Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 am – 12:30 pm on Tuesday 16 May 2023

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What is the purpose of this meeting 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		
10:15	4. How well has the MHRA achieved the deliverables in its two-year Delivery Plan 2021-23 “Putting patients first: A new era for our agency”?	Assurance	Rose Braithwaite
10:35	5. What are the most important current activities and priorities from the CEO’s point of view?	Context	June Raine
10:55	6. What was the operational performance of the MHRA for the year up to 31 March 2023?	Assurance	Rose Braithwaite
	DYNAMIC ORGANISATION		
11:15	7. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Mandy Calvert
	FINANCIAL SUSTAINABILITY		
11:25	8. What assurance can be provided by the Audit and Risk Assurance Committee?	Assurance	Michael Whitehouse

	HEALTHCARE ACCESS		
11:35	9. What are the strategic priorities for a progressive MHRA Compliance Strategy to enable new product innovation?	Approval	Laura Squire
	CORPORATE PLAN		
11:55	10. How well does the final draft Corporate Plan capture our strategic ambitions for the next three years?	Approval	Rose Braithwaite
	EXTERNAL PERSPECTIVE		
12:15	11. What questions do members of the public have about the items on this Board Meeting Agenda?	Public Engagement	Chair
12:30	CLOSE OF MEETING		

MHRA Board Declarations of Interest – May 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
Stephen Lightfoot Chair of Board	NHS Sussex Integrated Care Board	Chair	Yes	Yes
	Sussex Community NHS Foundation Trust	Deputy Chair and Non-Executive Director	Yes	No
	Sussex Primary Care Limited	Chair and Director	No	No
	Gainsborough Property Development UK Limited	Director	No	No
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
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
Rose Braithwaite Chief Finance Officer	Mental Health Foundation	Treasurer	No	Yes
Amanda Calvert Non-Executive Director	Astrazeneca	Ex-employee shareholder 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.	Yes	Yes
	University of Manchester digital Experimental Cancer Medicine Team	Quince Consultancy providing strategy and data protection consultancy	Yes	No
	Cambridge Judge Business School	Member of Advisory Board	No	Yes
	Fennix Pharmaceuticals	Founder of start-up company planning to develop oral chemotherapy product into Phase 2 trial. Not yet trading.	No	Yes
	High Value Manufacturing Catapult	Non-Executive Director	Yes	Yes
Dr Alison Cave Chief Safety Officer	None	N/A	N/A	N/A
Professor Graham Cooke Non-Executive Director & Deputy Chair	Imperial College NHS Trust and Chelsea & Westminster NHS Foundation Trust	Honorary NHS Consultant	Yes	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
	Debevoise and Plimpton LLP	Consultant/Advisor in relation to COVID protocols	Yes	No
	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
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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	MDU Ltd	Director	Yes	Yes
	MDU Investments Ltd	Director	Yes	Yes
	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	Yes	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	Royal College of Podiatry	Consultancy	Yes	No
	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

Name and MHRA Role	Name of Other Company or Organisation	Nature of interest	Paid	Current
	EU Innovative Health Initiatives (IHI)	Advisory Expert for this EU public-private partnership funding health research and innovation funded by European Commission	Yes	Yes
Laura Squire OBE Chief Healthcare Quality & Access Officer	None	N/A	N/A	N/A
Michael Whitehouse OBE Non-Executive Director	South East Coast Ambulance Services NHS Foundation Trust	Deputy Chair & Senior Independent Non-Executive Director Chair of Audit Committee Chair of Charities Committee	Yes	Yes
	Cruse Bereavement Charity	Trustee 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 21 March 2023

(10:00 – 12:00)

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

Present:

The Board

Stephen Lightfoot	Chair
Dr June Raine DBE	Chief Executive (via Zoom)
Dr Marc Bailey	Chief Science, Research & Innovation Officer
Rose Braithwaite	Chief Finance Officer
Dr Alison Cave	Chief Safety Officer
Amanda Calvert	Non-Executive Director
Professor Graham Cooke	Non-Executive Director and Deputy Chair
Dr Paul Goldsmith	Non-Executive Director
Claire Harrison	Chief Digital & Technology Officer
Haider Husain	Non-Executive Director
Mercy Jeyasingham MBE	Non-Executive Director
Raj Long	Non-Executive Director (via Zoom)
Dr Laura Squire OBE	Chief Healthcare Quality & Access Officer
Dr Glenn Wells	Chief Partnerships Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications and Engagement, MHRA
Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC
Carly McGurry	Director of Governance, MHRA
Natalie Richards	Head of the Executive Office, MHRA

INTRODUCTION

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

1.1 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.

1.2 The Chair welcomed Rose Braithwaite who has been appointed as Chief Finance Officer of the MHRA.

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

2.1 Apologies were received from 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. No new declarations were made this month. The Chair reviewed the existing 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 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) Scientific Research and Innovation – including latest updates on influenza, new SARS-CoV-2 variants; polio; group B streptococcus; the UK stem cell bank; anti-tumour immunity; antibody standards; WHO guidelines on evaluation of biosimilars; formulation science; the Innovation Accelerator; and clinical trials;

(ii) Healthcare Access – including updates on innovative medicines; established medicines; manufacturing and distribution; medical devices regulation; regulation of innovative in-vitro diagnostics; and a roundtable on in silico trials;

(iii) Partnerships – including updates on the Multi Agency Advisory Service; international guidelines; and the Access Consortium;

(iv) Patient Safety – including updates on sodium valproate; pholcodine; pseudoephedrine; CPRD support for digitally enabled decentralised research; the Criminal Enforcement Unit; Modified Vaccinia Ankara vaccine for Mpox; COVID-19 vaccines; and pharmacovigilance strategies;

(vi) Digital and Technology – including updates on the Regulatory Management System; the Agency data centre move; and the laptop refresh;

(vii) Dynamic Organisation – including updates on the All Staff Meeting; service transformation; the Corporate Plan; and the graduate scheme; and

(viii) Financial Sustainability – including an update on fees.

4.2 The Board thanked Dr Raine for her report and thanked all MHRA staff for the excellent work over the last month. The Board provided comments relating to the evolving work of the innovation accelerator and how to showcase this work; the work of the Access consortium and how to expand capabilities with our partners; management of the clinical trials backlog to ensure the UK remains an attractive place to run clinical trials, while ensuring any risk to patients is controlled; international interoperability; development of career pathways and exploring other options such as PhD training schemes for regulatory science and secondments across academia; and CPRD being utilised to recruit patients to a long COVID study. The Board noted the update.

Item 5: What was the financial and people performance of the MHRA for the year up to 31 January 2023?

5.1 The Board considered a report on the financial and people performance of the Agency and provided comments relating to managing underspends; providing assurance to the Board that this will be addressed to avoid underspend in the future; recruitment; levels of sickness absence and actions taken to address this; the lower than expected income for CPRD and how investments are being made to mitigate this in future; and assurance around the delivery of the Regulatory Management System (RMS) and delivery of a minimum viable product as the first step, to ensure a system which will make the Agency more effective is delivered. The Board noted the report with thanks.

Item 6: What are the proposed financial budgets for 2023/24?

6.1 The Board considered the proposed budget for 2023/24. The Board noted this includes income of £162.3m, a 9% increase from last year from regulatory and trading activities. It includes total operating costs of £154.3m, a 6% increase from last year which leads to a £7.3m operating surplus. This will be invested during the year in projects to improve the quality and range of MHRA's services. The Board noted that the budget is recommended with a deficit for the year of £0.1m; this is a very low risk position and will be managed during the year so that expenditure does not exceed our income. The Board noted that capital investment of £25.5m is being sought from DHSC to invest in new digital systems to replace core legacy casework systems and improve other digital systems.

6.2 The Board considered the proposed budget and provided comments relating to ensuring optimism bias is taken into account; prioritising health and safety maintenance work; reviewing trends from previous years when predicting trading income; focusing on efficiency of the organisation; and monitoring corporate cost overheads. The Board agreed to approve the proposed budget.

Action 93: Submit the 2023/24 MHRA Budget to DHSC for final approval.
Rose Braithwaite

EFFECTIVE GOVERNANCE

Item 7: What assurance can be provided by the Audit & Risk Assurance Committee?

7.1 The Board considered an assurance report provided by the Audit & Risk Assurance Committee (ARAC). The ARAC met on 2nd February 2023 and discussed progress in resolving issues raised by the Health and Safety Executive at the South Mimms site; the Gateway review of the MHRA's transformation programme; the Agency's financial statements; the Agency's preparedness for ensuring the Annual Report and Financial Statements; and standing ARAC agenda governance items. The Board reviewed the report and provided comments relating to the timeline for the approval of the Annual Report, which includes bringing the date of the Board meeting in July forward by one week to 11 July 2023 to address this. The Board noted the report for assurance.

Item 8: What assurance can be provided by the Annual Health & Safety Report of the MHRA?

8.1 The Board considered the Annual Health & Safety (H&S) Report. The Board noted the 2022/23 year has been challenging and has resulted in pressure on H&S systems leading to an increase in issues and incidents, and subsequent actions to address them. The Board reviewed the report and provided comments relating to H&S training; the SAPO4 licence and actions being taken to ensure this licence is retained; H5N1; and training up multiple members of staff to address staffing issues. The Board agreed H&S should be reviewed frequently by the Board, and H&S Key Performance Indicators should be included in the performance reports. The Board noted the report for assurance.

Action 94: Publish H&S annual report on website and include H&S KPIs in quarterly performance report to Board. ***Marc Bailey***

Action 95: Add H&S Strategy to Board Schedule of Business. ***Chair***

Item 9: How effective are the Assurance Committees and how can the Terms of Reference for the Board, Executive Committee and Assurance Committees be improved?

9.1 The Board considered a paper detailing updates to the Board Terms of Reference (ToR) following their annual review; the conclusions of a recent survey of members on the effectiveness of the Board assurance committees and updated ToR for each committee in response to those conclusions, for review and approval. The Board provided comments relating to how partnerships, strategic plans and substantial contracts are approved in the Executive Committee (ExCo) ToRs; opportunities for the Board to provide topics for discussion to the Executive; annual reviews of governance; the framework agreement; applying learnings from the survey results; adding value; the use of deep dives; the usefulness of holding joint assurance committees to review specific topics. The Board were content to approve the Board, ExCo (with corrections), Audit & Risk Assurance Committee (ARAC), Patient Safety & Engagement Committee (PSEC) and Organisational Development & Remuneration Committee (ODRC) ToRs.

Action 96: Clarify how MHRA partnerships, strategic plans and substantial contracts are approved in ExCo Terms of Reference and circulate final version to Board. Carly McGurry

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.

ANY OTHER BUSINESS

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

ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 21st March 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. 21/03/2023: Science Strategy to be presented to the Board in July	Marc Bailey	~~21/09/21~~ ~~16/11/21~~ ~~17/05/22~~ ~~15/11/22~~ ~~21/03/23~~ 11/07/23	
59	21/09/21: Board assurance committees to review their combined effectiveness and hold a board discussion on this topic.	Michael Whitehouse, Mercy Jeyasingham, & Mandy Calvert	~~15/03/22~~ ~~16/08/22~~ ~~13/12/22~~ ~~17/01/23~~ 21/03/23	Completed
62	19/10/21: Review the Corporate Risk Register to consider whether all strategic risks to Agency outcomes are accurately captured.	Carly McGurry	~~19/04/22~~ ~~17/11/22~~ ~~17/01/23~~ 18/04/23	Completed
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~~ 19/09/23	
71	18/01/22: Using the input from the public consultation and Board discussion, develop and publish a new regulatory framework for Artificial Intelligence as a Medical Device.	Laura Squire	~~21/06/22~~ ~~20/09/22~~ ~~21/03/23~~ 16/05/23	Verbal Update

73	15/02/22: Develop a Sustainability Strategy.	Glenn Wells	~~17/01/23~~ 16/01/24	
79	19/04/22: Hold a discussion on the Yellow Card Biobank at an upcoming Board meeting.	Alison Cave	~~21/03/23~~ ~~16/05/23~~ 18/04/23	Completed
80	19/04/22: Implement the Budget as approved by the Board for 2022/23. Ensure the deficit is balanced by end of the year.	ExCo	31/03/23	Completed
88	15/11/22: Present the Agency's Compliance Strategy to the Board.	Laura Squire	~~21/02/23~~ 16/05/23	On Agenda
89	17/01/23: PSEC to review the implementation of sodium valproate safety measures at a future agenda.	Mercy Jeyasingham	~~21/03/23~~ ~~18/04/23~~ 20/06/23	
90	17/01/23: Explore the feasibility of deprioritising MA applications for companies who have unpaid debts with the Agency, without compromising public health, to help address the established medicines backlog.	Laura Squire & Rose Braithwaite	21/03/23	Completed
New Actions				
93	21/03/23: Submit the 2023/24 MHRA Budget to DHSC for final approval.	Rose Braithwaite	16/05/23	Verbal Update
94	21/03/23: Publish H&S annual report on website and include H&S KPIs in quarterly performance report to Board.	Marc Bailey	16/05/23	Verbal Update
95	21/03/23: Add H&S Strategy to Board Schedule of Business.	Chair	16/05/23	Completed and on schedule for 21/11/23
96	21/03/23: Clarify how MHRA partnerships, strategic plans and substantial contracts are approved in ExCo Terms of Reference and circulate final version to Board.	Carly McGurry	16/05/23	Verbal Update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 2023

Title	**How well has the MHRA achieved the deliverables in its two-year Delivery Plan 2021-23 "Putting patients first: a new era for our agency"?**
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

How well has the MHRA Achieved the Deliverables in its Two-Year Delivery Plan "Putting Patients First: A New Era for Our Agency"?

1. Executive Summary

1.1. We have reached the end of the Delivery Plan's second and final year. A significant amount has been done and there is much to celebrate. The Executive Committee (ExCo) has agreed that we publish an update to mark the occasion.

1.2. The Plan published on 4 July 2021 originally set out 68 actions under 7 strategic goals to be completed over a two-year period from 1 April 2021 - 31 March 2023. New priorities were added at the halfway point, many actions were delivered and some replanned for beyond the two-year timeframe. By the final year, 59 actions were due within the original timeframe and 59% have been completed and a further 11% should be by 30 June 2023. There are 16 actions due beyond 2022/23 that are being considered for the 2023/24 MHRA Business Plan.

2. Introduction

2.1. The Delivery Plan 2021-2023, published in July 2021, set out an ambitious roadmap to ensure we put patients first, become a truly world-leading, enabling regulator and that we continue to protect public health through excellence in regulation and science. A huge amount has been done over the 2 years, during a time of change and against a backdrop of the UK's exit from Europe and our ongoing support of COVID-19 efforts. A summary of accomplishments for the second year is in Annex 1. This should be seen alongside a great deal of other high-priority work arising in-year.

3. How well have we achieved the deliverables in its Delivery Plan 2021-23

3.1. In the first year, we successfully delivered a new **One Agency structure**, becoming a more simplified, joined-up and accessible organisation, and one which **brings together medicines and medical devices** for the first time. We published our **Patient Involvement Strategy** to ensure a more systematic approach to listening to and meaningfully involving patients. We progressed new access pathways, and legislative reform across a range of areas. We also began establishing our **position as a sovereign regulator**, with productive partnerships, e.g. Project Orbis and the Access Consortium, yielding new products and access routes.

3.2. As we moved to the second year, we have shown a big **shift in how we engage and involve patients**. We have worked closely with partners to ensure the **supply of vital medical products**, as well as delivering **new access pathways** and making more progress on **legislative reform**. We have continued to deliver **cutting-edge science** to accelerate the development of new products for patients and demonstrate our **worldwide influence**.

3.3. We have **strengthened our ability to manage safety issues** by modernising our systems and ensuring **greater involvement of patients**; all whilst **continuing to protect public health**. We have taken important steps to **promote equality in healthcare** via legislative change work. We've deepened our position as a sovereign regulator, **developing our national and international partnerships** to drive our priorities for the UK, yielding **new products and access routes** and furthering our ability to protect public health. We also took important steps to improve our **leadership capability, governance functions, culture and systems.** Finally, we put the Agency on a **financially sustainable footing** when we transitioned from being a trading fund to operating within the annual accounting boundary of the Department of Health and Social Care on 31 March 2022.

4. What were the delivery achievements in the year up to 31 March 2023?

4.1. Overall, 58 actions were due in the Delivery Plan's final year and, by the end of Q4, 34 (59%) were completed. There are 7 actions facing minor slippage that are expected in Q1 2023/24 (shown as Amber / Green in the attached report in Annex 2), at which point the total of completed items will be up to 70%.

4.2. There are 16 items scheduled beyond 2022/23. These were either planned for delivery beyond the 2-year time frame of the Delivery Plan or have been replanned following agreement in earlier quarters. The most notable of these are below. These are mostly long-term complex projects and progress has been made (often in a phased way with outputs delivered on route). All outstanding deliverables have been fed into the new Business Plan drafting process. Many have timescales showing as "at risk" and will need to be updated.

- **Outstanding legislative change** (clinical trials, medical devices, "second tranche" updates): there has been much progress (policy development, public consultations, EAMS Statutory Instrument being laid, etc.) but the more complex elements have had their timescales extended. As noted in the Q3 report, external dependencies have played a role but there have also been some internal challenges, such as capacity. Stakeholder communication is ongoing given the nature of this work.

- **Systems and services refresh** (e.g., service redesign, Regulatory Management System, established medicines and new devices pathway etc.): the original timescales for this work have been replanned. Project plans are being updated alongside the work dealing with COVID-19 related backlogs and this will be in the new Business Plan.

- **Patient safety work with a link to the Independent Medicines and Medical Devices Safety Review** (sodium valproate risk mitigation, teratogen use during pregnancy review, pelvic mesh benefit-risk review): in the case of the first two, timescales were replanned in response to the receipt of new data and/or decisions to improve the approach being taken. In all 3 cases, there has been extensive ongoing stakeholder and patient involvement.

4.3. The fact this work has been rescheduled is already in the public domain. Many of the projects already involve stakeholder engagement (departmental, public, industry etc.) and revised timeframes are either public or should not be a surprise. Patient risk is relatively low and already being managed. Many actions are improvements to the status quo (e.g. updating current systems) and in many cases (e.g., work on the regulation of Software and AI as a medical device and SafetyConnect) delivery has been phased, with some improvements already live.

5. Recommendation

5.1. The Board is asked to reflect on what the Agency has achieved over the term of the Delivery Plan and confirm if it is happy to consider the Plan closed so we can turn our focus to the new Corporate Plan. We will issue communications about these achievements and the completion of the Delivery Plan shortly.

Rose Braithwaite
May 2023

Annex 1: summary of accomplishments for the second year of the Delivery Plan

1. Patient involvement

- The Agency has undertaken a major shift in how it engages with and involves patients. This priority was put at the heart of the Delivery Plan.
- This year, we celebrated the anniversary of our **Patient Involvement Strategy** and highlighting examples of our commitment to more systematically listen to and involve patients, including:
- Involving patients in the **Innovative Access Licensing Pathway** to influence medicines development and reduce time to market.
- Incorporating more **patient input in our benefit-risk reviews** to make sure they better reflect patient experience and concerns.
- Improving how we **support the public in responding to our consultations** to ensure their insight better informs our decisions.
- Engaging with the public on our **Yellow Card Biobank** project and designing the set-up of the Biobank around what we have learnt from them.

2. Scientific innovation

- We have continued to deliver cutting-edge science to accelerate the development of new products for patients and demonstrate our worldwide influence.
- Active global involvement in a range of high-profile scientific area e.g., assessing new SARS-CoV-2 variants, work on polio eradication, ongoing work on existing and new standards, the response to Monkeypox etc.
- In March 2023, we published our plans to improve and strengthen the UK legislation that underpins the **regulation of clinical trials,** and we will lay the SI as soon as possible.
- In July 2022, we launched our **Innovation Accelerator service**, following consultation with stakeholders, to help provide innovators better access to our scientific expertise and regulatory guidance.
- Our risk-based strategy for the **independent testing of biological medicines** is going through its final stages of approval and will ensure biologicals on the UK market continue to be safe and effective in years to come.
- We improve our IT platforms to support **delivery of an enhanced clinical trials service** by moved our clinical investigations service onto our clinical trials platform.

