and proportionate approach to health and safety (H&S). The HSW Strategy commits the Agency to continually improve the health and safety of its staff and those affected by the Agency's business activities. The HSW Strategy is delivered through the annual H&S Action Plan.

**Aim:**

The Agency will ensure the integration of health and safety into overarching business management, enabling the work of the Agency through clearly defined roles and responsibilities; workable policies and procedures; effective training and risk management processes which ensure lessons are learnt from incidents. The ultimate goal is to ensure staff safety, visitors, contractors and the public whilst enabling Agency business activities.

**Strategic themes:**

1. Excellence in H&S Leadership *which ensures efficient, proactive and pragmatic ways of delivering health and safety*
2. Ensuring and maintaining an engaged, healthy and motivated workforce
3. Ensuring a safe and healthy working environment
4. Ensuring a skilled and competent workforce
5. Excellent standards and continuous improvement

6. Management of change in science and technology
7. Planning for danger

**Delivering the Strategy:**

The overall responsibility for health and safety of staff, visitors and contractors lies with the Chief Executive Officer and the Corporate Executive Team. The day to day operational management of health and safety is delegated to line managers and supervisors at the Agency.

The Health and Safety Team is responsible for the initial development of the strategy, the implementation and subsequent monitoring of the required actions. The day-to-day management of health and safety is the responsibility of line managers but the H&S Team will work with staff to enable and empower managers and others to actively manage health and safety. The H&S Team will work closely with all Divisions, Trade Unions and other stakeholders to promote ownership of H&S across the Agency and will develop the Corporate H&S action plan supporting this strategy.

The annual H&S Action Plan and Key Performance Indicators (KPIs) are developed by the H&S Team, in consultation with staff via the Main H&S Committees and approved by the Health and Safety Strategy Group (HSSG). The H&S Champion presents the annual plan and KPIs to the Corporate Executive Team (CET) for final approval.

Progress against the plan and KPIs is monitored via the quarterly updates at the Main H&S Committees and the Senior Management Teams, and 6-monthly at CET. The Agency Board receives an annual report on H&S performance.

## Activities to meet the strategic aims

| Excellence in H&S leadership | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| | Audit at Board and CET levels of implementation of Institute of Directors (IoD) leadership guidance | | | | | |
| | Definition of leadership behaviours for supervisors, managers and directors to underpin leading by example | | | | | |
| | Engagement of leaders with front line staff | | | | | |
| | Link personal appraisal to leadership behaviours and discharge of H&S duties | | | | | |
| | Planned schedule of exchange learning between MHRA/NIBSC and other similar bodies | | | | | |
| | Document role and visibility expectations of H&S Champion | | | | | |
| | Focus on leadership during H&S week | | | | | |

## Activities to meet the strategic aims

| | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| **Ensuring and maintaining an engaged, healthy and motivated workforce (with a focus on wellbeing and stress)** | Occupational Health (OH) and Wellbeing Lead to deliver initiatives on staff wellbeing | | | | | |
| | OH to deliver guidance and training to managers and staff on recognition of stress symptoms, the effect of behaviour on stress and stress management | | | | | |
| | Celebration of success | | | | | |
| | A consistent approach to managing cases where reasonable adjustments are required or additional support to enable staff to carry out their duties (TD, HR, OH, H&S) | | | | | |

| Ensuring a safe and healthy working environment | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| | Performance reporting from OH on cases of work-related ill health and OH referrals | | | | | |
| | Proactive delivery of OH support so that staff are fully informed of the risks associated with their work | | | | | |
| | Review OH performance to ensure that is meets the needs of NIBSC and is appropriate for the needs of all staff and so that the Agency can discharge its statutory duty | | | | | |
| | Fire safety management issues are prioritised on all sites, valid risk assessments in place and followed up | | | | | |
| | Containment facilities are maintained to the required standards | | | | | |
| | H&S implications of project work and maintenance activities are considered | | | | | |

