Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:50 on Tuesday 18 May 2021

Chair: Stephen Lightfoot

	AGENDA ITEM	**PURPOSE**	**PRESENTER**
10:00	INTRODUCTION		
	1. What are the priorities for this meeting and how will the meeting run?	Information	Chair
	2. Are there any Apologies or new Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
	CURRENT CONTEXT		
10:10	4. What are the current key issues from the CEO's point of view?	Discussion	June Raine
10:30	5. What is the current performance of the MHRA on the Balanced Scorecard?	Assurance	Jon Fundrey
	SCIENTIFIC INNOVATION		
10:50	6. How can we build on the Combined Ways of Working with the Health Research Authority to accelerate the approval of clinical trials?	Discussion	Christian Schneider
	PATIENT SAFETY		
11:10	7. How is SafetyConnect going to improve the safety monitoring of all medical products?	Assurance	John Quinn
	COLLABORATIVE PARTNERSHIPS		
11:30	8. What are the communication priorities to build public and stakeholder trust in the MHRA?	Approval	Rachel Bosworth
	FINANCIAL SUSTAINABILITY		
12:00	9. What assurance can be provided by the Audit and Risk Assurance Committee?	Assurance	Michael Whitehouse
	EXTERNAL PERSPECTIVE		
12:20	10. What questions do members of the public have for the MHRA Board?	-	Chair
12:50	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 20th April 2021

(10:00 – 12:10)

By Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb CBE	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Barbara Bannister MBE	Non-Executive Director
Amanda Calvert	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Jon Fundrey	Chief Operating Officer
Mercy Jeyasingham MBE	Non-Executive Director
John Quinn	Interim Chief Technology Officer
Anne-Toni Rodgers	Non-Executive Director
Dr Christian Schneider	Interim Chief Science Officer
Michael Whitehouse OBE	Non-Executive Director

Others in attendance

Rachel Bosworth	Director of Communications
[Section 40: redacted: personal data]	Secretary to the Board and Head of Directorate
[Section 40: redacted: personal data]	Executive Assistant to the Chair

Government Legal Department (GLD)

Fleur Ruda	Deputy Director, MHRA, Medicines & Pharmacy, GLD

Department of Health and Social Care (DHSC)

Ronan McDonald	Head of Medicine Regulation, DHSC

Devolved Administrations

Kerry Chalmers	Medical Devices and Legislation Head of Unit, Scottish Government

Item 1: Introduction

What are the priorities for this meeting and how will the meeting run?

1.1 The Chair set out his expectations and priorities for this public Board meeting which was being live streamed to the registered audience and recorded.

1.2 The Chair welcomed all to the meeting, including a broad range of observers representing a broad range of patient groups, other health bodies, staff and industry colleagues.

Item 2: Are there any Apologies or Declarations of Interest

2.1 Apologies were received from Dr Sam Atkinson, Interim Chief Quality and Access Officer, Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland, and Alison Strath, Interim Chief Pharmaceutical Officer at The Scottish Government.

2.2 There were no Declarations of Interest.

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 on the outstanding actions.

CURRENT CONTEXT

Item 4: What are the current issues from the CEO point of view?

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities: (i) healthcare access – including updates on vaccine batch testing by NIBSC; the Moderna Covid-19 vaccine; Covid-19 Test and Trace; the Innovative Licensing and Access Pathway (ILAP); Clinical Trials and patient involvement in clinical research; and the Medicines and Medical Devices Act; an update on UK partnership and on international regulatory and scientific collaboration; (ii) patient safety – including updates on Covid-19 vaccine Adverse Drug Reaction reports (ADRs); how an Artificial Intelligence tool is being used to support ADR processing; improving our understanding of Long Covid; the Safer Medicines in Pregnancy and Breastfeeding Consortium; regulatory science; Medical Devices Clinical Investigation transparency; and an infusion pumps quality issue; (iii) dynamic organisation – including an update on accommodation and on the Agency's Mental Health and Wellbeing Campaign; and (iv) financial sustainability – including an update on the Change Strategy.

4.2 Dr Raine noted that the Agency has a number of important priorities running concurrently at present; however patient safety remains the top priority in all activities. Activities continue in the areas of safety, access, and a dynamic organisation delivering for patients. It was noted that the efforts and commitment of Agency staff are enabling the Agency to take forward its responsibilities for today and deliver change for the future.