3. Healthcare access

- We worked closely with our partners to ensure a continued supply of vital medicines and medical products, as well as delivering new access pathways and legislative reform.
- The Life Sciences Council agreement to accelerate the delivery of the **future UK HealthTech regulatory system** and we are developing SIs to deliver on proposals.
- In October 2022, we published our roadmap to reform the legislation for **Software and AI as a Medical Device** and are pushing forward the delivery of its 33 deliverables.
- Our **Compliance Strategy** is complete and its delivery will enable innovation and access in the regulated supply chain via more risk-proportionate compliance approaches.

- The **Early Access to Medicines Scheme** became law under the Medicines and Medical Devices Act, improving safe supply of innovative medicines to UK patients.
- Recognition of the importance of our work came in the Spring Budget 2023 as we secured **a £10 million grant package** to help bring innovative new medicines and medical technologies to UK patients more quickly.

4. Patient safety

- We continue to protect public health and have strengthened our ability to manage safety issues - modernising our systems and ensuring greater involvement of patients.
- **SafetyConnect** has become more effective, accessible and transparent, delivering several Independent Medicines and Medical Devices Safety Review recommendations.
- In March 2023, we **launched a new synthetic data generation service** that provides clients with bespoke synthetic data based on non-CPRD datasets.
- We completed the development of the **CPRD GOLD synthetic dataset** which will be launched in the Summer of 2023.
- We **upgraded CPRD's observational research infrastructure** to deliver the second iteration of a Trusted Research Environment ready for testing by external users so we can continue delivering our research data services.
- Further action has been taken to drive down the **risks of valproate** using patient evidence to inform the approach and improve risk materials.
- We made good process in setting up the UK's **statutory committee on the safety of medical devices**, which will strengthen our ability to manage safety issues, and the Interim Committee had its first meeting in April 2023.
- We have taken prompt action to **protect public health** e.g., Operation Pangea; mexiletine hydrochloride and pholcodine product recalls; action on faulty insulin pumps, a naloxone product defect, and contaminated perfusion solutions.

5. Equity in healthcare

- Equity in healthcare was a new priority at the Delivery Plan's halfway refresh. We took steps to lead by example and promote it in UK regulation via our legislative change work.
- Our **ethnicity algorithm was completed** and will be launched as a value-added product in the new year. We used it to confirm CPRD-HES data has good representation of all ethnic categories.
- We have made **healthcare equity a priority in legislative change,** with commitments in our consultation responses for clinical trials and medical devices.
- We have developed a **web-based tool that detects and corrects biases** due to underrepresented populations for AI applications, market research is now being undertaken to consider how this can be developed further.
- Our **Biobank** project, now jointly overseen with Genomics England, is set to launch its pilot to investigate the role of genetics in adverse reactions and to define a business model. This will lead to safer treatments and reduce patient side effects.
- We **translated our webpages** on how to engage with the Yellow Card scheme into the most commonly spoken languages in the UK to improve inclusion and accessibility.

6. Dynamic organisation and innovative ways of working

- To ensure we deliver the vision of the Delivery Plan we have updated the Agency's structure as well as our leadership capability, governance, culture and systems.
- We successfully delivered a **new One Agency structure** and largely populated it, to create a more simplified, joined-up and accessible organisation.
- In December 2022, we published our new **People Strategy 2022-2026** which sets out commitments and targets to make a thriving workplace with the qualities needed to deliver change at the heart of the Delivery Plan and new Corporate Plan.
- Work to **strengthen our health & safety system** and ensure our **committees** continue to consistently operate well and with greater patient involvement is nearly complete.
- We have embedded new ways of working to make the agency more dynamic, including **refreshed values**; a new **workforce planning framework,** a **culture action plan** and refreshed inclusive **hybrid working policy**.
- We have completed the actions in this year's **Leadership Action Plan**, including work to set expectations and to evaluate and develop capability.

7. Collaborative partners

- We've established our position as a sovereign regulator, developing international and national partnerships to drive our priorities, yielding new products and access routes.
- We became a full participant in the FDA's **Project Orbis**, a programme to accelerate access to new cancer medicines. In June 2022, the first medicine to be awarded an Innovation Passport was authorised via the Orbis initiative for cancer medicines.
- We became a full member of the **Access Consortium** in January 2021 and our term as Chair is now underway. In May 2022, faricimab became the first treatment approved in the UK via the Consortium's 'New Active Substance Work Sharing Initiative'.
- We initiated the first phase in the creation of an **international recognition framework** working closely with Australia, Canada, Swissmedic, Japan, Singapore and the FDA.
- To help pursue greater global harmonisation and cooperation, we became members of a range of international collaborations, including the IMDRF, ICH, MDIC, etc.

8. Financial sustainability

- We have now put the Agency on a financially sustainable footing.
- We successfully **balanced our annual budget** and moved within DHSC's accounting boundary. We secured investment for systems such as SafetyConnect and the Regulatory Management System via our **Spending Review bid**.
- Plans have been developed and are in train to make more savings by **overhauling our legacy IT systems** and by **reducing corporate costs**.
- On 1 April 2023, we **introduced a new fee structure** that ensures we fully recover the costs for the services we offer.

Annex 2 – summary of performance as at Q4 2022/23

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →	Q1 23/24 and beyond →
Patient and public involvement	Pilot patient "listening sessions" approach as a better method of seeking patient input, and define its role going forward by end Q1	Deliver staff training and support via new "Patient Champion Network", to improve staff understanding and ability to deliver patient engagement by end Q2	↓ Develop new process to safely and ethically expand patient engagement in our work. For example, developing training and support for patients and members of the public in contributing to our work by Q3	↓ Tailor patient engagement guidelines to ensure the needs of different parts of the population can be included; for example, those who are already engaged with us and those who are not by Q4	Define deliverables on Patient Reported Outcome Measures to better understand the impact of regulation on patients by end Q2 2023/24 (Revised due date agreed Q3)
				Pilot new patient engagement guidelines through two patient "listening sessions" as a method of seeking patient input in an ethical, respectful and consistent manner by Q4	
			Develop a more consistent and effective approach to public consultations by end Q3	Develop plans to support patient contributions to committees and groups to improve patient representation and contributions by end Q4	
				Incorporate patients' views and lived experience in at least 50% of our substantial benefit-risk reviews by Q4	
				Develop our understanding of patient perceptions of benefit-risk to enhance regulatory decision-making by end Q4 (captured in the Corporate Plan)	
Equity in healthcare	Nothing scheduled in the Delivery Plan, focus on core business	Improve diversity of our patient group consultative forum to enhance its contribution to regulatory decision-making by end Q2	Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3	→ Reform UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; put legislation before Parliament by end Q4	↑ Improve UK medical devices legislation by requiring more representative product clinical data to increase assurance of reduced bias and appropriateness for different populations; put legislation before Parliament and publish guidance and best practice phased over mid-to-late 2023
				↑ Review women's health regulatory inequities by end Q4	
				Improve our ethnicity data by using a new algorithm and integrating a more accurate and updated ethnicity record into the anonymised patient records within our databases by end of Q4	
			Define deliverables for integrating our suspected side effect data with NHS healthcare records to deepen our understanding of the representativeness of our data and the impact of demographics in patient adverse drug reactions by end Q3	Develop a prototype web-based tool that detects and correct biases due to underrepresented populations for AI applications by end Q4	↓ Review teratogen use during pregnancy by end Q2, independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4 (Revised deadline pending following decision in Q3 to undertake more involved patient involvement approach)
				Improve UK regional representativeness of our clinical practice research data service to include at least 10% of GP practices across all UK regions by end Q4	
				Provide translated webpages on how to engage with our Yellow Card scheme in languages other than English commonly spoken in the UK to improve inclusion and accessibility by end Q4	
Embedding innovative WoW	Refresh culture action plan by end Q1 and continue driving culture change needed for new operating model	→ Engage with staff to refresh vision statement and values and behaviours framework to align with the new operating model by end Q2	→ Deliver a refreshed health and safety system, including high hazard assurance monitoring, by end Q3	→ Implement innovative devices pathway in conjunction with innovative medicines and build foundations for collaborative approach with the Access Consortium by end Q4	→ Embed operation of new risk proportionate established medicines pathway by end Q3 (As agreed in Q3 to be updated to: Plan to resolve established medicines backlogs: all fully compliant applications for new national marketing authorisations received from 1 January 2024; and all fully compliant applications for new Type 1b variation applications received from 1 July 2023.)
		Delivery of leadership development plan from Q1 to Q4 to support Delivery Plan implementation			
		Update talent management model by end Q2 to ensure we attract, develop and retain world-class scientific and regulatory capability	Implement new inclusive hybrid working policy by end Q3 to ensure an effective working approach that balances business and staff needs		Launch key redesigned services and supporting process and systems, including design of a refreshed underpinning quality management system, by end Q3 (Deliverable to be updated once project planning of North Star outputs is complete)
		Publish new people strategy by end Q2 to support the implementation of our Delivery Plan and retain our status as a world-leading regulator and employer			

KEY: Red: late or no longer possible; Amber: at risk; Green: on-track; Blue: complete (n.b. colour combinations also possible); Trend arrows: RAG change from previous quarter (↑ improved, → no change, ↓ worsened)

	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →	Q1 23/24 and beyond →
Scientific Innovation	Nothing scheduled in the Delivery Plan, focus on core business	Nothing scheduled in the Delivery Plan, focus on core business	Publish new regulatory science strategy by end Q3 (captured in the Corporate Plan)	→ Reform UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; put legislation before Parliament by end Q4	Nothing scheduled in the Delivery Plan, focus on core business
				↓ Risk-based approach to batch release: guidelines drafted by end Q3; implement independent testing based on risk-based strategy by end Q4	
				Work with the HRA and the NIHR Clinical Research Network to provide regulatory support for expediting delivery of defined clinical trials; support a pilot to improve set-up of phase 1 oncology trials by end Q4	
				↓ Work with our Access consortium partners to deliver a clinical trial work and information sharing mechanism, put forward proposals for a common assessment template, and associated guidance to ensure a more harmonised approach by Q4	
				Improve our IT platforms to support delivery of an enhanced clinical trials service by end of Q4	
Healthcare Access	Nothing scheduled in the Delivery Plan, focus on core business	Finalise Compliance Strategy through consultation with external stakeholders by end Q2	Embed visual technology capabilities as a standard part of inspections by end Q3	→ Lay the statutory instrument for remaining elements of the first tranche of legislative change proposals by end Q4	↑ Establish new medical devices framework to support safe innovation and ongoing access to products: lay statutory instrument and publish guidance and best practice phased over mid-to-late 2023 (also shown above under equity)
				→ Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by end Q4	
				Ensure integrated UK regulatory pathways for products that combine medicinal products and devices; consultation by end Q4 (will be considered alongside priorities for broader regulatory reform in the Corporate Plan)	
Patient Safety	Nothing scheduled in the Delivery Plan, focus on core business	Upgrade observational research infrastructure to enable timely and secure delivery of research data services: define requirements and commence implementation of new systems by end Q2	Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3	→ Review the available evidence on pelvic mesh benefit-risk by end Q4	↓ Work with others in the healthcare system to implement new, strengthened safety measures for sodium valproate by end Q2 2023/24, and to continue to drive down the number of exposed pregnancies (deadline updated in Q3 following revision of approach based on CHM advice)
				↓ Develop risk communication strategy to ensure more coordinated, pro-active communications by end Q4	↓ Improve model of the Devices Expert Advisory Committee: launch consultation by end Q3; and establish statutory committee by July 2023
				→ Deliver enhanced signal detection process; roll out from Q3, 2022/23 to end of Q4	↓ Review teratogen use during pregnancy by end Q2, independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4 (also shown above under equity) (Revised deadline pending following decision in Q3 to undertake more involved patient involvement approach)
				Deliver expanded scope of NHSX-funded synthetic data research project and launch the synthetic data service by end Q4	
				Upgrade observational research infrastructure to enable timely and secure delivery of research data services: deliver MVP2 to enable pilot testing by clients by end Q4.	↑ Agree policy for an enhanced devices transparency regime by end Q3, with key elements delivered over 2022/23 and 2023/24

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	Q1 (Apr – Jun) →	Q2 (Jul – Sep) →	Q3 (Oct – Dec) →	Q4 (Jan – Mar) →	Q1 23/24 and beyond →
Dynamic organisation	Deliver HR support and guidance to staff during restructuring throughout Q1-Q4, 2021/22	Deliver our Transformation Programme including a plan for optimised services benefits realisation and implement restructuring; operationalise the future operating model and redefine and optimise prioritised core services by end of Q2	Deliver our data strategy, including a data sharing strategy, underpinned with robust security standards and privacy by design by end Q3 (Data Strategy is currently being circulated for review and comment)	↑ Review our use of expert and advisory committees to ensure best use of expertise, the application of consistent, high-quality standards of operation and safeguard their important independent advisory role, by Q4	↓ Fully scope what self-service functionality can be delivered via the Regulatory Management System by end Q2 and deliver the core system by end Q1, 2023/24
	Review workforce in Q1, identify follow-up actions to ensure we embed workforce planning by Q4	Complete main elements of our rebranding to ensure consistency and raise our profile by end Q2		Review workforce in Q1, identify follow-up actions to ensure we embed workforce planning by Q4	Support revised medical devices regulations, deliver the digital self-service, automation and data platforms required by early- to mid-2024 (tbc - in line with legislative deadlines)
Collaborative Partnerships	Nothing scheduled in the Delivery Plan, focus on core business	→ Identify key policy areas for the second tranche of legislative change and define timescales for putting legislation before Parliament over 2022/23 and beyond by end Q1	Nothing scheduled in the Delivery Plan, focus on core business	Publish a partnerships strategy by end Q4: setting out our long-term partnerships approach and the impact that partnerships can achieve (captured in the Corporate Plan)	Improve our ability to exchange data with partners by adopting international standards; define adoption approach by end Q2; new system full implementation by end Q1, 2023/24
		↓ Identify which flexibilities introduced in response to COVID-19 are safe to embed by end Q2			↓ Agree policy on reliance and recognition to be implemented globally by Q4 2023/34
		Launch consultation on engaging with healthcare professionals by end Q2			Consult on a national GB scheme to replace Falsified Medicines Directive safety features regulation; put legislation before Parliament as per departmental timescales; and agree position on Falsified Medicines Directive for Northern Ireland post 3-year EU derogation, by end 2023 (to be updated given Windsor Framework)
Financial Sustainability	Finalise plan to overhaul outmoded legacy IT systems by end Q1	Consult on a new fee structure	Nothing scheduled in the Delivery Plan, focus on core business	Implement a new fee structure from Q1, 2023/24	Implement organisational design, creating a new, leaner organisational structure and balancing costs by end Q4, 2023/24
					Reduce corporate costs including technology costs by 15% by the end of 2024/25

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Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 2023

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

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

'TOP 10' HEADLINES

- Proposals are being prioritised for using the £10m awarded in the Spring budget to accelerate routes for innovative medical products to patients and will include clinical trials
- We convened a meeting of Heads of Access regulatory agencies (Australia, Canada, Singapore & Switzerland) to take stock of strategic progress including reliance/recognition
- The Coalition for Epidemic Preparedness Innovations is funding key research reagents to improve vaccines, diagnostics & therapeutics against pathogens including SARS-CoV-2
- The Commission on Human Medicines has established an Expert Working Group on cancer vaccines which will advise on the regulatory pathway for this important innovation
- The transition provisions for the new Medical Devices regime have been put into statute and this will protect the supply of medical devices to the healthcare service beyond 2023
- An Interim Devices Working Group has been convened to provide independent expert advice on medical devices safety, pending establishment of the new statutory Committee
- The Commission on Human Medicines Expert Working Group Report on Isotretinoin safety was published recommending strengthened oversight of prescribing in under 18s
- Data from the Clinical Practice Research Datalink has been successfully used to recruit patients to two asthma medication studies in collaboration with Imperial College London
- We contributed to a major cross-sector initiative resulting in blocking or removal of 7000 websites illegally trading in unlicensed medicines into the UK
- The new Fees regulations for medicines, medical devices and blood safety and quality have come into force on 1st April helping maintain the Agency's financial sustainability.

SCIENTIFIC RESEARCH AND INNOVATION

Innovation

1.1 The MHRA was awarded £10m as part of March's Spring Statement, to accelerate routes for bringing innovative medical products developed in the UK onto the market, as well as those made and approved by other trusted regulatory partners globally. Over the next two years this funding will support development of a thorough but shortened process to speed up the approval process for cutting-edge treatments with the greatest promise to meet the UK's healthcare priorities, such as cancer vaccines and AI-based therapeutics for mental ill-health. We are currently prioritising areas for investment, likely to include the Innovation Accelerator Group and clinical trials.

Future vaccines manufacturing research hub

1.2 The Viral Vaccines team (R&D) supported, as proposed project partner, the application of the Future Vaccines Manufacturing Research Hub (Vax-Hub) led by University College London and University of Oxford to the Engineering and Physical Sciences Research Council call for Manufacturing Research Hubs. The outcome was successful with over £10 million granted to the Vax-Hub which will start September 2023 until March 2028. We have been a non-partner collaborator of the Vax-Hub since 2018 when it was created, and we aim to participate more actively in the Vac-Hub funded projects now that we have acquired project partner status. Vaccine and food manufacturing hubs will save lives and cut carbon.

Cancer vaccines

1.3 The Commission on Human Medicines (CHM) has agreed to establish an Expert Working Group to advise on the regulation of cancer vaccines. The Expert Working Group will initially highlight the questions that personalised immunotherapies pose of the existing regulatory system. Ensuring that regulation is proportionate whilst allowing for a high degree of clarity over the safety and efficacy of cancer vaccines is of paramount importance, and once the appropriate regulatory path is determined, there is potential for this to similarly apply to the regulation of other immunotherapies targeting rare diseases. Highly relevant will be the forthcoming legislation on Point-of-Care manufacture.

Mycobacterium tuberculosis standard

1.4 The First WHO International Standard for Mycobacterium tuberculosis (H37Rv) DNA for Nucleic Assay Test-based assays was established in 2021. To promote the use of this standard in a wider scientific community, a scientific manuscript has been published by the R&D Global Diseases team in the biologicals journal: 'The development and establishment of a heat inactivated preparation of Mycobacterium tuberculosis (H37Rv) as the first international standard for nucleic acid amplification techniques'.

Influenza

1.5 Scientists from the R&D Seasonal Influenza Team published one of the major outcomes from a 7-year collaborative project funded by the EU's Innovative Medicines Initiative (IMI concerning standardisation and development of assays for assessment of influenza vaccine correlates of protection. The paper highlights that two different formats of a virus neutralisation assays are not comparable. However, both assays benefitted from inclusion of biological standards which reduced between-laboratory variability. In addition, one of the neutralisation assays was comparable with the classic haemagglutination inhibition assay and thus a conversion factor could possibly be established between these two assays.

Haemophilia A anti-drug antibodies

1.6 An article in the journal 'Blood' regarding reference material for clinical assessment of anti-drug antibodies in haemophilia A has been published by a member of R&D Biotherapeutics. These antibodies can prevent therapies for this disease from working properly. The recombinant antibody, termed NB33, was derived from a patient with FVIII-neutralising antibodies and was used by collaborators at Western Washington University for electron microscopy studies that revealed the immunogenic site bound by the antibody. It is hoped that identifying these sites will enable engineering of the Factor VIII molecules to be less immunogenic and better tolerated. Two further studies are currently under way to map the epitopes of other patient-derived antibodies and to look at the mechanism of action.