## Activities to meet the strategic aims

| Ensuring a skilled and competent workforce | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| | Regular technical training is embedded in the mandatory training programme | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Revision of risk assessments, SOPs and work procedures in line with current knowledge about risk | | | | | |
| | Identification of the training needs of new starters | | | | | |
| | Managers to identify if training undertaken elsewhere is fit for purpose | | | | | |

| **Excellent standards and continuous improvement** | **The Agency will:** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
|---|---|---|---|---|---|---|
| | Effective arrangements for internal communication so that managers and staff are kept informed and that information is communicated upwards from front line staff | | | | | |
| | Sample staff opinions on communication arrangements | | | | | |
| | Review TOR and work arrangements for HSSG and related groups | | | | | |
| | Open and timely communication on root causes of accidents/incidents | | | | | |
| | Bench marking with similar organisations | | | | | |
| | Gap analysis in relation to HRO characteristics | | | | | |
| | Identification of which HRO characteristics to adopt | | | | | |
| | Implementation of agreed HRO characteristics | | | | | |

## Activities to meet the strategic aims

| Management of change in science and technology | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| | Horizon scanning to identify new pathogens, emerging infections and global imperatives to eradicate disease | | | | | |
| | Networking and literature review with respect to technological developments to prevent or control risk and work equipment | | | | | |
| | Use of risk assessment arrangements to pin-point implications of change | | | | | |
| | Establish an ad hoc sub-group (of HSSG) to consider implications of change and how to be managed | | | | | |
| | Define role and expectations of Board, CET, HSSG and other relevant groups in relation to the management of change | | | | | |
| | Establish a documented system for gaining authorisation for new/novel work with H&S implications | | | | | |

## Activities to meet the strategic aims

| Planning for danger | The Agency will: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|---|
| | Successful containment of unexpected events:<br>• Back-up systems in the event of failures and cross-checking of important decisions. Redundancy in systems and resilience in operations<br>• Enabling staff with expertise, irrespective of rank, to make important safety related decisions in emergencies, whilst during routine operations there is a clear hierarchical structure and an understanding of who is responsible for what (deference to expertise in emergencies; oscillation between hierarchical and flat organisational structure); investment in training and technical competence, and<br>• Have well defined procedures to maximise the ability to predict and effectively manage unexpected events | | | | | |
| | Effective anticipation of potential failures:<br>• Engagement with front line staff in order to obtain the bigger picture of operations (where failures are likely to occur)<br>• Attentiveness to minor or what may appear as trivial signals that may indicate potential problem areas within the organisation and use incidents | | | | | |

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| | and near misses as indicators of a system's health (preoccupation with failure)<br>• Systematic collection and analysis of all warning signs, no matter how trivial they may be, and avoid making assumptions regarding the nature of failures. Explanations regarding the causes of incidents tend to be systematic rather than blaming individuals | | | | | |

## Appendix 2: Medicines and Healthcare products Regulatory Agency health & safety action plan - 2023-24

## Q2 Update

### Introduction

The Medicines and Healthcare products Regulatory Agency (the Agency) is committed to continual improvement in health and safety management to ensure the health, safety and wellbeing of staff and others affected by our activities.

A Health and Safety Action Plan (H&S Action Plan) is required that sets out the planned and mandatory activities for the Agency based on the Health, Safety and Wellbeing Strategy.

The purpose of the objectives are to ensure:

- An effective H&S provision is maintained following transformation including clear leadership, governance, and accountability.
- continual improvement of the H&S management system
- H&S initiatives are driven through the Health and Safety Champion, Agency Executive Committee (ExCo) and Agency Senior Management Teams
- A consistent approach to risk assessment with a focus on implementation and monitoring the effectiveness of controls.
- A positive health and safety culture
- Best practice for health and safety in all activities
- Competence of staff throughout the Agency.

These objectives will be driven through the Health and Safety Strategy Group (HSSG), H&S Committees and throughout the Agency up to Board level.

It is a requirement that all staff comply with relevant H&S policies and are aware of their obligations outlined in this plan.