Microbiome related biological products

1.7 The Microbiome lead in R&D Diagnostics has been able to make valuable contacts with colleagues involved in the regulatory science and regulation of Microbiome related biological products as a result of presentations at back-to-back meetings in the US and Asia. The trip was funded in part by the Regulators Pioneer Fund.

Research into emerging diseases

1.8 Scientists in R&D Diagnostics and R&D Vaccines attended the Microbiological Society's annual meeting in Birmingham, where they presented 3 oral presentations and 2 posters on topics pertaining to diagnostics, pathogenesis and correlates of immune protection of emerging diseases including SARS-CoV-2, Chikungunya virus, Mpox and Crimean Congo Haemorrhagic Fever virus. A PhD student presented her data on the development of pseudotyped viruses as safe reference materials for high consequence pathogens. Discussions with fellow scientists at the meeting have led to new opportunities for further collaborative science.

Collaboration with National Measurement Institutes in diagnostic assays

1.9 The Head of R&D Diagnostics attended meetings at the International Bureau of Weights and Measures with scientists from National Measurement Institutes (NMIs) world-wide. In a one-day meeting discussions regarding how NMIs can best help in the development of high-quality diagnostic assays in a pandemic situation led to a proposal to run a "fire drill" later this year where the NMI's expertise in measurement would be used to develop national reference measurement materials that harmonise measurement for the emerging pathogen. In a subsequent 2-day meeting the value and limitations of digital PCR for accurate measurement of specific nucleic acid targets in disease, diagnostics and foodstuffs were discussed and ways of harmonising calibration of assays discussed.

CEPI funding

1.10 The R&D Research Reagents Repository has secured further funding from the Coalition for Epidemic Preparedness Innovations (CEPI) for two 12-month scientific positions to support its activities. This financial support will be instrumental in sourcing and supplying scientists globally with a variety of key research reagents (including monoclonal antibodies, recombinant proteins, virus isolates and cell lines) to help develop and improve vaccines, diagnostics and therapeutics against various pathogens, including SARS-CoV-2. Access will be prioritised to support the CEPI Centralised Laboratory network, of which MHRA is a member, which contributes to development of new vaccines against emerging pathogens.

Tuberculosis research funding

1.11 The MHRA is one of the 19 organisations successfully being awarded with the European Commission funding (for the UK partners, funding will be from the UKRI to the R&D Global Diseases team) under the Horizon Europe programme to start working on the TBVAC-HORIZON project in April 2023 with the aim to innovate and diversify the global TB vaccine pipeline. This 4-year project will increase our understanding and develop new tools pertaining to immune protection in the lung, the major site of tuberculosis infection. This knowledge will be exploited to develop mucosal strategies for translating towards clinical evaluation and possible implementation. The interwoven activities will consolidate Europe's leading role in TB vaccine research and innovation, with the ultimate goal of accelerated availability of affordable, accessible and more effective TB vaccines.

Vaccine research award

1.12 A member of the Pandemic Influenza team in Vaccines, R&D, was recently awarded the University of London 150th Anniversary Prize for Academic Achievement and best performance on the Infectious Diseases MSc programme. Sponsored by the MHRA, the MSc was successfully completed with distinction, and included an exciting research project that investigated the use of novel techniques to generate candidate vaccine viruses for Influenza A virus vaccines. As a WHO Essential Regulatory Laboratory for influenza, it is critical to seek out novel interventions to combat the continual evolution of influenza viruses and to ensure vaccines remain effective for the public.

HEALTHCARE ACCESS

Personalised immunotherapy

2.1 The Commission on Human Medicines has agreed to establish an Expert Working Group (EWG) on cancer vaccines, to provide independent scientific advice on this important new type of personalised immunotherapy. The EWG will be considering the distinction between platform technology and personalised product delivery, and how it influences the pathway that is initiated following biopsy of a cancer, to enable sequencing, analysis, antigen/target selection and development of the vaccine.

Innovative medicines

2.2 A new lower-strength oral granule formulation of a combination of lumacaftor and ivacaftor (Orkambi) for the treatment of cystic fibrosis in patients who are homozygous for the F580del mutation in the transmembrane conductance regulator gene, was approved via an ACCESS Consortium work-sharing procedure, involving the MHRA, Health Canada and TGA. The Orkambi indication has been extended to children aged 1 to <2 years of age. Health Canada led on the assessment of quality data and MHRA led on the assessment of clinical data. This month, authorisation was granted to a new active substance: baloxavir marboxil (Xofluza tablets) via the European Commission Decision Reliance Procedure. This product is for the treatment or post-exposure prophylaxis of influenza in individuals aged 12 and over.

Innovative devices

2.3 On 27th April a Statutory Instrument was laid in Parliament to put the transition provisions to the new Medical Device regime on to a formal legal footing, protecting the supply of devices to patients beyond the previous cut off of 30th June 2023. We are now progressing with the laying of an SI to strengthen the rules on Post Market Surveillance which will need to be notified to World Trade Organization (WTO) and draft regulations will be published by the WTO for interested stakeholders to review. We have begun to assemble focus groups to inform guidance requirements for these rules.

Product lifecycle management

2.4 A Task and Finish Group has been established with industry to agree new ways of working to bring current extended timelines for approval of generic medicines back to within the statutory period for determination. We are committed to make regulatory decisions in accordance with statutory timeframes for all fully compliant applications for new national marketing authorisations received from 1 January 2024 and all fully compliant applications for new Type 1b variation applications received from 1 July 2023.

2.5 On 13th April an industry presentation was held sharing best practices, outlining the outputs of the Task and Finish group, and offering an opportunity for questions to be clarified. Metrics detailing performance are now available on the GOV.UK website on the 15th day of each month. New more efficient ways of working include, for example, development of checklists for Industry to improve likelihood of a 'right first time' assessment process. Longer term aspects of this approach include development of training programs and integration of new starters as rapidly as possible, taking into account the approximately 2-year training program requirement for an accredited assessor.

PARTNERSHIPS

Access Consortium

3.1 In November 2022, MHRA took over the Chair of the Access Consortium (the regulatory authorities of Australia, Canada, Singapore, Switzerland and the UK), with our tenure lasting until the end of June 2023. The original Consortium was formed in 2007, with MHRA joining in January 2021. Being part of the Consortium has resulted in a number of successful medicines approvals. For example, the New Active Substance Work Sharing Initiative (NASWSI) allows the joint review of innovative medicines and the MHRA has now approved three procedures through the NASWSI, all of which have concluded prior to the equivalent EMA Centralised Procedure. The most recent approval was for Lumacaftor/Ivacaftor to treat cystic fibrosis (see above). We are keen to promote Access as an attractive option to industry, demonstrating to patients and the international audience, the value of successful work sharing between trusted regulatory partners.

3.2 We have recently published our intent as a consortium to hold pipeline discussions with industry to promote an increase in expressions of interest across all our work sharing initiatives, and we are hosting an Access Consortium session at the DIA global summit in June 2023. The session at DIA, titled "Access Consortium – What next?" will see guest speakers present on a variety of topics related to Access, as well as an interactive panel Q&A.

Clinical trials legislation

3.3 On 21 March the government published its response to the UK Consultation on legislative proposals for clinical trials, which represents the biggest overhaul of the legislation in over 20 years and will help to make the UK one of the best countries in the world to conduct clinical research for patients and researchers. The key outcomes are: (a) clinical trials processes will be more proportionate, streamlined and flexible without compromising on safety, (b) a regulatory framework that is responsive to different types of trials and innovative designs, and (c) transparency will be improved with a requirement to register the trial in a WHO public register, to publish a summary of results, and to share trial findings with participants.

Health service alignment

3.4 The national partnerships team is progressing efforts to promote system alignment between the health system partners and is supporting the creation of working groups looking at horizon scanning for medicines and medical devices, patient pathways and information sharing. The aim of these group is to promote collaboration on our shared objective to improve the health of the UK population.

PATIENT SAFETY

Report of the Commission on Human Medicines' Isotretinoin Expert Working Group

4.1 The Report of the Commission on Human Medicines' Isotretinoin Expert Working Group was published on 26th April 2023 with a number of recommendations to strengthen the safe use of isotretinoin, a medicine for the treatment of severe acne. The report includes recommendations to have strengthened oversight of the use of isotretinoin in people under 18 to ensure it is only used for severe acne when other standard treatments have been sufficiently tried and not worked The Report recommends improved safety information for patients so that they can make better informed decisions about their treatment, and consistent monitoring for potential mental health and sexual side effects in all patients throughout treatment.

4.2 The CHM has formed an Implementation Advisory Group to advise on how best to introduce the new measures into clinical practice with further communications and guidance to be published in due course. Alongside the main report, we also published a plain English summary of the recommendations and an article in Drug Safety Update. Two briefing sessions were held to inform patients (38 attendees) and healthcare professionals (91 attendees) of the recommendations just prior to publication. The briefing panel was the Chair of CHM, Chair of the Expert Working Group and the MHRA's Chief Safety Officer.

Criminal Enforcement Unit

4.3 April saw the culmination of a programme of operational collaboration between the Criminal Enforcement Unit (CEU) and cross-sector partners. The joint initiative resulted in the blocking or removal of more than 7000 websites illegally trading in unlicensed medicines into the UK. As part of the CEU's criminal justice work, two defendants were requisitioned to appear at Westminster Magistrates Court for offences relating to the unlawful importation and distribution of medicines of a variety of medicines. Both defendants were sent to Southwark Crown Court for a pre-trial hearing. In a separate case, an asset confiscation hearing took place at York Crown Court following the conviction of a defendant in May 2022 for the illegal supply of medicines including Diazepam, Zopiclone and Nitrazepam.

CPRD asthma studies

4.4 Since September 2022, CPRD has been working with Imperial College London on two related Asthma studies: 'StepDown Feasibility' and 'StepDown Views'. These are patient questionnaire-based studies to examine patient views and experiences on stepping down asthma treatment dose, as around 80-90% of the benefits from inhaled steroids are achieved using a low dose, and Asthma guidelines recommend that medication should be used at the lowest dose that maintains good asthma control.

4.5 The CPRD has been used to recruit targeted patients into these studies. Stepdown Feasibility involved participation from 26 of 50 invited practices which reviewed 859 patients, of which 15.7% of those invited enrolled in the study. The study target of 60 patients was reached in 12 weeks. Stepdown Views involved participation from 13 of 42 invited practices which reviewed 1240 patients of which 1121 were invited onto the study. The study is ongoing with 142 patients enrolled (12.7% of those invited), with a target of 153 patients. Of the enrolled patients, 89 have agreed to participate in a subsequent interview. Using CPRD, the study has recruited to 93% of target in 13 weeks.

4.6 These studies use the core model for CPRD clinical study recruitment which involves interrogation of the primary care data to find patients suitable for a specific study, and engagement with General Practitioners to reach out to patients and invite them to take part in studies. This process is also central to recruitment into clinical trials such as the NIHR funded academic data enabled clinical trial DaRe2THINK and the CPRD SPRINT service recruiting patients into commercial clinical trials. These results demonstrate the potential of this approach which we expect to be able to bring on for further trials and SPRINT contracts.

Increased reporting requirements for devices

4.7 In response to device manufacturer feedback about the time needed for their change management activities to implement new database-to-database transmissions for incident reports, we have extended the deadline for implementation by four months, to the end of August 2023. We will continue to support manufacturers during this time to assist in any questions they have about the new systems, after which time full transition either to web reporting or database-to-database transmissions will be required.

Interim Devices Working Group

4.8 The Interim Devices Working Group (IDWG) has been established to provide independent expert advice to the MHRA on the safety of medical devices pending the development of the Statutory Committee that was made possible through the powers provided in Medicines and Medical Devices Act (MMDA). The IDWG Chair, Professor Tom Clutton-Brock, chaired the first meeting on 19 April. The meeting attendees comprised Safety and Surveillance Assessors, Devices Compliance Inspectors, Committee Members, Invited Experts and Observers including NHS England and the Devolved Administrations.

DYNAMIC ORGANISATION

Business Plan

5.1 Now that work on the Corporate Plan 2023/26 is complete, the One Agency Leadership Group held a meeting to discuss and agree ‘SMART’ objectives for the first year’s actions of the Business Plan 2023-24. The Business Plan will follow a similar structure of maintaining trust, enabling predictable healthcare access, scientific and regulatory excellence through strategic partnerships and flourishing careers for our staff, alongside responsive customer service.

Upcoming BSI audit

5.2 The Agency's ISO 9001 BSI audit is scheduled for 26th June to 3rd July. The Auditor will be assessing activities within the operational and support Groups for evidence of compliance to the requirements of the Standard looking at policies and procedures for accuracy and control, records management, effective internal audit, management review and improvements. They will also be interested in evidence of effective documented change management particularly around the restructuring and planning activities under the new structure. Senior management are to ensure that policies and procedures are up to date and accurate, records are complete and retrievable, internal audits are undertaken and issues addressed, management review documents are in place, evidence of improvements is recorded, and plans are in place to document and manage the changes that have been undertaken with future plans proposed.

FINANCIAL SUSTAINABILITY

Fees changes

6.1 Both the Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 statutory instrument and the Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023 have come into force on 1st April 2023. All applications and orders that come in from that date will be charged the new fees. All applications and orders received prior to that will be charged at the previous rates. This is the first time for a number of years that the Agency's statutory fees have been amended, and the changes will be important in achieving a sustainable funding model.

AGENCY PRIORITIES

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

i. Finalise discussions on the use of the £10m additional funding to establish a streamlined innovation pathway for healthcare products to reach patients

ii. Progress our programme of legislative reform to realise the benefits of EU Exit and make UK an attractive place to develop and deploy medical products

iii. Continue to design and implement the redesigned services for established medicines, clinical trials and compliance, so that our performance is efficient and effective

iv. Ensure we address new and emerging patient safety issues swiftly and proportionately, involving patients and the public in regulatory decision-making

v. Maximise our opportunity as Chair of the international Access Consortium, to build agreement on an innovation pathway and international recognition.

Dr June Raine, CEO
May 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 2023

Title	What was the operational performance for the MHRA for the year up to 31 March 2023?
Board Sponsor	Rose Braithwaite
Purpose of Paper	Assurance

What was the operational performance for the MHRA for the year up to 31 March 2023?

1. Executive Summary

1.1 The attached report shows MHRA's Key Performance Indicators in the fourth quarter (Q4) of 2022/23 and where available data from previous quarters.

2. Performance of the Agency

2.1. There are a number of metrics that are showing good or improved performance in the final quarter of the year.

2.2. The customer experience centre (CEC) (slide 5) has reduced the average time to close a query to 3 days, and 2 days within the CEC, despite the volume of queries remaining very high. This is from a high of 11 and 8 days just 6 months ago.

2.3. The Clinical Practice Research Datalink (CPRD) (slides 16 – 18) have achieved all 3 of their key targets for the year of over 27% population coverage, over 10% of GPs providing data in each region and the number of new research applications.

2.4. People data (slide 19) shows that vacancies are down which will benefit the whole agency. This is helped by a reduction in turnover of staff from 23% in Q1 to a now acceptable 14% in Q4.

2.5. Long-term debt (slide 22) has come down quarter on quarter improving agency liquidity and reducing financial risk.

2.6. Some metrics show areas where further work is needed to drive improved performance.

2.7. Complaints (slide 5) increased significantly in Q4 to 423, from 159 in Q3. The reporting of complaints changed in January 2023 to capture all complaints which the Customers Experience Centre (CEC) receives. Previously it was mostly administrative complaints that were reported on. This recent change means we are ensuring all non-administrative complaints received in CEC are correctly captured and reported on. 40% of all non-administrative complaints received by CEC have come from industry, primarily relating to the increase in assessment timeframes. We expect to see this volume reduce over the coming months as work is underway to clear the backlogs across key groups. CEC has also supported the efficient handling of these types of complaints by issuing standard lines, providing timelines where possible and signposting to the newly available published metrics. It is important to note that not all Agency complaints are captured in this report, work is underway to explore how best we capture and report on all data from all groups.

2.8. The total number of clinical trial applications assessed (slide 6) in the financial year was 160 less than the same period last year (ie 847 for 2022 compared to 687 for 2023). The timeline for assessment performance is above target and HVT studies are still being prioritised, but the internal target of 14 days cannot currently be met. Discussions on current performance have taken place to review the process and a new way of working is currently being implemented. As well as recruiting and training new staff discussions on current performance have taken place to review the process and a new way of working is currently being implemented to improve performance.

2.9. Scientific Publications (slide 8) were very low for Q4 and are expected to remain low in the near future due to the staffing changes in the teams.

2.10. Elapsed time for Established Medicines (slide 10) has been increasing and during February the top of the range of time taken to complete rose to over 1,300 days, as older applications are addressed. This is to be expected on a more regular basis as we work to close down long-term applications, some which have been in process for a number of years. The data for variations relates to the whole agency performance on these post marketing applications undertaken in both Healthcare Quality & Access (HQ&A) and Safety & Surveillance (S&S). We remain confident that we can deliver the improvements in variation and national performance committed to in the recent letter to industry for both applications and management of ongoing production and supply. Internal data are showing that time to first Request For Information (RFI) for April is down however the variance on the data is large, so it is too early to take this as a trend indicating improvement.

3. Recommendation

4.1 The Board is asked to review the report on the MHRA's performance.

Rose Braithwaite
May 2023

Medicines & Healthcare products Regulatory Agency

MHRA Performance Report

Operational Performance
Quarter 4, 2022/23

Finance Division

April 2023

OFFICIAL-SENSITIVE

Summary – Top Key Performance Indicators

Science, Research and Innovation

1. Clinical trial applications assessed (slide 6)
   Q4 = 116, Q3 = 159, Q2 = 204
2. Q4 IP approvals through ILAP SG (slide 8)
   Q4 = 24, Q3 = 10
3. Q4 IP refusals (slide 8)
   Q4 = 2, Q3 = 1
4. Diagnostic standards (slide 8)
   Q4 = 5,987 shipped and 143 customers,
   Q3 = 6,662 shipped and 127 customers
5. Number of TDPs granted (slide 8)
   Q4 = 1

Healthcare, Quality and Access

1. New licences (slide 10)
   Q4 = 9
2. Established medicines number of abridged complex determined (slide 12)
   Q4 = 1,289
3. CT site inspections (slide 14)
   Q10 (Q2 9, Q3 12)), **2** (Q2 1, Q3 2)) referral for critical findings**.**
4. Supply chain site inspections (slide 14)
   126 (Q3 126), **8** (Q3 13) referrals for critical findings.