### Plan Content

The plan is generated from actions that have arisen from the following main areas:

1. Agency H&S objectives based on strategic priorities
2. Internal Management Actions – arising from internal audits/inspections, actions from the H&S Committees and lessons learnt following internal investigations of incidents
3. External Agencies – arising from external audits/inspections by such agencies as the Health & Safety Executive and Environment Agency

This H&S Action Plan is developed by the HSSG and is monitored on a quarterly basis by the site H&S Committees for 10SC (South Colonnade) and South Mimms

Key Performance Indicators (KPIs) are set for the Agency

**Key to status:**

| | |
|---|---|
| **BLUE** | Completed |
| GREEN | On track |
| AMBER | Risk of delay |
| RED | Significant risk of delay |
| PURPLE | Postponed |

# MHRA H&S Action Plan 2023 - 2024

| 1 | Objectives & Actions | Who | Target Date | Status | Resources Required | Action / Outcome to be achieved |
|---|---|---|---|---|---|---|
| **1** | **Objective: Excellence in H&S Leadership & Culture** | | | | | |
| **1.1** | **Defining clear lines of accountability and reporting for H&S management within the new governance framework:** | | | | | |
| 1.1.1 | Define the H&S competency and training requirements (and refresher periods) of Agency Staff and board members | H&S | Q3 | | | |
| 1.1.2 | Development of 'H&S leadership behaviours' using Institute of Director's Guidance and including PSLG principles for major hazard control. | Deputy Director of H&S and Quality Assurance / H&S | Q4 | | | |
| 1.1.3 | Review and finalise the H&S Meeting structure, terms of reference and reporting arrangements for the Agency | Deputy Director of H&S and Quality Assurance / H&S / HSSG | Q3 | | | Currently reviewing H&S reporting at senior management committees and SRI SMT. |
| **1.2** | Board level approval and oversight of the Agency's H&S Strategy | Deputy Director of H&S and Quality Assurance / Agency Board / ExCo | Q4 | | | |
| 1.2.1 | Review of existing strategy by HSSG | Deputy Director of H&S and Quality Assurance and HSSG | Q2 | | | The strategy went directly to ARAC and RAG, with no comments received. The strategy is being reviewed by the H&S Team and Deputy Director for HSQA. |

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|---|---|---|---|---|---|---|
| 1.2.2 | Present proposed strategy to ExCo and Agency Board and agree annual review going forward | Deputy Director of H&S and Quality Assurance / H&S / Agency Board / ExCo | Q3 | | | The revised strategy will be presented to the Board in November 2023 |
| **1.3** | Further develop the mapping of safety critical roles to include safety critical activities and workload analysis | H&S / Deputy Directors | Q3 | | | Need to add ILS safety critical roles |
| 1.3.1 | Implement a monitoring system to ensure there is oversight of cover for safety critical roles and activities to ensure there is adequate resilience | H&S | Q2 | | | Presented quarterly at Main H&S Committee |
| **1.4** | Work with key stakeholders to develop a proposal to ensure that relevant H&S Objectives are considered in the staff appraisal process | Deputy Director of H&S and Quality Assurance / H&S | Q2 | | | The objective has changed in ownership – now being reviewed at ExCo and RAG |
| **2** | **Objective: Ensuring and maintaining an engaged, healthy, motivated workforce** | | | | | |
| **2.1** | Develop a project plan for the launch of the new Cardinus system which includes hybrid working | H&S | Q3 | | | |
| **2.2** | Create an improvement plan for continued development of the human factors work across high containment areas | H&S | Q4 | | | Gap analysis to be completed using the Energy Institutes guidance |
| 2.2.1 | Identify training to support further development of the human factors analysis process for high containment areas | H&S | Q3 | | | Training options are currently being reviewed. ExCo and RAG supportive of the development required. |
| 2.2.2 | Review Agency guidance on human factors in safety critical tasks and develop and plan of improvement | H&S | Q3 | | | |

| | | | | | | |
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| 2.2.3 | Identify tools and support to conduct an analysis of the workload of safety critical roles and activities | H&S | Q2 | | | |
| **2.3** | Ensure a plan for the management of stress is in place for the Agency supported by a suitable and sufficient stress risk assessment | H&S | Q3 | | | |
| **3** | **Objective: Ensuring a safe and healthy working environment** | | | | | |
| **3.1** | Schedule fire drills for each site – bi-annually for South Mimms and as per Landlord requirements 10SC. | H&S Team | Q4 | | | One planned drill completed successfully at South Mimms |
| **3.2** | Ensure that valid fire risk assessments are in place for all sites and actions progressed. Progress to be monitored via H&S Committees | H&S Team | Ongoing | | | |
| **3.3** | Monitoring the implementation of the contractor Policy and Procedure to ensure that the relevant monitoring of contractors and project work is effective | H&S/ Deputy Director Infrastructure & Laboratory services | Ongoing | | | |
| **4** | **Objective: Ensuring a skilled, competent workforce** | | | | | |
| **4.1** | Develop a mechanism to ensure accurate reporting of H&S training statistics to be presented through KPI's at Main H&S committees | H&S | Ongoing with quarterly updates | | | |
| 4.1.1 | Provide support to HR in the review of the requirements for a learning management system to ensure H&S training statistics can be captured | H&S | Q3 | | | |
| **4.2** | Roll out of health and safety workshops for managers and risk assessors, inclusive of key updates following transformation | H&S | Q2 | | | |

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|---|---|---|---|---|---|---|
| **4.3** | Review the training schedule to identify any gaps or requirement for additional courses | H&S | Q2 | | | |
| **4.4** | Ensure the delivery of human factors in accident and investigation training to all nominated lead investigators | H&S | Q2 | | | Training delayed due to the provider being unable to deliver the course due to resource. |
| **5** | **Objective: Excellent standards and continual improvement** | | | | | |
| **5.1** | Prioritise H&S policy development and review schedule based on the Gap analysis, Policy and Procedure tracker and role changes from transformation and report to main H&S Committees | H&S | Quarterly | | | |
| **5.2** | Relaunch the travel safety app across the Agency to encourage wider use now travel is increasing again. | H&S | Q3 | | | |
| 5.2.1 | Review of UK and Overseas Working processes, developing a cross agency system following transformation | H&S | Q3 | | | |
| 5.2.2 | Development of new UK offsite working Policy and updated lone worker policy to ensure they are aligned | H&S | Q3 | | | |
| **5.3** | South Mimms to be a Poliovirus Essential Facility (PEF)<br>- Progress GAP IV application, to allow work to continue with Polio once it is eradicated – updates on programme of work | HSSG and Polio Group | Q4 | | | |
| 5.3.1 | Prepare for the HSE audit in Feb 2024 against the GAP IV requirements | H&S and Polio Group | Q3 | | | Met with HSE to plan the audit. First documents to be submitted 17th October. |
| **6** | **Objective: Management of change** | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 6.1 | Identify changes required to H&S software systems following the organisational changes | H&S | Q3 | | | Cardinus and Driving Monitor – under review |
| 6.2 | Identify areas of possible collaborative working with QA for efficiency and consistency across the H&S and QA function following transformation | H&S | Q2 | | | Review of joint processes including change control procedures. Work undertaken to review audit schedules and approach. |

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**17 November 2023**

| | |
|---|---|
| **Title** | **What assurance can be provided by the Audit Risk and Assurance Committee?** |
| **Board Sponsor** | Michael Whitehouse |
| **Purpose of Paper** | Assurance |

# What assurance can be provided by the Audit Risk and Assurance Committee (ARAC)?

## 1. Executive Summary

1.1. The Audit and Risk Assurance Committee (ARAC) met on Tuesday 12 September. The Committee reviewed progress in implementing the recommendations of the Health and Safety Executive. We reviewed the Agency's current financial position and the likely end year performance. We received assurance that the Agency will implement lessons learned from the 2022-23 external audit. The Committee considered three reports from Internal Audit exploring in more detail the Agency's cyber security resilience. We considered the Agency's risk register including new and emerging risks. Finally, the Committee received a report on the Agency's performance in responding to complaints.