Safety and Surveillance

1. Public assessment reports (slide 3)
   Q4 = 84, Q3 = 58, Q2 = 92
2. Safety signals identified for further assessment (slide 15)
   Q4 = 23, Q3 = 30
3. Safety variations assessed (slide 15)
   Q4 = 372
4. Actions taken to minimise risk to patients (slide 15)
   Q4 = 38, Q3 = 32, Q2 = 29, Q1 = 31
5. CPRD all regions now above GP coverage target (slide 18)

Corporate

1. Financial surplus (slide 28)
   £5.7m
2. Voluntary turnover (slide 20)
   Q4 = 14%, Q3 = 16.3%, Q2 = 16.7%, Q1 = 23%
3. Incidents and accidents (slide 21)
   Q4 = 15, Q3 = 14, Q2 = 9, Q1 = 3

Enablement

1. CEC queries (slide 5)
   Q4 = 18k, Q3 = 17k, Q2 = 16k
2. Complaints (slide 5)
   Q4 = 423, Q3 = 159, Q2 = 124

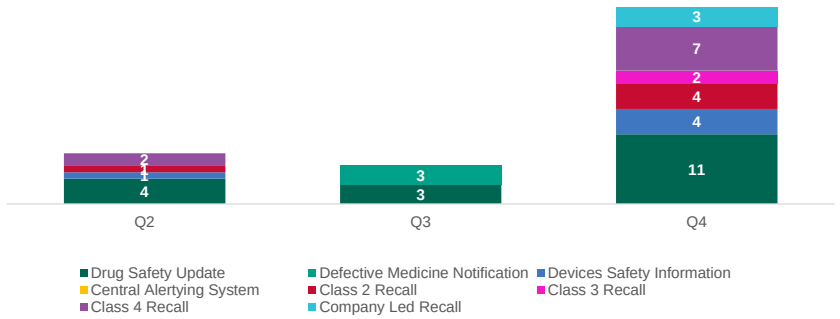
Digital and Technology

1. Security score (slide 26)
   60.18

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

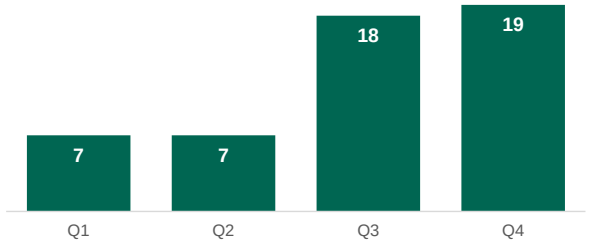
Q4 Communication to Healthcare Professionals



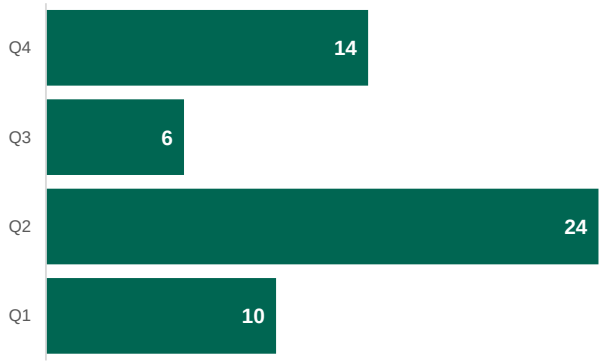
Patient Engagement Training Completed by Staff

The training launched 25 October 2022 and all staff needed to complete this by end of March 2023. 1,048 activated accounts of a total staff population of 1,149. Of these 868 have successfully completed the training which represents 76% of the agency.

Internal requests for patient engagement activities



Scientific Papers Published



Reputational Index From Q4

Reputation research is being conducted using a consumer omnibus tracker, customer survey and stakeholder interviews. Target date for initial debrief is mid-May 2023.

Public Assessment Reports

- 0 PARs on self-mediation reclass procedures – 1 in Q3
- 0 on safety – 3 in Q3

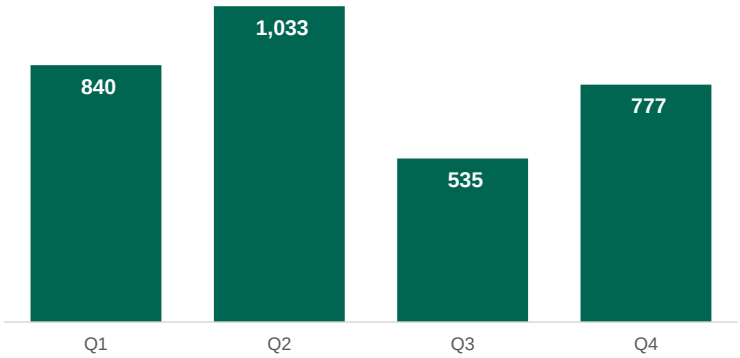
PARs published for new marketing authorisation – *(Target is 60 calendar days from licence grant, plus any clock off time)*

- Q2 - 92 (78; 85% completed on time)
- Q3 - 58 (33; 57% completed on time)
- Q4 – 84 (56; 67% completed on time)

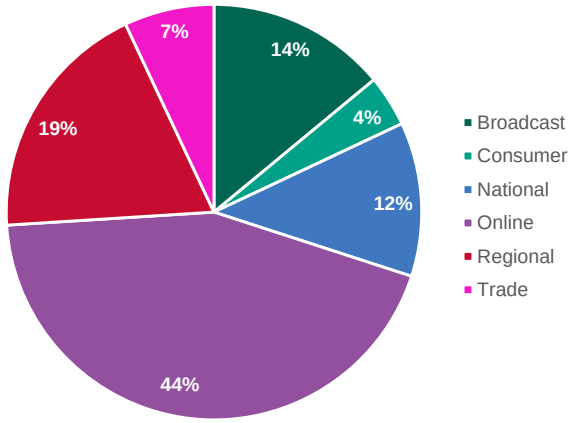
Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

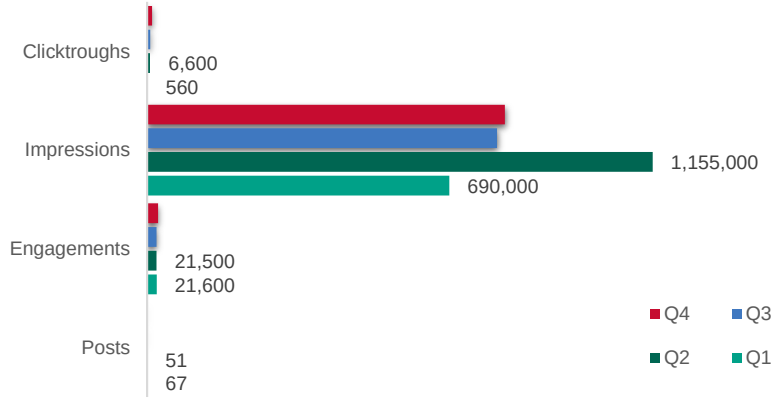
Media Article Mentions



Q4 Articles by Media Type



Social Media Reach – by quarter



This reporting period MHRA generated 777 mentions, representing a quarter-on-quarter increase of 45%. 49% of the articles were strongly favourable and 51% were slightly favourable towards MHRA. The most prominent mentions driving coverage for Q1 included reports that the new drug CADD522 bring a "*new hope*" for children with bone cancer. *The Independent* and *The Evening Standard* reported that following the results of the toxicology assessment, the team intends to approach the MHRA for approval to start clinical trials. Elsewhere, outlets reported prominently on the recall of 20 popular cough medicines following concerns surrounding allergies. Major high-readership outlets such as the *Daily Mail* reported on the decision made by the MHRA to remove popular cold and flu remedies from the shelves, the outlet noted that the removal was taken "*as a precaution following a review*" with outlets reporting that the "*Medicines and Healthcare products Regulatory Agency (MHRA), which polices the safety of drugs used in Britain, was behind the review announced today*" (*MSN*). Covid-19 vaccines continued to be a prominent driver of coverage as MP Andrew Bridgen continued to make headlines following a speech in which the Conservative MP labelled the Covid-19 vaccination as having *"robust data of significant harms and little ongoing benefit*". In response high-reach outlet *BBC News* notes that the "*MHRA said the fact that more people were reporting to the scheme was expected, given the scale of the Covid-19 vaccination programme, and publicity in the context of the pandemic, rather than indicating a real rise in side effects*".

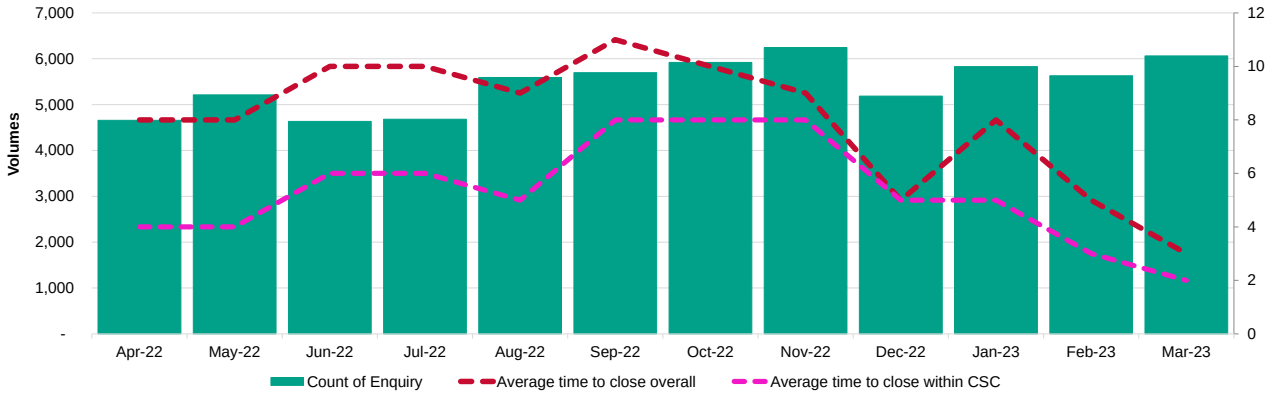
Dame June Raine became the most prolific spokesperson for the quarter, featuring in 38 articles as outlets reported on the MHRA Chief Executive's previous remarks concerning the Covid-19 vaccines international partnerships; "*we have been able to authorise the supply of this vaccine using provisions under European law*". The quote is in response to former Prime Minister Boris Johnson's remarks regarding the role of the MHRA in the process of vaccine rollout, the politician insisted "*rollout was as rapid as it was because 'we'd taken back control' of the Medical Health Regulation Agency (MHRA)" (The Independent).*

Reporting for the quarter was favourable as outlets reported that Celadon had managed to "*clear regulatory hurdle*" to become the first company in the UK to legally manufacture medical cannabis, *The Evening Standard* noted that *"Celadon Pharmaceuticals was granted a Good Manufacturing Practice or GMP registration by the UK Medicines and Healthcare products Regulatory Agency (MHRA) to produce medical cannabis that's high in Tetrahydrocannabinol*"". The results follows new MHRA issued guidance for cannabis companies to obtain licenses into make products on UK soil, which include site inspections and Home Office clearance (*MSN*).

Patients, Public, Partners and Customers

Delivery Plan Priority – Patient and Public Involvement

Customer Experience Centre – Queries per Month

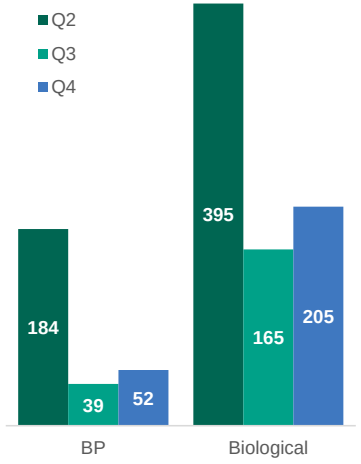


Count of enquiry refers to any telephone call, email or letter received at the Customer Experience Centre, including Freedom of Information requests and complaints.

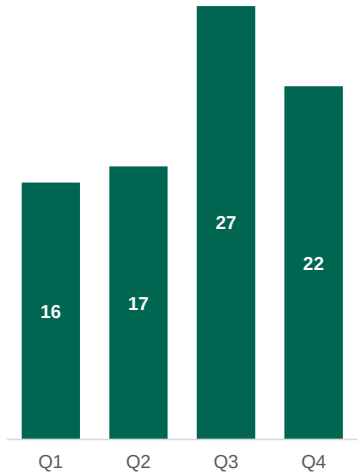
Updates to enquiry volumes and average time to close data from Oct-Feb to reflect ongoing work to reduce query backlogs and close off older queries. Due to this activity, average time to close peaked in Q3 with a reduction in response times seen in Q4.

Application status requests from Industry and Research & Academia continued to be a common theme during Q4. CEC have been responding using standard lines and working with key groups to support the handling of these.

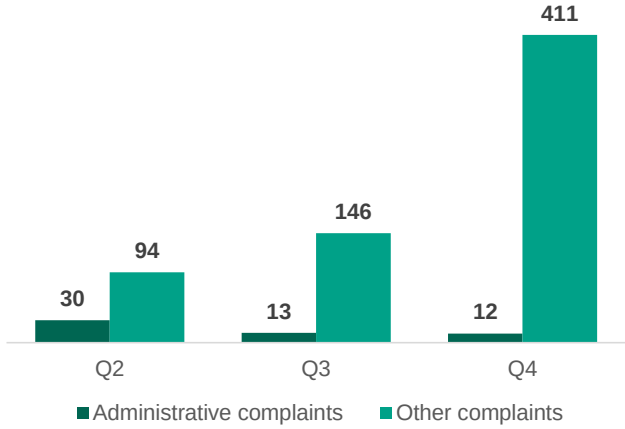
New Customers - Standards



Parliamentary Questions Received



Complaints

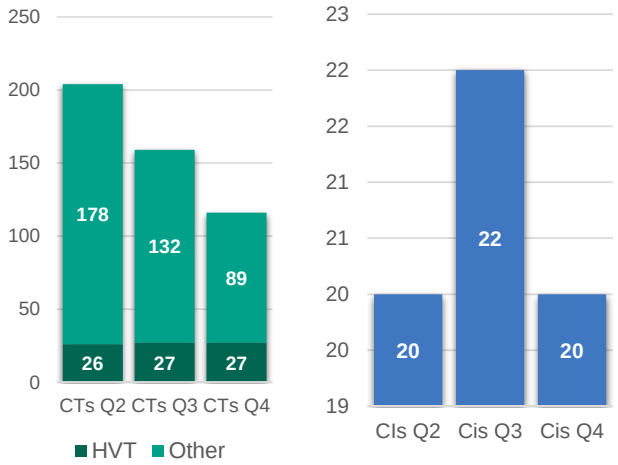


Rise in Q4 complaints with assessment timeframes remaining a common theme, improved categorisation and logging of complaint themes across CEC has also contributed to the rise.

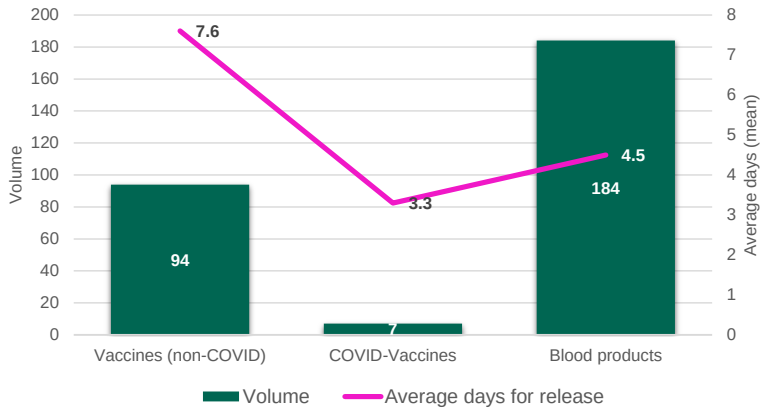
Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

Clinical Trials & Clinical Investigations Volumes



Q4 Control Testing Batch Releases Volume and Time



95% of vaccine batches certified within 43 days

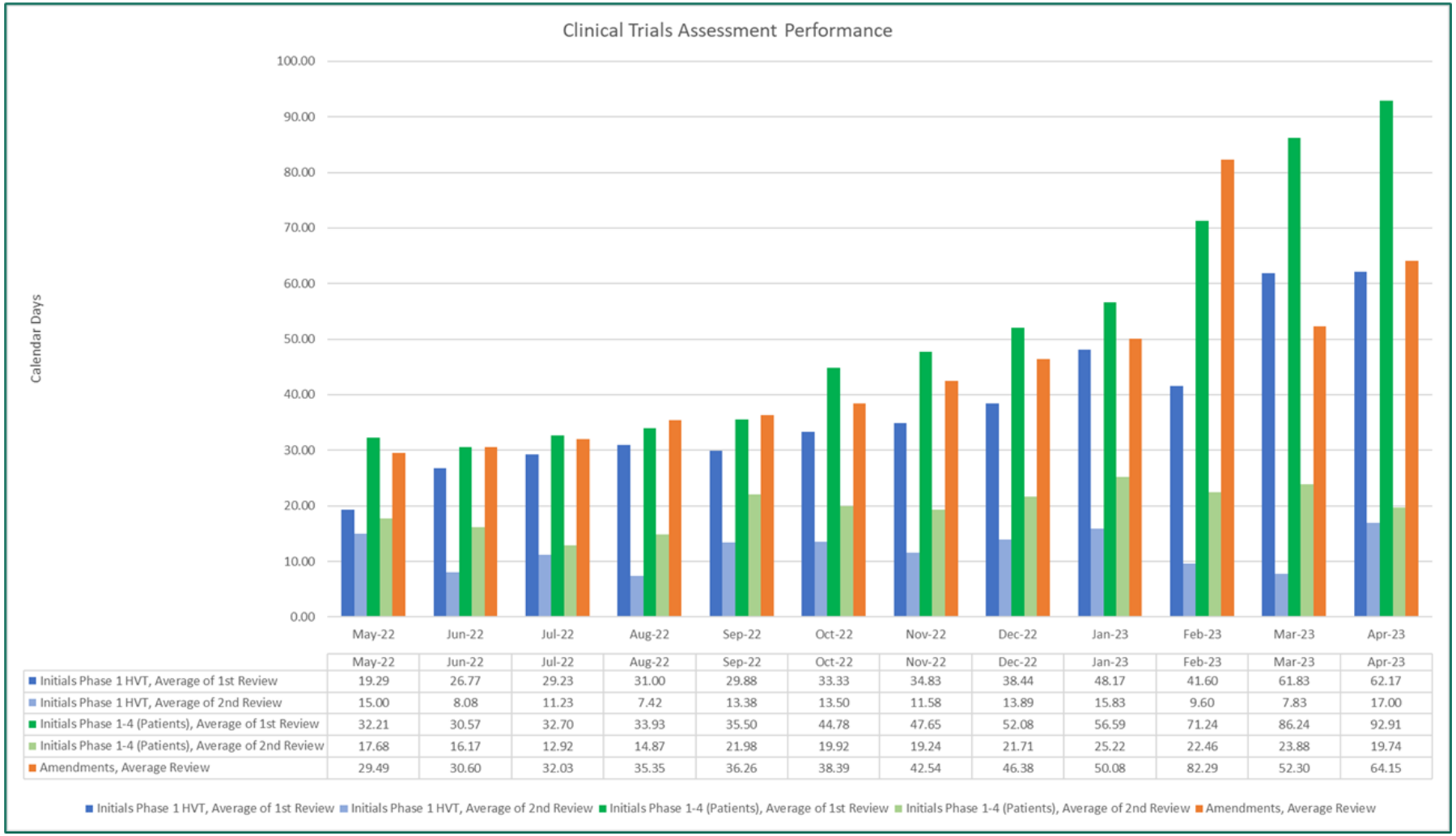
99% of blood product batches certified within 15 days

The total number of clinical trial applications assessed in the financial year is 160 less than the same period last year (847 for 2022 compared to 687 for 2023). The timeline for assessment performance is above target and HVT studies are still being prioritised, but the internal target of 14 days cannot currently be met. Details of the delivery timelines are on the following slide. As well as recruitment and training of new staff members discussions on current performance have taken place to review the process and a new way of working is currently being implemented.

Clinical Investigation assessment performance remains well within target (60 days). The total number of clinical investigation applications is 12 more compared to the same period last year (73 in 2022 compared to 85 in 2023).

Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation



	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23
Initials Phase 1 HVT, Average of 1st Review	19.29	26.77	29.23	31.00	29.88	33.33	34.83	38.44	48.17	41.60	61.83	62.17
Initials Phase 1 HVT, Average of 2nd Review	15.00	8.08	11.23	7.42	13.38	13.50	11.58	13.89	15.83	9.60	7.83	17.00
Initials Phase 1-4 (Patients), Average of 1st Review	32.21	30.57	32.70	33.93	35.50	44.78	47.65	52.08	56.59	71.24	86.24	92.91
Initials Phase 1-4 (Patients), Average of 2nd Review	17.68	16.17	12.92	14.87	21.98	19.92	19.24	21.71	25.22	22.46	23.88	19.74
Amendments, Average Review	29.49	30.60	32.03	35.35	36.26	38.39	42.54	46.38	50.08	82.29	52.30	64.15

Initials Phase 1 HVT, Average of 1st Review | Initials Phase 1 HVT, Average of 2nd Review | Initials Phase 1-4 (Patients), Average of 1st Review | Initials Phase 1-4 (Patients), Average of 2nd Review | Amendments, Average Review

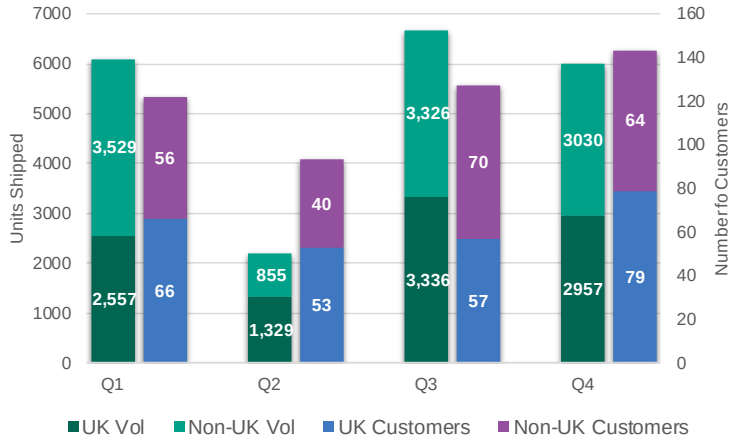
The graph shows the average time taken for MHRA assessment of clinical trial applications, divided into the following categories: initial clinical trial authorisation (CTA) applications for Phase 1 healthy volunteer trials (HVT); initial CTA applications for Phase 1–4 patient trials; and substantial amendments. Since December 2021, applicants have had the flexibility to request additional time to respond to grounds for non-acceptance (GNA); therefore, the data are further categorised into: 'first review' – time from receipt of valid CTA application to initial opinion letter; and 'second review' – time from receipt of GNA response to final opinion. The monthly average for each category represents clinical trials for which the final opinion letter was issued in that month (ie outright approval, approval with conditions, or approval of amended request further to a GNA response).

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

Q4 IP applications – **12** (23 in Q3)

Q4 IP MHRA review meetings – **16** (25 in Q3)

Q4 IP approvals through the ILAP steering group – **24** (10 in Q3)

Q4 IP refusals - **2** (1 in Q3)

Innovation Passport applications appear to be reaching a steady state of around 4-5 per month. All IP designations are now delivered through the innovation Accelerator and SRI group.

There is a growing backlog of TDP designation requests to fulfil.

The ongoing ILAP Refresh programme is delivering a new governance structure and proposed changes to the ILAP offer.

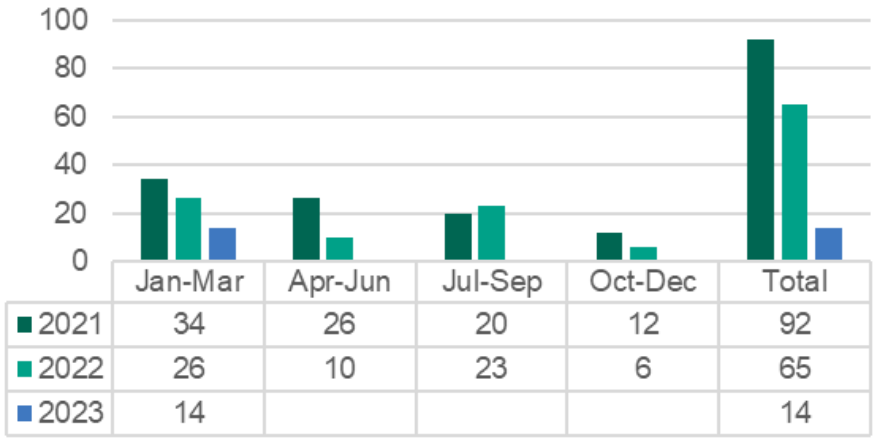
Performance – Science, Research & Innovation Group

Delivery Plan Priority – Scientific Innovation

Grants and research contracts progress

	Quarter 1 Apr-Jun 22	Quarter 2 Jul-Sep	Quarter 3 Oct-Dec	Quarter 4 Jan-Mar	Total 22/23
Grants applied for since April 2022					35
Successful	4	4	5	2	15
Pending - ongoing	1	0	4	1	6
Unsuccessful	5	3	3	1	12
Closed as not going ahead	0	2	0	0	2
Win Rate (%)					42.86

Communicating our science and its impact: Scientific publications



	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Total
2021	34	26	20	12	92
2022	26	10	23	6	65
2023	14				14

The 2022 calendar year yielded approximately 70% of the target number and there is a lower number for the Jan-Mar 23 period. This is not unexpected given the staffing changes experienced across the teams. Similarly, the submissions of papers for publication have approximately halved from the previous year thus the lower trend in publications may continue for the coming quarters. 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.

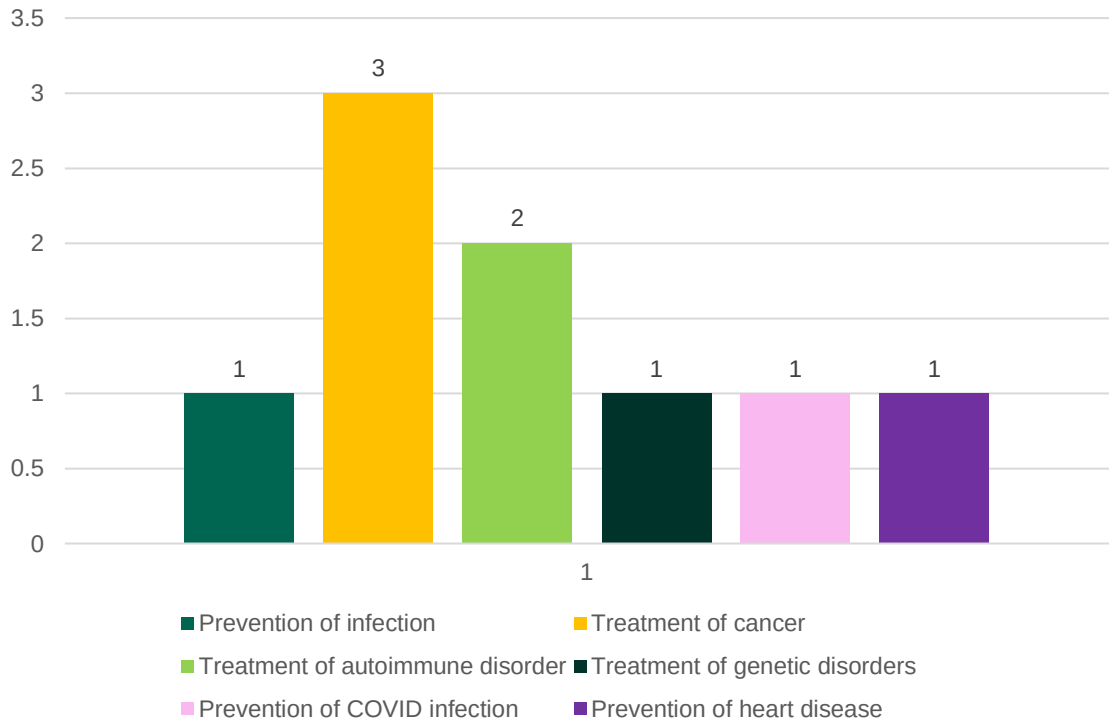
Publications include

- Sensitive detection methods for poliovirus
- Use of the SARS-CoV-2 reference materials for assess vaccination induced antibodies
- Methods for production of stable peptide standards
- Review on progress with vaccines against Group A streptococcus
- Generation of Trastuzumab conjugates for induction of anti-tumour immunity

Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

New Licences – Q4 New Active Substances (NAS)



NAS resulting from ORBIS & ACCESS during March Q4 (none approved Jan/Feb 23)

Product	Active substance	Submission	Proposed Indication
Tabrecta	CAPMATINIB DIHYDROCHLORIDE MONOHYDRATE	ORBIS	Tabrecta, as monotherapy, is indicated for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) with a MET exon 14 skipping mutation

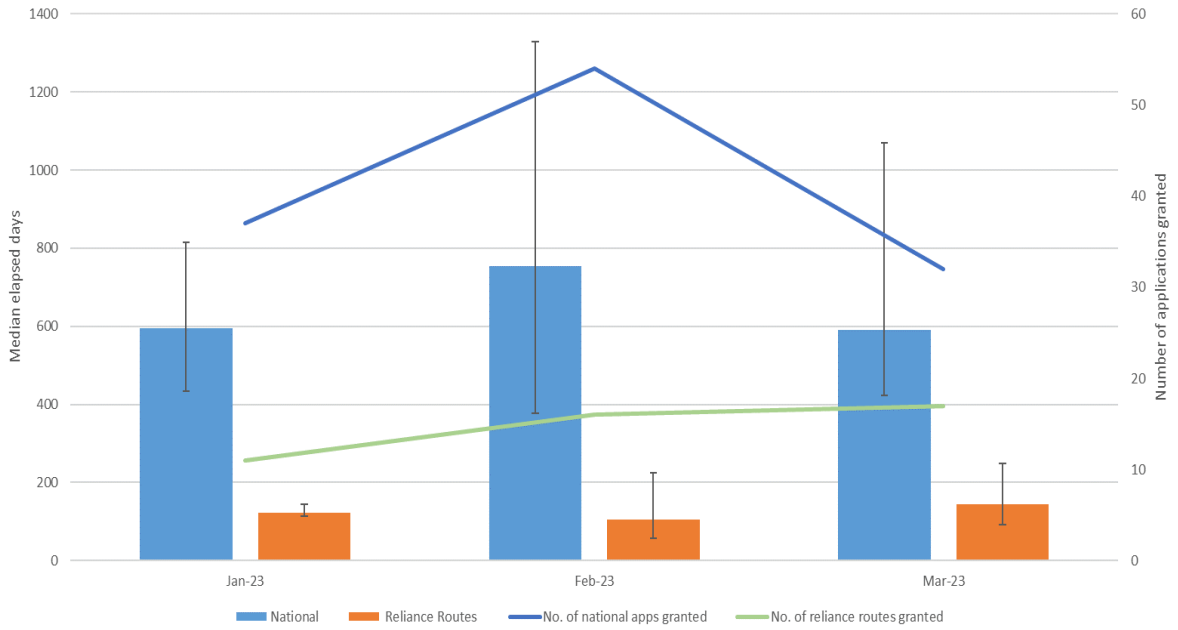
In Q4, 9 new licenses were granted. Of these, 8 medicines are for non-COVID indications across a range of therapeutic areas including treatment of cancer and autoimmune disorders. Two licences were granted following national applications, one medicine for treatment of cancer (Project Orbis) and one medicine (radionucleotide) for the diagnosis of heart disease. In addition, one negative scientific opinion was issued under the Early Access to Medicines Scheme.

Whilst total elapsed time is not entirely in the MHRA's control, it is a vital measure for patients as it represents how long they are waiting for new treatments. Work is ongoing to reduce total elapsed time by limiting rounds of Request for further information (RFIs), ensuring only decision-relevant questions are raised, and streamlining processes. RMS will also improve this.

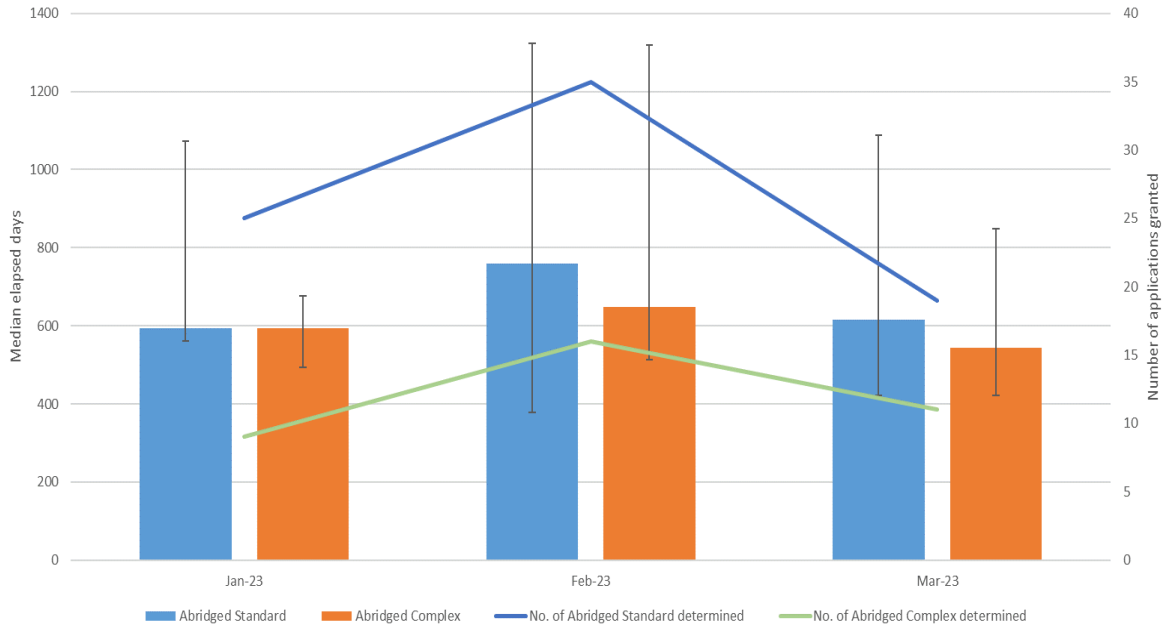
Performance – Healthcare, Quality & Access Group

Delivery Plan Priority – Healthcare Access

Established Medicine Initials – Median days elapsed to determination with 10% to 90% interpercentile range includes number of applications determined



Established Medicine – Standard/Complex initial national applications – median days elapsed to determination with 10% to 90% interpercentile range and number of applications determined

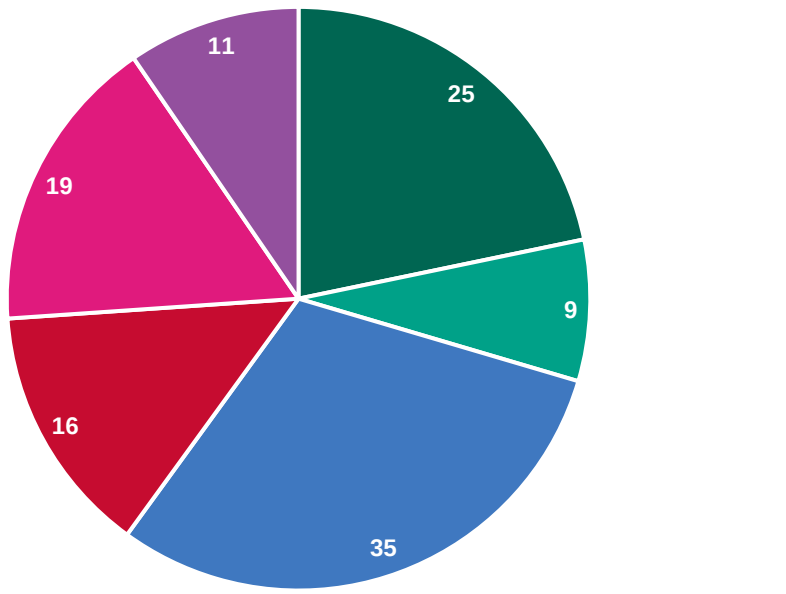


Focus on clearing applications through activities generated in the Task and Finish Group. First actions which are driving change over the period agreed with ExCo at the end of the period. Communicated broadly with Industry 13th April 2023, further actions under review.
Processing times will vary and 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 January to March 2023 (Q4)



abridged standard January
abridged complex January
abridged standard February
abridged complex February
abridged standard March
abridged complex March

Parallel Import Licence Applications granted - January to March 2023

Measure	January 2023	February 2023	March 2023
Initial Parallel Import Applications received	49	61	49
Initial Parallel Import Licences granted	27	33	58
Minimum time to grant (months)	4.3	4.2	1.6
Median time to grant (months)	10.9	11.3	11.5
Time to start assessment (months)	9.5	8.4	9.9
Variations received	610	595	997
Variations granted	923	701	526
Time to grant leaflets (months)	3.1	3.8	3.0
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 granted has continued in March and will continued 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

Standards and Compliance

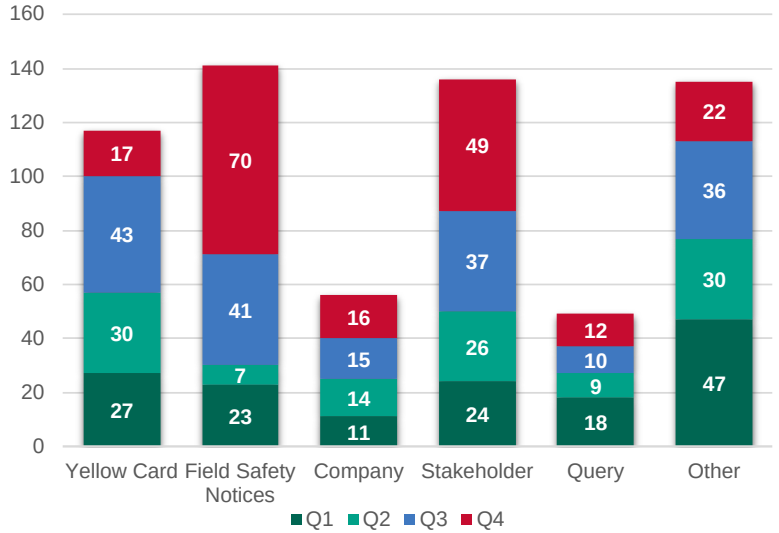
Nature of activity	How does this improve compliance?	Q4 Performance
Initial reviews of new Approved Bodies.	Ensures bodies approved to undertake assessments of conformity against regulations for Medical Devices used in the UK meet required standards	1 new applications received in Q4. 5 initial reviews undertaken since Q1, 75% completed within 2 weeks - target 90%
Designation of new approved bodies.		7 open applications for designation We are expecting 2 further organisations to submit in the coming months
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 19,013 (Q2 17,298 Q3 18,134) Unique Page Views 26,178 (Q2 24,184 Q3 28,672,
GXP Guide Sales		Orange Guide – 2022-2023 Financial Year. £211,024, of which £73,857 royalty received from Pharmaceutical Press (PP) Green Guide – 2022-2023 Financial Year £114,282, of which £39,998 royalty received from PP
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.	10 (Q2 9, Q3 12)) Clinical Trial sites inspected. 2 (Q2 1, Q3 2)) referral for critical findings. 16 (Q2 22, Q3 17) Laboratories (GLP/GCP/GMPQC) Inspected, 1 (Q2 2, Q3 1) referrals for critical findings. 4 (Q2 4), Q3 7) Pharmacovigilance (safety monitoring) systems inspected. 2 (Q2 2, Q3 1) referrals for critical findings. 39 (Q3 71) Manufacturers Premises Inspected, 6 (Q3 5) referrals for critical findings. 126 (Q3 126) Supply Chain sites inspected. 8 (Q3 13) 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 (Q4) = £2,100,935 [Δ 15% vs same period last year (£1,818,262)] Total revenue (YTD) = £7,774,356 [Δ 8% on same period last year (£7,178,471)]

Performance – Safety & Surveillance

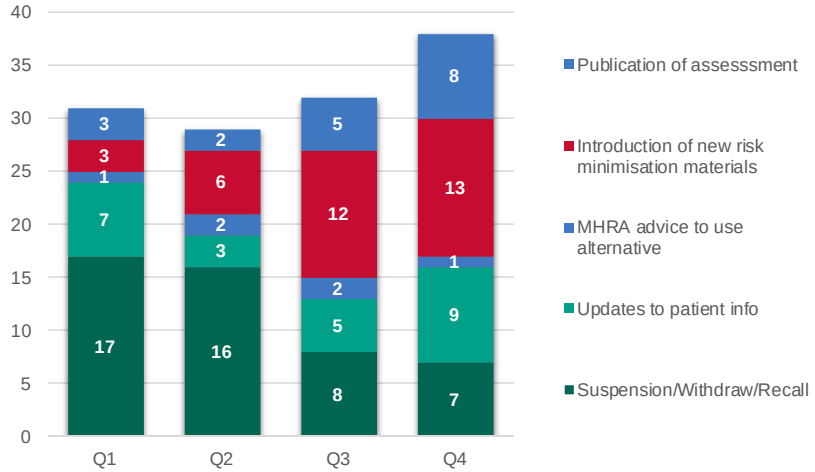
Delivery Plan Priority – Patient Safety

Yellow Card – Q4 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: 23,902 - 26,941 in Q4.
- Established substances**:** 47,893 - 53,859 in Q4

The total number of new safety signals identified for further assessment* **23 –** 30 in Q4

Yellow card seasonal variation in reporting volumes is to be expected. Q3 covers the period in which the Autumn booster vaccination campaign began so reporting for the COVID-19 vaccines is expected to be higher than in Q4.