## 2. Health and Safety Executive

2.1.The Health and Safety Executive recently completed a follow up visit in July. We were pleased that the Executive had confirmed that many of their earlier recommendations had been implemented. The Agency is not yet fully compliant in terms of its SAPO (Specified Animals Pathogens Order) Licence. A key post to help resolve this has now been filled. We understand that full SAPO compliance will not be achieved until 2025. In the interim the Agency is putting in place a strategic relationship with a recognised external organisation to ensure that the MHRA's capability is maintained. We encouraged the Agency to look for ways to accelerate returning to full SAPO compliance.

## 3. Financial Performance

3.1. The Agency is broadly on track in terms of spending in accordance with its planned financial profile. Expenditure on non-payroll costs and capital is less than budgeted but the profile still shows that all monies will be utilised by 31 March 2024. The Committee supports Finance in emphasising that budgets need close monitoring and careful management for the remainder of the financial year if the full added value from allocated funds is to be realised. Any unspent money cannot be retained at the year end. Delivering the RMS project and associated change management activities in accordance with the project's revised critical path is essential for the Agency to utilise its 2023-24 budget effectively.

3.2. ARAC were assured that the Agency and the National Audit Office (NAO) had jointly undertaken a lessons learned review of the preparation and audit of the MHRA's 2022-23 Annual Report and Financial Statements. Building on the success of 2022-23 further good practice will be implemented for 2023-24.

## 4. Internal Audit

4.1. The Committee received a progress report on the implementation of recommendations from an earlier Internal Audit review of payroll. We were given assurance that controls to prevent payment to staff no longer employed by the Agency were now stronger. The Deputy Chief People Officer confirmed that meetings with the external payroll provider to review performance were now much more frequent.

4.2. The Committee welcomed the route map presented by Internal Audit which sets out the key improvements which the Agency needs to implement to help it move from limited control assurance awarded by Internal Audit for 2022-23. A key requirement is for the Agency to have a transparent map of the processes which the Accounting Officer relies upon to provide her with assurance that controls and risk management are operating effectively. Work is in progress to develop an assurance map and the Committee will consider a first draft at its December meeting.

4.3. Reasonable progress is being made in implementing Internal Audit recommendations. ARAC support the enhanced recommendation tracking system which is now in place.

4.4. We considered three Internal Audit reports:

4.5. **Sustainability Reporting:** This is a report commissioned by the Department of Health and Social Care's Audit Committee. It is intended to provide assurance over the processes for capturing sustainability information which the Department places reliance on. Internal Audit awarded limited assurance. The Agency has accepted the report's recommendations. ARAC agrees however that the report assesses compliance with generic reporting good practice which given the size of the Agency and its associated budget may not be affordable in the short term. Nevertheless ARAC was assured that the Agency takes sustainability reporting and its transparency seriously and will seek to ensure that as best it can that its approach reflects good practice. No issues have arisen with how the Agency reports sustainability performance in its Annual Report.

4.6. **Cyber Security:** The Committee considered a draft report together with a paper from the Chief Technology Officer setting out the Agency's overall approach to maintaining its resilience to cyber attacks. Internal Audit have awarded limited assurance (subject to the Agency's response). The report highlights the need for the Agency to strengthen its cyber security governance and management of cyber risks. The report also points to the need to have an action plan to demonstrate compliance with the Cabinet Office's recently issued Cyber Assurance Framework.

4.7. **Cyber Security training:** ARAC considered this report in draft at its July meeting. The confirmed Internal Audit assurance rating as unsatisfactory largely because take up cyber security training was relatively low when Internal Audit undertook its fieldwork.

4.8. The Committee welcomed the assurance which the Executive gave as to the importance and priority it places on ensuring cyber resilience. We also recognise that staff shortages have also been a constraint. Cyber security remains rated as a significant risk on the Agency's risk register. We have asked for a detailed response for ARAC's December meeting on how cyber resilience is being maintained and strengthened together with how Internal Audit's recommendations have been implemented.