Variations Q4	National	Reliance	CMS
Received	156	91	67
Assessed	155	90	127
Completed	174	101	223
% Assessed within Agency target time	40%	59%	38%

During Q4 more variations were assessed than received, reducing the current backlog.

Performance – Safety & Surveillance

Delivery Plan Priority – Patient Safety

Assessed threat reduction impact	Quarter 1	Quarter 2	Quarter 3	Quarter 4
MAJOR	2	0	0	1
MODERATE	6	6	2	6
MINOR	309	280	250	257
TOTAL	317	286	252	264

The number and distribution of threat reduction interventions increased from Q3 with major and moderate impact interventions returning to the baseline set in Q1 and Q2. The unit's delivery of TRIs continued to be impacted by the need to onboard new recruits and upskill new and existing staff. With almost all vacancies now filled, the focus in the first half of 2023/24 will be on consolidating the unit's new operating model to strengthening the flow of new and impactful TRIs.

A Threat Reduction Intervention (TRI) is recorded when activity led, supported or coordinated by the CEU is assessed to have disrupted or degraded an identified criminal threat. The intervention will have reduced or removed the means, motivation and opportunity (MMO) to offend. TRIs can occur at an operational level (e.g. the seizure of illegally traded medicines) and at a strategic level (agreement reached with an internet search engine to adjust their search algorithms to remove links to illegal websites).

To arrive at the impact score for a completed TRI, its immediate effect on the MMO is considered alongside the likely duration of that effect. A MAJOR TRI is recorded, for example, where the MMO is assessed to have been reduced significantly (>60%) for the long term (>12 months). The initial impact score for each TRI is moderated by an independently chaired panel prior to submission to the corporate dashboard.

The assessed and moderated impact TRIs is considered a reasonable proxy for criminal threat reduction

CPRD01: Percentage of UK population coverage of CPRD

CPRD's coverage of the UK population is:

27.8%

Completeness of CPRD data coverage

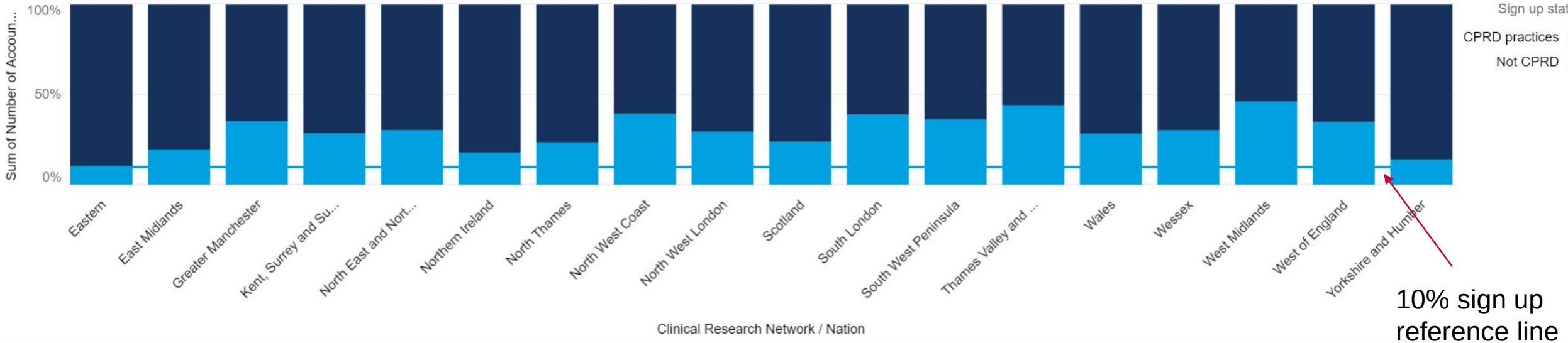
CPRD Aurum Nov 2022 Current Acceptable patients 15,713,221
+ CPRD GOLD Jan 2023 Current Acceptable patients 2,965,915
ONS estimates of UK population Jun 2021 67,081,000

This measures CPRD's reach and is one of the factors contributing to representativeness of the data.

Target by end of FY22/23 Q4: 27%

CPRD has exceeded Q4 target

CPRD02: Percentage of GP practices contributing to CPRD in each region



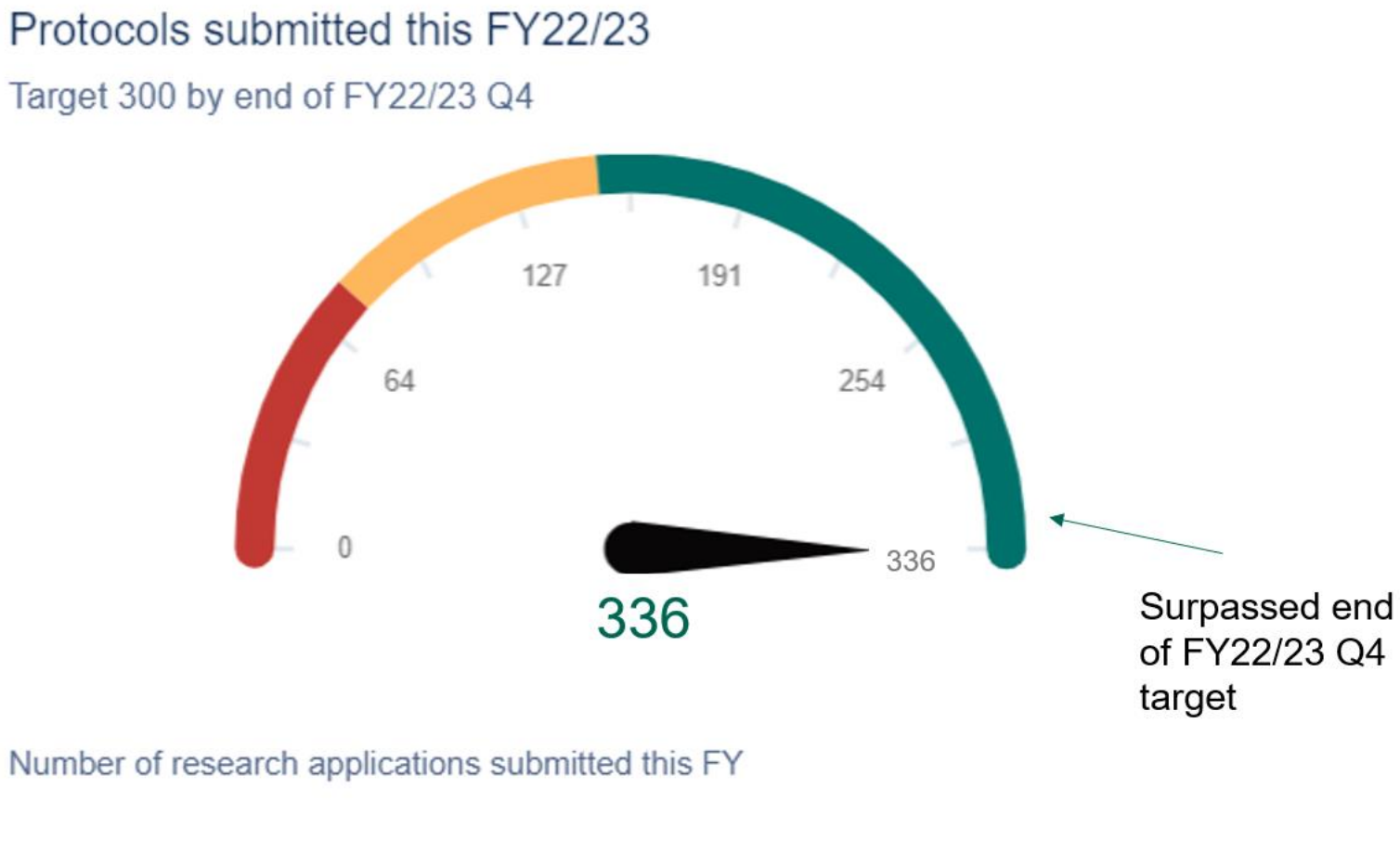
10% sign up reference line

This measures regional representativeness and inclusivity of CPRD coverage.

Target by end of FY22/23 Q4: To recruit at least 10% of GP practices in each UK region.

CPRD is currently above target for all regions.

CPRD03: Total number of new RDG applications submitted in 2022/23



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

Q4 Target by end of F22/23: 300.

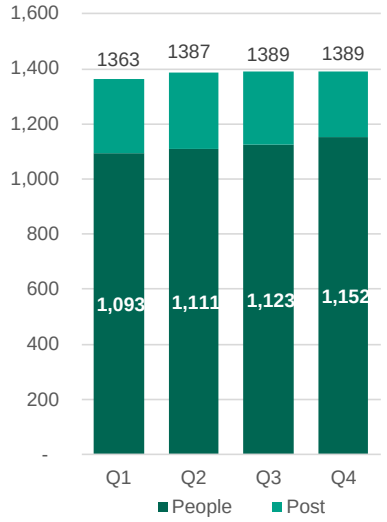
To consider:

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

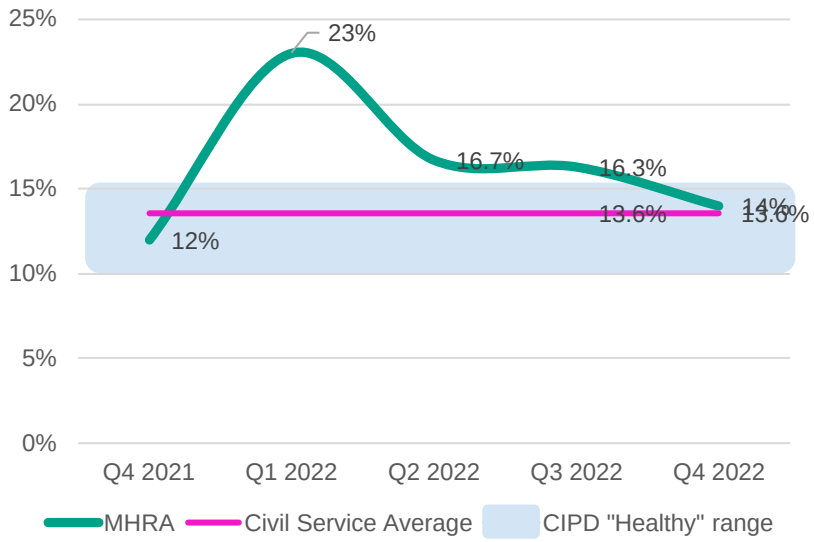
People

Delivery Plan Priority – Dynamic Organisation

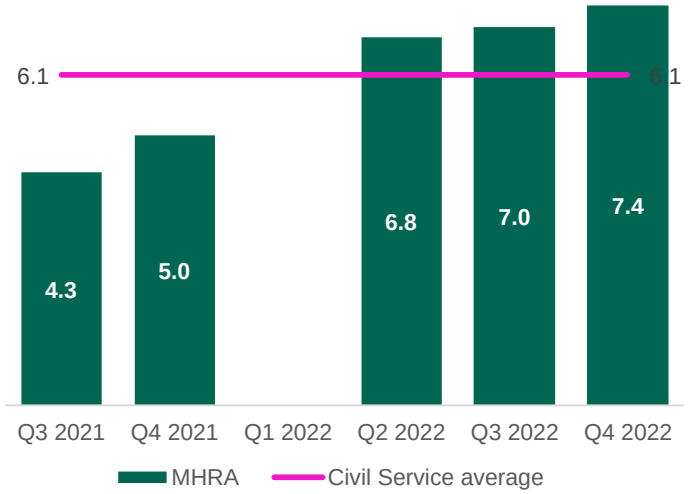
Recruitment
Posts filled v structure



Voluntary Turnover – Annualised



Sickness Absence Days – Annualised



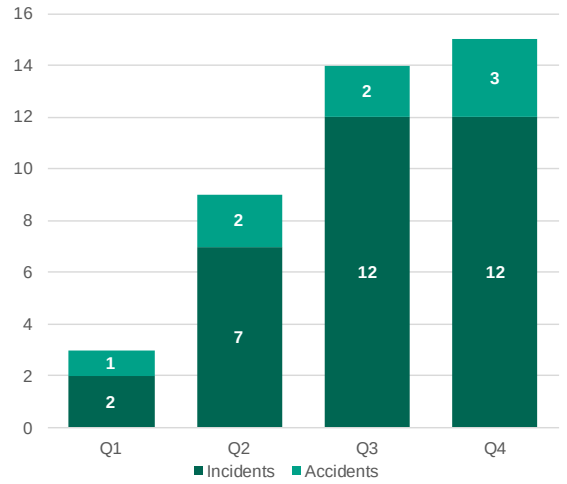
We report a further reduction in our turnover as we increasingly fill vacancies, with a slowdown in the rate of leavers versus starters. Reassuringly our turnover now falls into the category considered 'healthy' by the CIPD.

Absence remains stable and the same levels as reported in January. The highest reason reported for sickness absence is stress, anxiety and depression and we continue to support staff who are unwell through occupational health and our Employee Assistance Programme as well as through our range of related policies and procedures and wellbeing interventions. We are unable to report by Group in an annualised way as Fusion was rebuilt as of 4/7/22 to reflect the new structure but looking at data from that date (which will not compare with the annualised figures) we note that the highest absence by Group is in Partnerships and Corporate. The long term absence of one individual will skew the data for small Groups so should be read with that caveat.

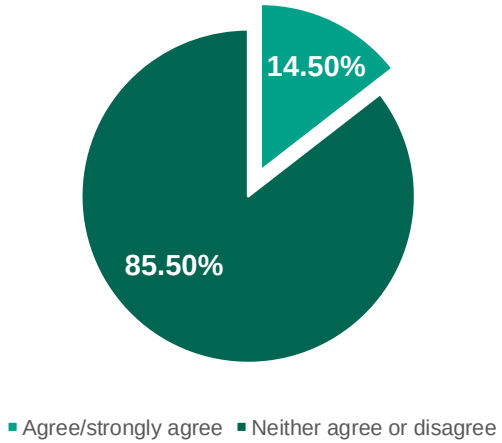
People

Delivery Plan Priority – Dynamic Organisation

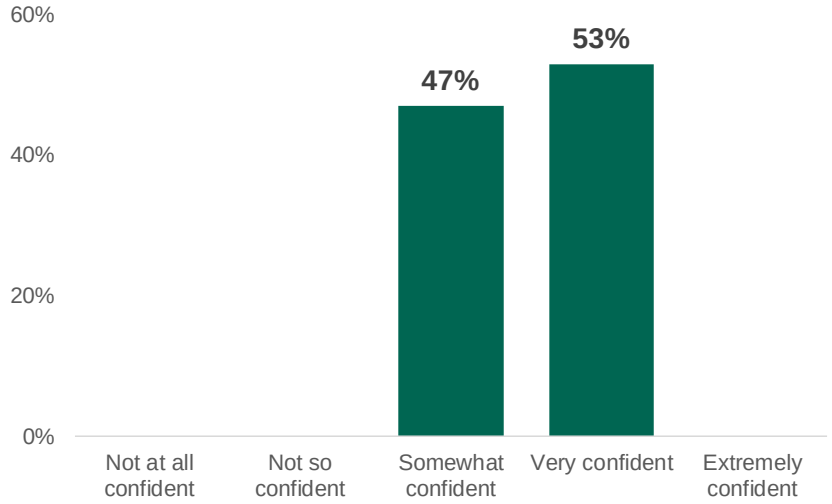
Incidents and Accidents



Applicability of learning across 2023 training programme



Senior leader training- increased confidence



Accidents overview:

2 accidents were minor cuts, first aid treatment was given and the investigations completed.

1 accident related to a fall during icy conditions, water dripping from a roof created an icy patch. The risk area was dealt with immediately and the source of the leak investigated. The person was off work for less than 7 days and therefore was not reportable.

Incidents overview:

There has been increased reporting of issues related to the site and facilities as staff have been actively encouraged to report incidents – examples include water leaks, an issue with an automatic door (a part of the door opener fell), a light fitting fell, autoclave issues identified during routine checks. There have been no reportable incidents.

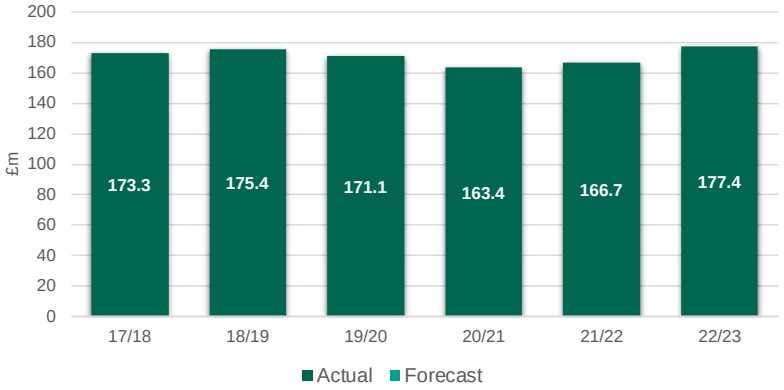
Summary:

There have been no reportable incidents in Q4. A higher level of incident and near miss reporting has been seen relating to site buildings and facilities due to raised awareness of the importance of reporting incidents, including precursor incidents, this will enable issues to be identified early and investigated to prevent more serious incidents and accidents from occurring.

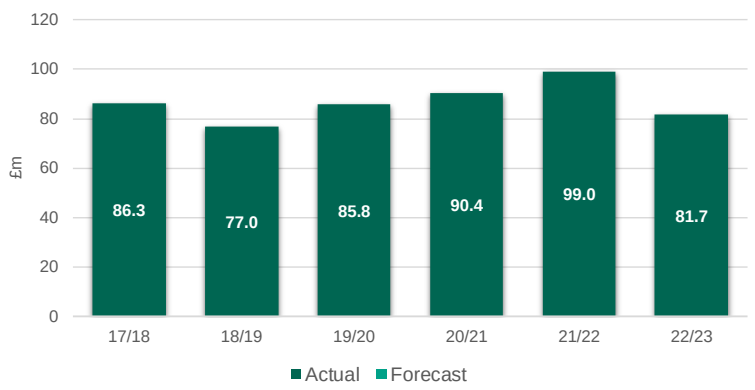
Finance

Delivery Plan Priority – Financial Sustainability

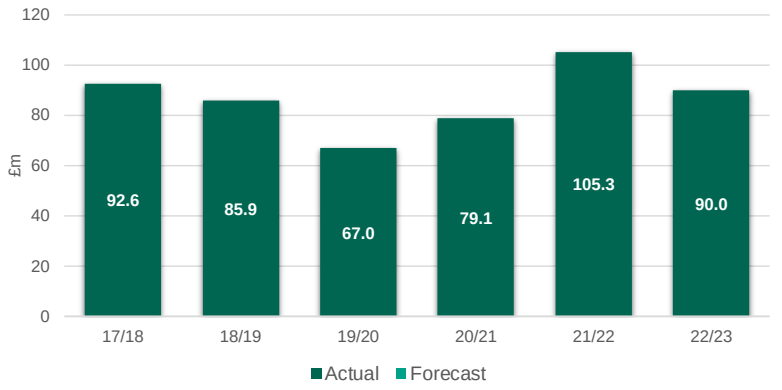
Income – 22/23 forecast **£177.4m** v budget £180.0m



Pay Costs – 22/23 forecast **£81.7m** v budget £90.5m



Non-Pay Costs – 22/23 forecast **£90.0m** v budget £89.6m



22/23 surplus of **£5.7m** v £0.1m budget 22/23 total deficit, a 3.3% variance on the agency's total expenditure.

Large vacancy rates during the first half of the year have led to full year operational staff costs being **£11.2m** under budget (12%). Staff related change costs of £2.4m have reduced this variance to **£8.8m**.

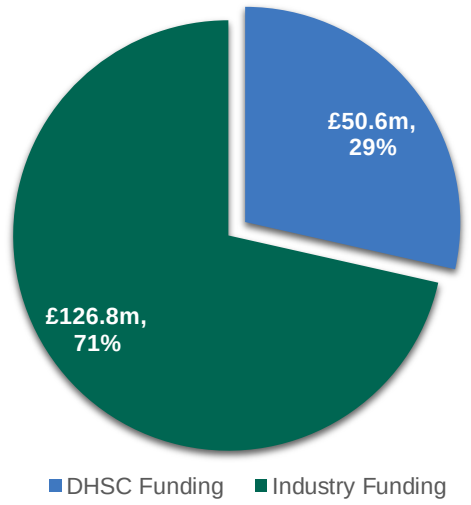
Targeted growth within Licensing income was based on assumption of additional FTE, however income overall in the first half of the year was affected by the high number of vacancies we experienced.

Accommodation costs for the full year were impacted by a delay in handover of 10SC floorspace.

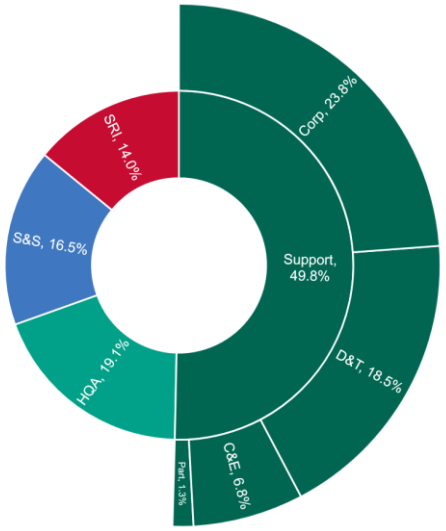
Finance

Delivery Plan Priority – Financial Sustainability

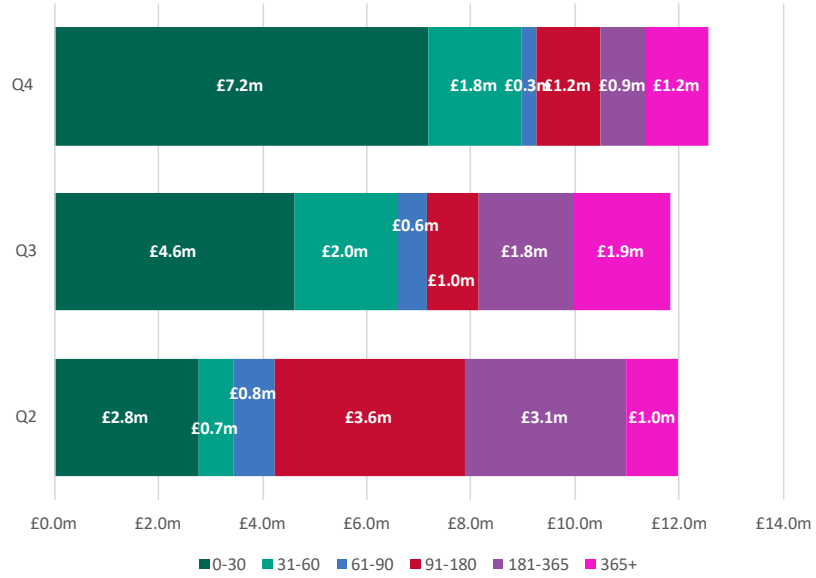
DHSC / Industry Income Split



Support Expenditure %



Debt by Days Due exc Service Charge



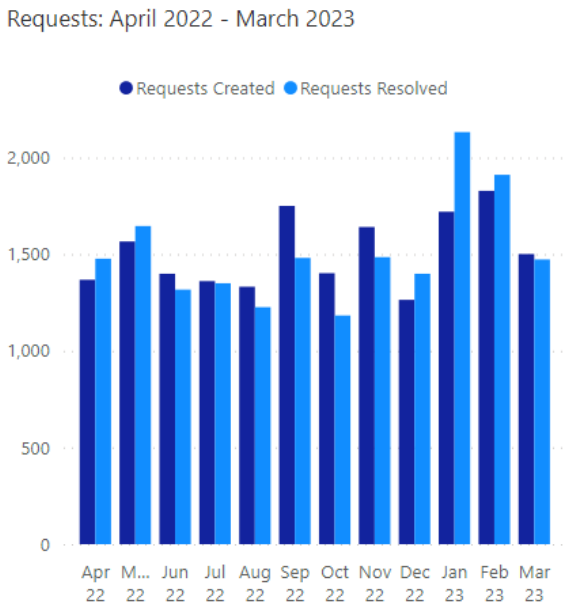
The agency has an ambitions to reduce DHSC reliance on DHSC funding to support our costs base and reduce relative expenditure within the support groups.
DHSC funding for 22/23 is higher than usual due to additional spending review funding including £9m for RMS and £1.2m for SafetyConnect. This will reduce in the future.

The 49.8% of support spend is less than the 50.4% budgeted expenditure. Despite an increase in accommodation and depreciation the disproportionately large number of vacancies within partnerships and D&T, as well as below budgeted IT costs, more than offset this.

Debt appears to have increased but the majority of this is debt within 0-30 days. Debt over 30 days has decreased from £9.2m at the end of Q2 to £5.4m at the end of Q4 and debt over 180 days has decreased from £4.1m to £2.1m over the same timescale.

Digital & Technology

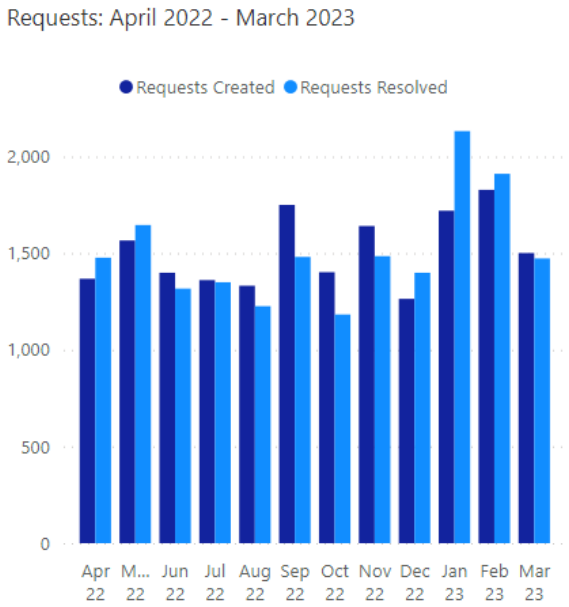
Delivery Plan Priority – Dynamic Organisation

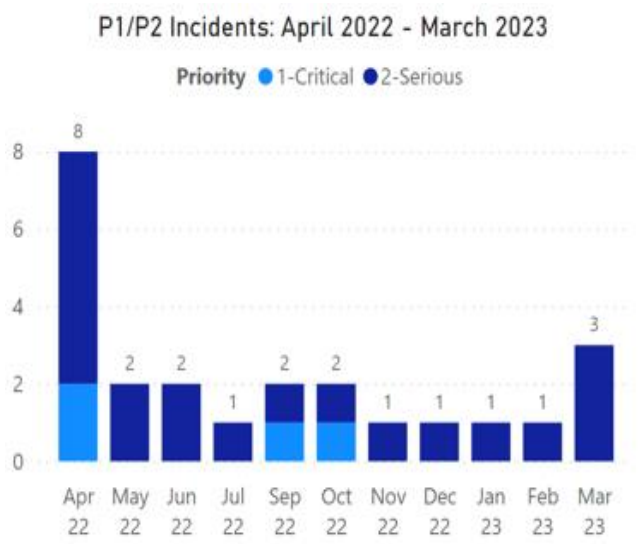


Over the past quarter the number of internal support requests made saw a slight increase from the previous quarter (5,409 vs 4,307) although March's figure returned to more normal levels. January's peak was, in part, due to people forgetting passwords over the Christmas break or passwords expiring during that period and to an increase in new joiners at the start of the new year. Previously reported issues with new joiners have now been improved significantly. The vast majority of requests (99.5%) in Q4 were low priority.

Digital & Technology

Delivery Plan Priority – Dynamic Organisation





February saw a peak in reported incidents, although only one was a Priority 2 incident and related to the use of technology which is at the end of service life. Discussions are taking place about this, and other architecture at the South Mimms site which is also out of service, and support, life. Two of the P2 incidents in March related to access to VDI (a form of remote use of our systems) which were quickly resolved. There have been no P1 incidents since October.

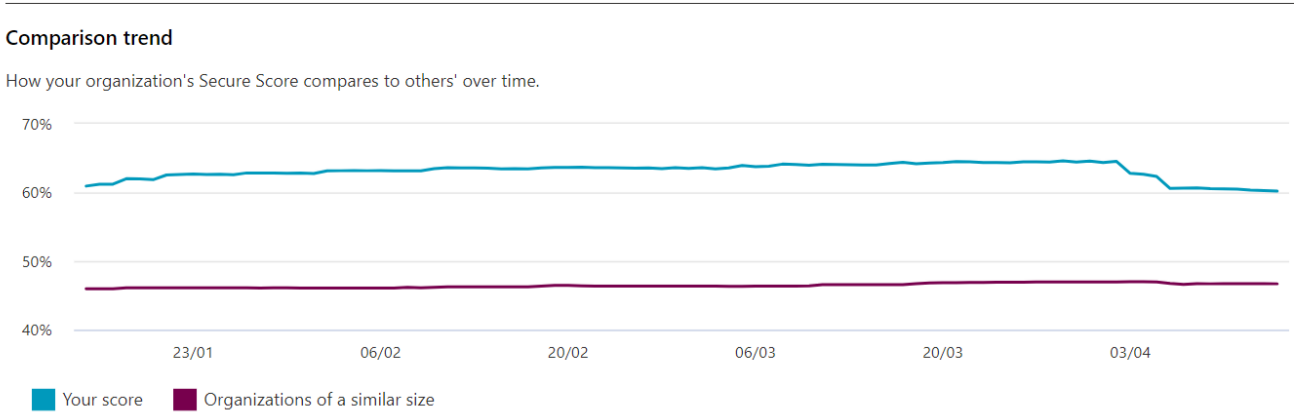
During this period the programme to move out data centre has been taking place in earnest but there have been almost no incidents related to this move which is very positive. Updates were also made to Fusion and Taleo Learn during the quarter.

We have recently appointed a new organisation to manage our IT Helpdesk. As part of the onboarding process and are working with them to creating new performance monitoring and reporting processes. We are also looking at how automation of some processes could help to improve the onboarding of new staff.

Digital & Technology

Delivery Plan Priority – Dynamic Organisation

IT Security



The Agency's MS Secure Score has increased very marginally since last reported, from 60.09% to 60.18% and it still significantly higher than our comparator organisations. There was a slight decline in early April, which is a reflection of Microsoft's assessment of changes to the current cyber threat and what changes organisations should make in response.

Digital & Technology

Delivery Plan Priority – Dynamic Organisation

	Q3	Q4
High risk emails inspected	43,165	34,505
- **delivered to junk**	26,275 (61%)	18,128 (53%)
- **confirmed malicious and blocked**	14,338 (33%)	10454 (30%)

Whilst the number of high-risk emails fell from Q3 to Q4 (there was a spike before Xmas which often occurs), the Agency continuous to be heavily targeted for email spam and malware and everyone needs to remain alert to spot them if any get through our security filtering. However, our email filtering mechanism is currently working well to deal with these such emails.

The Information Security (InfoSec) team is currently considering other monitoring results that could be drawn from our systems which, in combination with email filtering outcomes, will present a clearer view of the cyber threat to the Agency. These will be included in the next report.

Our MS email filtering tool is showing a consistent rate of proven malicious (phishing) emails that have needed to be blocked (32-30%)

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 2023

Title	**What assurance can be provided by the Organisational Development and Remuneration Committee?**
Board Sponsor	Amanda Calvert
Purpose of Paper	Assurance

What assurance can be provided by the Organisational Development and Remuneration Committee?

1. Introduction

The Organisation Development and Remuneration Committee (ODRC) met on 14th March 2023 with the following objectives:

- Review and agree the updated Terms of Reference (TOR) and membership of the ODRC.
- Review and discuss feedback from the leadership team and agree the forward workplan for 2023/24
- Review the approach to improve communications to all staff to facilitate the delivery of the Agency's corporate and business plans.
- Review the proposals to improve governance and establish new roles and ways of working across the Agency.

2. Terms of Reference and Committee Membership

The committee reviewed and agreed the revised Terms of Reference and it was confirmed that the membership will comprise 3 executive members including the CEO and two Chief Officers including the Chief People Officer. The Director of Delivery will also attend the Committee. The TOR were submitted to the March 2023 Board for approval.

3. Key Feedback from Executive Team Members and Forward Workplan

The Board had requested that the chair of this committee engage with Executive team members to get their feedback on how ODRC could provide support and guidance, to address key organisational development challenges and to deliver the new service delivery model for the Agency.

There were several common themes emerging from the discussions with the chair of the committee which were impeding progress and delivery of the Agency objectives. These were discussed at the ODRC meeting and the progress is summarised below.

3.1. **Role of ODRC**

- Discussions revealed that the scope and role of ODRC were not well understood. The revised TOR and membership will go some way to address this deficiency and the chair will ensure that the agenda items are aligned to support the delivery of the Agency business plans as well as providing assurance to the Board.

- There were 4 Chief Officers and 2 Directors at the March meeting which enabled some excellent discussion on the common issues and challenges that were being faced and to agree actions that can be taken by the executive team to address them.

3.2. **Remuneration, Staff Recruitment and Retention**

- There have been significant delays in filling roles within the organisation. The impact of this has been that many leaders have had too little time to focus on change and preparing for the future operating environment as they have in some cases needed to cover gaps in their organisations. This focus is now changing as the vacancies are being filled in the new teams.
- An effective and creative talent management process for the Agency will be essential to broaden opportunities for staff whilst also recognising the value of technical expertise and growing this where appropriate.
- Whilst remuneration is a key issue and base salaries remain lower than those offered in industry, there are many reasons why the Agency can deliver a rewarding and rounded career with a very strong sense of purpose.
- Talent Management and Remuneration Processes will be reviewed at future meetings of ODRC.

3.3. **MHRA Core Purpose and Sense of Identity**

- The Agency has a very strong core purpose “to improve patient and public health”. However, in some areas there has been a less clear and compelling narrative communicated about the purpose of the transformation during the period of organisational change. This has led to a lack of clarity for some individuals on the purpose of their own role.
- In line with the Gateway 0 Review recommendation, it is imperative that there is better communication of this core purpose and leaders work with their teams to build a new identity and sense of purpose to replace that which was lost following the exit from the EU and the transformation programme.
- The corporate plan and business plan are key vehicles to enable all teams to feel connected to the Agency’s objectives.

3.4. **Coping with a Dynamic External Environment**

- The organisation has done remarkably well considering the magnitude of the changes in the external environment with the biggest impacts being the exit from the EU, which required a complete change of governance, and the COVID pandemic, which required new ways of protecting public and patient health.
- The new governance structure based on the four pillars of people, services, technology and finance are now in place and will give a foundation on which to build resilience to help ”future-proof” the organisation.
- To build on the foundations of the new organisation, greater clarity on how responsibilities work on a day-to-day basis could be achieved through the use of tools such as RACI (ie Responsible, Accountable, Consulted, Informed).
- Building confidence to deal with change will need to continue to be built through taking small steps, including improved communications, celebrating successes and meeting face-to-face. These small steps complement the larger changes that are already being progressed such as recruitment to new roles and defining ways of working to deliver the services that the Agency is responsible for.

3.5. **Decision Making – Empowerment, Delegation and Trust**

- As staff settle into the new organisational structure, new leaders grow their skills and new governance structures are put in place, it will be essential to take small steps to grow confidence to delegate decision making and to build trust.
- Empowerment, delegation and trust are not built overnight and the committee thought it was useful to use models and stories to build confidence and celebrate small steps and successes as they are achieved.
- Whilst the Agency is very data driven when making regulatory decisions, there is a need to improve the reporting and data to help monitor progress of change and delivery of key elements of the corporate plan.

4. Delivering One Agency – Improving Communication to Staff

4.1 The corporate plan will be the primary vehicle that will be used to build alignment and common purpose across all the teams in the Agency. The importance of linking personal targets to team plans up through the organisation to the corporate plan was recognised by the chief officers and work is progressing to establish this way of working.

4.2 The high workload levels experienced by many staff members was discussed as was the importance of prioritisation. Much of the Agency's workload is defined in statute and therefore delivering the statutory provisions remains the top priority for everyone within the organisation. The Committee were assured that performance against these priority areas is being regularly reviewed and actions taken to maintain or improve performance where required.

4.3 The Executive team members are developing metrics and team plans with the appropriate level of detail to be meaningful to their teams and these metrics will be more detailed than those reported to the Board.

4.4 The committee supported the progress that is being made to cascade the objectives outlined in the corporate plan throughout the organisation so that team objectives and individual targets and objectives can be linked to the corporate plan.

5. How is the revised structure helping staff to develop into their new roles and adopt new ways of working?

5.1 The strategic delivery team is focusing on a few key areas including established medicines and clinical trials to establish new ways of working to improve efficiency for delivering services and hence reduce workload for staff.

5.2 External pressures over the past few years including COVID and exit from the EU as well as changes in external demands from patients, industry, government and the research environments have necessitated changes to both the organisation structure and in ways of working across the Agency.

5.3 The transformation programme has established new organisational structures which has had a major impact on staff roles and the organisation that they work within. The changes to new ways of working to deliver both established and new services have been slower to put in place.

5.4 The committee was pleased to hear of the progress being made by the Director of Delivery and his new team. There are signs that a corner has been turned. Backlogs are being addressed and teams are getting towards full strength which enables new processes and ways of working to be established.

6. Looking Towards the Future

6.1 There is a tension between the current pressures felt by the Agency and the aspirations that it has for the future. There is a need for a clear articulation by all leaders of the reasons for change and how it will improve the working environment for staff and deliver value to stakeholders. The committee were assured that the progress in filling key roles will allow leaders and particularly the Chief Officers to have time to concentrate on leading change to deliver the future vision.

6.2 The committee discussed the importance of metrics that will help to motivate teams as well as measuring performance. The committee were assured that progress is being made to establish the cascade of targets through to teams and individuals.

6.3 There was discussion on the importance of ensuring congruence of plans, objectives and behaviours throughout the organisation starting with the Board and continuing through the Executive Committee (ExCo) and their teams and to each staff member's targets. There was agreement that individual targets need to emphasise the "how' as well as the "what".

7. Concluding Remarks

7.1 The review of governance and Terms of Reference for the ODRC were subsequently approved at the March Board Meeting.

7.2 A forward workplan has been established to complement the board work plan.

7.3 The ODRC will organise a joint meeting with the One Agency Leadership Group. This will be an opportunity for leaders across the Agency and board members to work together and continue to build the strong culture required to cope with a dynamic external environment and deliver the corporate plan.

7.4 The committee recognised that the organisational change had left many people in the organisation working in new roles with many roles taking longer to fill than originally planned. Many leaders have had to fill these gaps and this has left little time to establish better ways of working suitable for the future challenges and operating as a stand-alone regulator. However, this is now changing and tangible progress is being made in key areas.

7.5 The committee welcomed the progress that is being made in all areas to build on the objectives in the corporate plan and establish local plans and objectives that are in turn linked to personal targets. This is an investment for the future and needs to be tailored to local needs but in a way that everyone feels they are contributing to the corporate plan.