## 5. ARAC Effectiveness

5.1. The Committee considered the annual assessment of ARAC's effectiveness using criteria recommended by the NAO. We concluded that the Committee complied with good practice. More could be done to improve training and induction provided to members. The ARAC secretary will bring proposals to the Committee.

## 6. Risk Management

6.1 The Committee considered the Agency's risk register and were assured that key strategic risks were included. ARAC welcomed the new reporting format and the way whether a risk is increasing or diminishing after mitigating actions is now better signposted.

6.2 ARAC discussed the wider potential systemic issues which arise from the risk register. The first is whether the risk to the Agency's reputation and how this is managed should feature more prominently in the register to give the Board appropriate assurance. The second is a related issue as to whether the Agency needs a more proactive communications strategy to demonstrate its added value and to help reduce uncertainty for those who rely on the Agency's services.

## 7. Non Regulatory Fraud and Whistleblowing

7.1. No significant issues of non regulatory fraud were reported. No whistleblowing instances were brought to ARAC's attention.

## 8. Complaints Report 2022-23

8.1. The Committee received the Annual Report on Complaint Handling. This is a comprehensive data driven report. We were pleased to note that wider systemic issues are drawn out to help promote continuous improvement. We were assured by the Agency's approach but emphasised the importance of ongoing proactive communication with all stakeholders to manage expectations and to reduce unnecessary uncertainty.

## 9. The Committee's next meetings are:

6th November 2023 – Horizon scanning

1st December 2023 – Normal business

**Michael Whitehouse**
**Chair, Audit & Risk Assurance Committee**
**September 2023**

Medicines & Healthcare products Regulatory Agency

# BOARD MEETING HELD IN PUBLIC

**November 2023**

| | |
|---|---|
| **Title** | **What assurance can be provided following the meeting of ODRC on 25th September 2023?** |
| **Board Sponsor** | Amanda Calvert |
| **Purpose of Paper** | Assurance |

# What assurance can be provided from the meeting of ODRC?

## 1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 25th September 2023 with the following objectives.

- To review the progress made in improving processes for the delivery of priority services.
- To review how the recruitment, talent management and succession planning strategies and processes support the delivery of the corporate plan objectives.
- Annual review of diversity, equality, and wellbeing
- Review of plans to improve business performance management reporting for the 2023/2024 business plan.

## 2. Review of service delivery processes

- Progress on improving the design and delivery of services has been slower than anticipated. Whilst this is disappointing there has been some progress.
- **Clinical Trials** – Work on service design was paused whilst the crisis management team was formed to focus on clearing the backlog of applications. However, some new ways of working were implemented as part of the crisis management work. The committee encouraged these new ways of working to be embedded quickly into the ways of working.
- **Established Medicines** – Improvements were identified earlier in 2023 and establishment of these processes has enabled the established medicines team to manage their backlog and maintain pace with current demand. However throughput has been adversely affected due to temporary transfer of staff to the clinical trials unit.
- **Compliance –** An improvement plan for delivering compliance has been developed. Pilots for the new processes are planned for Q1 2024.
- **ILAP and Safety Signalling –** There has been little progress on process improvements in these areas due to resources being re-focused to work on clinical trial and established medicines. However, safety signalling improvements are being developed through the roll-out of the Safety Connect system.

## 1. Recruitment, Talent Management and Succession Planning

- Becoming an Agency where people flourish is one of the 4 priorities embedded in the Agency Corporate Plan. The committee reviewed the progress that is being made against the people strategy priorities to; Attract and retain the best people and develop exceptional people and people leaders.
- There have been some key lessons learned from the Clinical Trials Improvement Programme, which has required both the redeployment of staff and recruitment of new staff into key roles to address the backlog. This has revealed some key areas for improvement in processes as well as the need for agility in the actual recruitment process.
- Recruitment of new staff into the agency remains a challenge, but this is not unique to the Agency. The first cohort of graduates started in September. The programme was oversubscribed which is very encouraging and the team were congratulated on this success.