7.6 The committee welcomed the openness and contributions from the Executive team members who shared the approaches that they were taking to establish new ways of working and to build confidence within their teams. They were being supported by the Director of Delivery and his team.

Amanda Calvert
Chair of Organisational Development and Remuneration Committee
May 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 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?

1. Executive Summary

1.1. The Audit Risk and Assurance Committee (ARAC) met on Friday 21 April. This was Mark Barker's first attendance as the Agency's new interim Deputy Director of Finance. The Committee welcomed Mark.

1.2. ARAC congratulated Graham Smith on his appointment as Director of Internal Audit at the Independent Parliamentary Standards Authority. Graham will take up post in the early summer. The Committee thanked Graham for his contribution to the Agency. The Government Internal Audit Agency will propose a successor to Graham as the MHRA's Head of Internal Audit shortly. Graham will attend the Committee's July meeting to provide his assurance opinion for 2022-23.

1.3. We received a progress update on resolving issues raised by the Health and Safety Executive (HSE) at the South Mimms site. We reviewed the Agency's financial position at the year-end together with progress in preparing draft financial statements. We discussed the outcome of NAO/KPMG's interim audit and the resilience of the remaining audit timetable. Internal Audit presented the outcome of three further reports and explained the implications for their annual assurance assessment. We considered the Agency's draft annual governance statement which will be published with the Annual Report in July. Finally, we received annual reports on the Agency's handling of fraud and complaints.

2. Health and Safety

2.1. The Board considered the Agency's Annual Health and Safety Report at its March meeting which was held in public. We were pleased to hear that key health and safety posts were now filled. The new incumbents are currently undergoing training and it will take some time before they are fully operational. The Board is scheduled to discuss the Agency's health and safety strategy at its November meeting. In advance of this, the Committee has asked to see the current implementation plan to resolve outstanding issues raised by HSE to ensure compliance. ARAC welcomed the decision that all MHRA staff will have responsibility for health and safety incorporated into their annual objectives. We asked to be notified when this had been done.

3. Financial Statements

3.1. We discussed the implications for the MHRA's financial statements of the Agency no longer being a Trading Fund. The main change is that unlike in previous years funding from the Department is no longer recognised as income. The Department's funding (£50m) is reported in reserves. The consequence is that the Agency will report both an Operating and Total Comprehensive Deficit (£36m - subject to audit) for 2022-23. Figures for 2021-22 have to be adjusted for comparative purposes and will similarly show a deficit (£54m). We agreed that this change will require careful explanation in the supporting narrative in the Annual Report and in external communications.

3.2. We were assured that the Agency is on target to submit Financial Statements for audit as specified in the agreed audit timetable for Board approval of the Agency's Annual Report at its meeting on 11 July.

4. External Audit

4.1 NAO/ KPMG have completed their interim audit as planned. No significant errors were identified. The delays that were experienced last year arose from issues that came to light during external audit's testing of end of year balances and so the next month will be pivotal in ensuring that the timetable for approving the Annual Report on 11 July is met. We were assured that Finance is well focused and resourced to respond to issues which may arise during the final audit.

4.2 External audit's interim report highlighted three areas – the accounting treatment of CPRD following the expiry of the Memorandum of Understanding with the Department; treatment of 2022-23 surplus; and retrospective approval for a special severance payment – which require formal external authority from either the Department or the Treasury. Obtaining this in a timely manner is important for meeting the timetable for approving the Annual Report as planned. The Chief Finance Officer will continue to keep the ARAC Chair informed of progress.

5. Internal Audit

5.1 Internal Audit's programme for the financial year just ended consists of 10 substantial pieces of work. Of these, the Committee has already considered four reports at previous meetings and has reported to the Board. These are Financial Controls; Payroll; Compliance with Cabinet Office Guidance; and the Innovative Licensing Access and Pathway (ILAP). At our April meeting we considered a further three reports - Conflicts of Interest; Patient Engagement (advisory); and Cyber Security.

Conflicts of Interest

5.2 The MHRA has strengthened and made more transparent its approach to managing conflicts of interest. Internal Audit awarded moderate assurance with two recommendations which the Agency has accepted.

Patient Engagement

5.3 This is an advisory piece of work to support the Agency as it continues to strengthen its patient engagement. Internal Audit have made a number of suggestions to improve metrics to provide assurance on the quality of patient engagement. The Agency's Patient Safety and Engagement Committee (PSEC) will consider the report further and how its recommendations are implemented.

Cyber Security

5.4 This report was considered in draft. It awards a limited assurance rating largely because the take up of cyber security training is low. While this clearly needs to improve the Agency has a comprehensive control framework to mitigate the threat of cyber-attack which has been externally validated. We advised that it is important that the scope of Internal Audit's review is made clearer in that their work assessed the take up of mandatory training and

was not a full review of the Agency's preventative measures. ARAC has asked for a further deep dive into cyber security at its Autumn meeting to gain further assurance.

Internal Audit Programme

5.5 Internal Audit's remaining three reviews for 2022-23 are at field work stage. These are: Regulatory Management System (RMS); Agency Fees; and Managing Backlogs which is advisory and intended to draw out lessons and good practice. ARAC will consider these reports at its July meeting. The ARAC Chair and the Chair of the Organisational Development and Remuneration Committee (ODRC) have also asked for a separate update on progress with RMS in the early summer.

5.6. The Committee reiterated its concern at the slippage in the Internal Audit Programme which we which have commented on in previous years. We appreciate the efforts which the Governance Office is taking to remedy this and secure a more even flow of reports. To support the Governance Office, ARAC has asked for a 12-month critical path to be prepared which sets out when each piece of work will start and finish. The Committee will routinely monitor this.

Internal Audit Recommendations

5.7 The implementation of Internal Audit's recommendations, which the Executive have accepted has slipped, with an increasing number not meeting their agreed timetable. Some recommendations are dependent on new technology such as RMS or new Medical Devices legislation. We have asked the Executive to identify such recommendations and assess whether they remain relevant in their current form. Where such recommendations are intended to strengthen controls or improve performance it is important however that that this objective is not lost but built into the new system or reflected in the way new legislation is implemented. The Committee asked for the updated recommendations tracker to be presented to the Committee.

5.8. Each year Internal Audit is required to provide the Accounting Officer with an independent assessment of the Agency's framework of controls. The Accounting Office refers to this assessment in the Governance Statement which is published with the Agency's Financial Statements. Based on the outcome of work completed to date, the Director of Internal Audit indicated that for the second year running the assessment is likely to be limited. How the Agency is responding to this needs to be carefully explained in the Governance Statement (para 7.2 below).

5.9. Internal Audit acknowledge that the Agency is making good progress in strengthening and enhancing its controls, particularly in the way governance has improved and risk management has become more strategic. More time however needs to elapse to provide sufficient evidence that these improvements are fully embedded.

5.10 Internal Audit confirmed that their proposed work programme for the next year should provide sufficient evidence to justify an improved assessment should the audit findings be sufficiently positive. We therefore support Internal Audits 2023-24 plan which has been agreed with the Executive.

6. Risk Management

6.1 At its April meeting the Board considered a detailed paper on the Agency's strategic risks and how risk management is being strengthened. Drawing on helpful comments made by the Board, ARAC discussed further enhancements. These include ensuring that the Agency's preparedness for another potential pandemic is sufficiently covered and ongoing focus on the effectiveness of the Agency in the wider health system to ensure long term benefits for patients.

6.2. The majority of strategic risks have a red rating. Mitigating actions that the Agency has put in place suggests that some of the ratings may now be reduced. The Board also suggested that the management of some risks might benefit from them being disaggregated. The Governance Team already intend to revisit the risk ratings and will consider the potential for further disaggregation.

6.3 In keeping with good practice, we intend to hold a second dedicated horizon scanning meeting in September to focus on new or emerging strategic risks. As before, this will involve Chairs of all of the Agency's Committees. We are also exploring with the Audit Committees of the National Institute for Health and Care Excellence (NICE) and the UK Health Security Agency (UKHSA) whether they would like to attend as many of the risks we face are shared.

7. Annual Report and Governance Statement.

7.1. The Agency is well advanced with drafting the Annual Report. ARAC focused specifically on the draft Governance Statement. The purpose of this is for the Accounting Officer to provide assurance that over the last 12 months the Agency has had the governance, risk management and processes and procedures in place to enable the MHRA to deliver its responsibilities cost effectively.

7.2. The draft is transparent about the challenges which the Agency has faced over the last twelve months as it has revised its governance structure and begun to address performance issues. We recommended that this should be balanced by setting out a small number of priorities that the Agency will be focusing on over the next year to continue to strengthen performance and in particular address the systemic issues raised by Internal Audit. We had some discussion about what these might include - for example better consistency in service-level delivery, smooth and efficient policy implementation and enhanced clarity of roles and responsibilities.

8. Governance

8.1 The Committee considered three reports on Regulatory Fraud, Non-Regulatory Fraud and Complaints Handling. We were assured that the Agency has appropriate policies and procedures. The nature and type of complaints is becoming a useful way of understanding how the Agency can continue to improve and also how it can better manage stakeholder expectations.

8.2 As in previous reports we noted a consistent number of payroll errors with employees having left the Agency not automatically being removed from the payroll. We have asked to be updated on controls over those joining and leaving the Agency. There is a related issue in that a significant proportion of those not having undertaken cyber security training were relatively new to the MHRA (para 5.4).

8.3 No new cases of whistle blowing were drawn to ARAC's attention. The Committees next meeting is on Tuesday 4 July.

Michael Whitehouse
Chair of Audit and Risk Assurance Committee
May 2023

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

16 May 2023

Title	**What are the strategic priorities for a progressive MHRA Compliance Strategy to enable new product innovation?**
Board Sponsor	Dr Laura Squire
Purpose of Paper	Approval

What are the strategic priorities for a progressive MHRA Compliance Strategy to enable new product innovation?

1. Executive Summary

1.1 This paper sets out the Agency's new medicines compliance strategy, which is a commitment in the existing Agency Delivery Plan, a key deliverable in the new Agency Corporate Plan and will be delivered over a three-year programme to 2025/26. The scope of this first phase of the compliance strategy is for medicines, with a follow-on phase to expand to include medical devices subject to the development of the new UK medical devices regulatory regime.

1.2 Compliance is a critical component of the medicines regulatory framework and the strategy set out in this paper established a range of proposals that will drive benefits to patient safety and access through focussing our resources where risk is greatest and enabling medical product innovation.

1.3 The Board are asked to consider and endorse the strategic direction set out in this paper.

2. Introduction

2.1 MHRA is responsible for ensuring compliance with standards and regulations throughout the product lifecycle across the pre-clinical, clinical, manufacturing & distribution and vigilance phases to ensure patient safety and enable innovation. Our current compliance model is risk-based and has been in place for >20 years. There is both a need and an opportunity to transform our approach to compliance to ensure we:

- Truly focus on risk and incentivise good compliance by developing a model for regulatory oversight that differentiates across the spectrum from the highly compliant to those with sustained poor compliance
- Enable lifecycle management for post-approval changes to support innovation and continuous improvement (ICH Q12)
- Prevent non-compliance and enable innovation through upstream support/guidance and development of compliance-by-design
- Use data and technology to radically improve how we understand risk and conduct inspections
- Ensure value for money and financial sustainability

3. Medicines Compliance Strategy Proposal

3.1 Business context

At a strategic level the UK Government's Life Sciences Vision is a key driver for the development of a new medicines compliance strategy. We need the strategy to support the

goal of making the UK the best place in the world to discover, test, trial, launch, adopt, manufacture, and distribute new treatments and technologies, whilst making use of the opportunity afforded by the UK's departure from the EU to drive innovation in regulatory processes to the benefit of patients.

At an operational level we must ensure that we are able to retain and attract our skilled workforce, adapt our operating model to changes in medicines and technology and upskill our people accordingly. The strategy must also recognise challenges to global supply chains and the emergence of global disease that require rapid and extraordinary regulatory support to ensure patient safety and access.

Our current technology platforms must enable an improved understanding of risk across the product life cycle and the integration of data from a wide and diverse range of sources, better enabling us to focus and target our resources. These factors are a component of the Agency's Regulatory Management Systems (RMS) programme and will be a key underpinning element supporting the delivery of the strategy.

3.2 Strategy

The medicines compliance strategy is set out under 6 key strategic pillars and priorities and its ambition is to pioneer new and innovative ways of ensuring risk-proportionate compliance across the product lifecycle that benefits patients and our sustainability. It recognises that poor compliance is a product of a range of factors – culture, knowledge, skill, resources as well as motivation and priorities. Inspections are one type of intervention but depending on what is driving the non-compliance, other interventions may be more effective, efficient and lasting. The strategy seeks to deploy a spectrum of interventions to drive compliance, of which Inspections will be an important component.

Pillar 1 – Enhanced use of Intelligence and Data

Optimal access and use of intelligence and data is critical to our ability to use an understanding of risk to drive our compliance programme and an outcome-based model for regulatory oversight. Better use of data will also better inform inspectors during the conduct of inspections. Understanding the data that we need to deliver this, where it is and how we can access, store, and assess this data is a key requirement/dependency from the strategy for the RMS project. This pillar will deliver:

- Enhanced accessibility of internal and external data for each inspection discipline informing the inspection programmes to enable a risk-proportionate and stratified approach to compliance.

- Enhanced use of data during the conduct of inspections to increase effectiveness by enabling focussed resource on critical areas and providing greater flexibility to support remote & hybrid inspection approaches.

Pillar 2 – Upstream Intervention

Poor compliance can have a significant downstream impact on patients, the supply chain, and the resources of the regulator. By increasing our upstream engagement across the product lifecycle with stakeholders we can inform, educate and reduce the cost of poor compliance and develop innovation enabling regulation. For example, the Agency's innovative proposals for the regulation of Point of Care Manufacture (PoC) manufacture. Modern technology offers the opportunity to engage a wider audience than was the case even 5-years ago in a 1:many approach using our data/intelligence model (pillar 1) to target our engagement.

Through the Innovative Licensing and Access Pathway (ILAP) there is the potential to ensure the applicant considers compliance throughout the product development lifecycle (compliance-by-design), with inspectors providing advice whilst maintaining our independent role as the regulator.

This pillar will deliver a cohesive suite of approaches to support new product innovation (including ILAP, innovation office, scientific and regulatory advice) by inspectors for future applicants to consider supporting compliance throughout the development of the product. It will explore the impact of upstream interventions by clearly stating and publicising our regulatory expectations (through the development of a programme of 1:many interventions - symposia, blogs, publications, conference participation etc), improving compliance by ensuring that stakeholders are clear on what is required of them and maintaining the MHRA's place as a world-leading regulator. It will identify novel or alternative approaches to influence the compliance status of stakeholder organisations via upstream interventions including improved compliance reporting and the use of behavioural insights.

Pillar 3 – Technology as an Enabler

Technology is a key enabler of how we undertake inspections as part of our compliance programme. Over time we will explore, develop, and implement new technologies that fully enable remote as well as hybrid inspections whereby the onsite element is augmented by a remote component. These technologies will enable our work to be more efficient and make best use of the deployment of inspectors in the field.

Crises like the pandemic spur innovation and this was demonstrated by the rapid and agile adoption of remote inspection technologies over the last 2-years. Building on the experiences of the pandemic and advances in technology we will use an array of tools to fully enable remote inspections and increase their use where fit-for-purpose by creating an inspection toolbox to support the conduct of hybrid/remote inspections.

This pillar will also develop and implement the initial use of software for the inspection of data by end of FY 23/24 and identify future opportunities and approaches onwards. The ability to remotely analyse the data of those we inspect, rather than needing to be onsite to do so, will be a key element of our inspection toolbox and enabling us to be more efficient. It will also identify opportunities and approaches to support the conduct of inspections of new data driven technologies associated with artificial intelligence and machine learning.

Pillar 4 – Drive and Incentivise Good Compliance

Our current approach to compliance is based on the premise that regular inspections will detect non-compliance, deter non-compliance and provide education for the regulated sector, all of which will have the outcome of improved compliance with regulations and good practice designed to keep patients safe. Regulators are increasingly recognising that good compliance is a behaviour, based on both a willingness to comply along with a capability through skills, knowledge and resources. This allows regulators to nuance their approach and the interventions used to drive compliant behaviour. This pillar of our strategy will explore, pilot, and develop the use of Outcome Based Cooperative Regulation (OBCR) approaches that incentivises good compliance in the system whilst ensuring we focus where risk is greatest.

Working with stakeholders we will develop a pilot model for an outcome-based framework for companies to understand and maintain the required standards. Provide tools for companies to evidence their level of compliance with recognition that demonstrably compliant companies can potentially benefit from a different regime for regulatory oversight. This will enable us to further target those who are non-compliant. These approaches supported with short notice and unannounced inspections where appropriate. If successful, this new model for compliance will help determine the future resourcing requirements for the Agency's compliance function.

Pillar 5 – Collaborate and Partner

Collaboration and partnering are cross-cutting elements of the compliance strategy. It will be crucial to work with our international partners to drive global standards and guidance in line with innovative regulatory approaches and work together to manage the demands of our work through mutual recognition and reliance of inspections.

Within the UK healthcare and regulatory ecosystem, we will work to develop best practice and joint cooperation across the pillars of our strategy. We will also collaborate with industry and patients where appropriate, for example to support building capability and capacity, and consider how patients can better understand our work respectively.

Pillar 6 – Capability and Capacity

Compliance is a knowledge-based activity that requires teams of highly skilled and motivated Inspectors across the different phases of the product lifecycle and there are sustained challenges to both the recruitment and retention of these highly valued staff. There is also a compelling need to maintain and develop our technical knowledge as medicines and technology evolves, becoming more specialist and diverse. This requires a sustained re-evaluation of how we grow and feed our talent pipeline and sustain our world-renowned technical capabilities. The current operating model is to cost recovery through our inspection fees, and we must continue to ensure our financial sustainability. These fees may need to evolve under a successful outcomes-based model.

Through this pillar we will establish a sustainable academy approach for inspector training and model for ongoing staff development and capability and utilise flexible approaches to recruitment including the development of potential apprenticeship standards and secondments. We will ensure the continued quality of inspection conduct through horizon scanning for new and developing science and technology aligned with new skills development. An array of new types of medicines and technologies are emerging that will challenge our existing skillsets – for example, in-silico trials, proliferation of Advanced Therapy Medicinal Products (ATMPs), increased uptake of biosimilars, the mRNA revolution, Point of Care Manufacture, digital-twins for pharma manufacturing, continuous manufacture, oligonucleotides, Artificial Intelligence (AI) and Machine Learning (ML) for drug discovery and development, use of Augmented Reality / Virtual Reality (AR/VR) and many more.

3.3 Patient Benefits

Patient Safety - Our enhanced use of data and intelligence to inform our risk model will ensure we focus our resources where the risk to patients is greatest and detect, resolve, or enforce with non-compliant organisations. Ensuring patients throughout the lifecycle of the product are protected from harm – from trial to supplied product and ongoing monitoring.

Patient Access - By engaging upstream with stakeholders developing innovative products and processes, we will be best positioned to support those in the early stages of the product lifecycle and ensure compliance-by-design. This will enable earlier product access as a component part of the Agency's wider innovation initiatives.

Secure Supply Chain - An effective compliance strategy is a critical component in ensuring a secure supply of medicines to patients. By preventing non-compliance and focussing our resources where risk to patients and supply is greatest, we will have an increased impact on the continued timely supply of medicines to patients.

Rapid Response - Our strategy will act to prevent non-compliance and focus our resources where risk is greatest, whilst exploring the opportunity to incentivise good compliance. Taken together this re-balancing of our resources, along with our capability and capacity plans, will ensure a greater level of resilience to our ability to rapidly respond to public health emergencies.

4. Recommendation

4.1 The Board is asked to consider and endorse the strategic direction set out in this paper for the Agency’s future approach to medicines compliance.

Dr Laura Squire
May 2023