- The Clinical Trials Programme highlighted the importance of having partnerships with organisations such as Faculty of Pharmaceutical Medicine. If roles and responsibilities are well defined and there is training available, it is possible to recruit staff from external organisations quickly. This can benefit both the individuals who will gain valuable skills and knowledge and for the Agency who will gain from new perspectives, skills and potentially ambassadors in the outside world.
- To become agile and attractive employer, it is essential that there is a clarity of definition of personal and corporate responsibilities. This is particularly important for physicians.
- There are good HR processes and tools in place for the development of people, talent management and succession planning. As the Agency changes its focus from recruitment into development of people it is important that leaders at all levels ensure that development of staff is a key priority for them.
- The talent pipeline is essential for achieving the corporate plan objectives. The committee was very supportive of the work being done as part of the DHSC cross-ALB working group.

**2. Annual Review of Equality, Diversity and Wellbeing**

- The diversity and inclusion framework was developed in 2021 and over the past year has been complemented by the people strategy, corporate and business plans. There has been progress made in all the key performance indicators within the framework except for data where there continue to be some gaps. External requirements continue to be reviewed.
- Other improvements continue to be made including the development of an internal access to work scheme despite the DWP ending the Access to Work scheme for civil servants.
- The Agency is on track to meet its objectives under the Public Sector Equality Duty in the current year.
- There has been good progress in delivering support to staff through the Mental Health and Wellbeing Programme including the launch of an Employee Assistance Programme and Fairness Ambassadors.
- Equality Impact Assessments (EIA) are now being used in the Agency in line with requirements of the Public Sector Equality Duty and are a good vehicle to help make equality and diversity a routine part of delivering services.

**3. Performance Reporting**

- Since the publication of the corporate plan 2023 -2025 an annual business plan has been developed. It was launched to coincide with the midyear point in the performance management cycle allowing for simpler updating of local plans and targets and incorporation into staff performance management targets.
- The 23/24 business plan incorporates both annual objectives and operational metrics. Performance will be reported quarterly.
- The cascade of objectives down through local targets and individual performance management targets is not working as smoothly as hoped. It is planned that additional guidance will be developed for 24/25.
- The committee reviewed the first draft of performance metrics and suggested that statutory baselines should be used as baselines where they are available.

4. **Concluding Remarks**

- The committee discussed how and why the Clinical Trials crisis had arisen. Whilst the loss of experienced staff was a factor, this exposed the fact that processes were insufficiently resilient to cope with the changes that had taken place within the organisation.
- The committee were encouraged to see the renewed focus on performance management and targets. The committee stressed the importance that every person has a clear set of personal targets that helps clarify their own and their collective responsibilities.
- The Clinical Trials recovery programme highlighted the importance of having a skilled, resilient and flexible workforce working to deliver services through streamlined processes. Many lessons have been learned and the committee encouraged this learning to be applied across the other priority service delivery areas; Established medicines, ILAP and safety signalling.
- The talent management and recruitment, and succession strategies are well designed to achieve the corporate and business plan objectives. Recruiting and developing staff who have broader leadership and change management skills as well as deep technical skills will be important to deliver the corporate plan.
- The committee welcomed the launch of the graduate scheme which was oversubscribed and is a foundation for developing the talent of the future.
- The collaborations with the Faculty of Pharmaceutical Medicine and NIHR have been successful in bringing more experienced staff into the Agency and will be important for the future.
- The Agency continues to make steady progress in delivering its Equality, Diversity and Wellbeing objectives. The committee were encouraged that the use of EIA's are being used to raise awareness and take action as part of delivering the agency's services.
- Effective communication of the Agency's objectives and ensuring every staff member feels engaged with their delivery continues to be challenging especially as the external environment is constantly changing. The committee supported the development of an internal communications plan that would improve messaging throughout the organisation.
- Effective business performance management and reporting remains a key tool for communication and delivery of objectives. The committee welcomed the progress achieved to date but emphasised that targets need to be in place quickly, utilising current knowledge and statutory timelines and emphasised that they can be adjusted as experience is gained.

**Amanda Calvert**
**Chair of Organisational Development and Remuneration Committee**
**October 2023**