4.3 The Board expressed sincere thanks to the professionalism and dedication of MHRA staff. The Board thanked Dr Raine for her report and provided comments regarding the proportion of applications which are now coming via the ILAP route and the costs of using this route; vaccine licenses in GB and in Northern Ireland; the Yellow Card Biobank; utilising the Medicines and Medical Devices Act to improve the clinical trial ecosystem in the UK; forward planning for managing Covid-19 vaccines batch testing and other aspects in the future; the excellent work of NIBSC on batch testing work; the importance of having full transparency of the costs incurred by NIBSC and the rest of the Agency from Covid-19 work; and how important international collaboration will be to maximise outcomes for patients.

FINANCIAL SUSTAINABILITY

Item 5: What are the priorities, accountabilities and key measures for the MHRA Delivery Plan 2021-2023?

5.1 The Board considered a final draft of the new 2-year Delivery Plan (2021-2023), containing a focused programme of work which will deliver a new organisation and the changes needed to ensure we put patients first, become a truly world-leading, enabling regulator and that we protect public health through excellence in regulation and science. The Board noted that the Delivery Plan is the product of an extensive development process led by the Executive Committee (ExCo); a draft version of the Balanced Scorecard will be presented to the Board at the next meeting. It was also noted that an art-worked branded document will be developed to support stakeholder engagement.

5.2 The Board provided comments on the Delivery Plan, which covered the importance of ensuring that patient and public involvement is thoroughly embedded throughout the Delivery Plan; ensuring the correct tone is applied throughout the plan; the importance of managing the Agency's systems; the implications of the loss of trading fund status and what this means for long term investment; the importance of considering outcome measures with patients and the public; the importance of maintaining independence as the regulator; whether some priorities in the Delivery Plan will become 'Business As Usual' work in 2 years' time and how to articulate the inherent risk of each of the priorities in the Plan.

5.3 The Board commended how every member of MHRA staff will have aspects of the Delivery Plan embedded in their personal objectives, and expressed confidence in the delivery of this significant change. The Board considered whether the Delivery Plan is ambitious enough and agreed that while this is an ambitious and challenging plan it has focus and is well thought through. Clarity of accountability is vital to delivery.

The Board approved the 2-year Delivery Plan.

Action 32: Text and art-worked Delivery Plan to be finalised and published; engagement to be undertaken with partners; Key Performance Indicators and Balanced Scorecard to be finalised to monitor delivery. JON FUNDREY

PATIENT SAFETY

Item 6: What assurance can be provided by the Patient Safety and Engagement Committee?

6.1 The Board considered a paper from the Patient Safety and Engagement Committee (PSEC) describing the ongoing work on the Implementation Plan for Clinical Practice Research Datalink (CPRD) data access; the Healthcare Professionals Engagement Strategy, the Yellow Card Scheme and the ILAP. The Board noted that the detail and analysis in all papers produced for PSEC were insufficient to assure PSEC that patient and public engagement and involvement were being delivered at the pace required – however the PSEC clarified what it would need to see to attain assurance going forward. This included more specific focus on patient-related aspects; and clearer metrics, including outcome measures, with plans for thorough audit and evaluation. All the areas under discussion will come back to the committee in due course.

6.2 The Board noted that Dr Alison Cave has recently been appointed as the Chief Safety Officer and will join the Agency in July, upon which Dr Cave will become a member of the Board and PSEC.

6.3 The Board also agreed that the assurance reports from the PSEC will form the public facing document of the meetings as these were available on a more timely basis than the minutes, which would need to be approved at the following PSEC meeting before they could be presented to the Board. The PSEC assurance reports will be published on the GOV.UK website. The Board were assured that the PSEC continues to challenge the Agency on patient safety and engagement.

Item 7: What assurance can be provided by the Organisational Development and Remuneration Committee?

7.1 The Board considered a paper from the Organisational Development and Remuneration Committee (ODRC) describing the ongoing work on the progress to date and the function and scale of the transformation and organisational change, executive remuneration responsibilities, and future work including the focus on diversity. The Board noted that the Culture Framework document will be presented to the ODRC at the May 2021 meeting for discussion. The Board noted that the previous remuneration committee had a detailed role in approving executive packages; however the role of the ODRC will only be to engage in remuneration on instances where there is an element of discretion required.

EXTERNAL PERSPECTIVE

Item 8: What questions do members of the public have for the MHRA Board?

8.1 The Board answered a range of questions from members of the public. There were questions relating to the branding of the Yellow Card Biobank, and the Life Sciences Sector Deal 2; these will be addressed after this Board meeting, alongside a specific question from a member of the public.

Action 33: Consult members of the public on the branding of the Yellow Card Biobank. ***CHIEF SAFETY OFFICER***

Action 34: The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment. ***JUNE RAINE***

Action 35: Answer specific question from member of the public. ***JUNE RAINE***

CLOSE OF MEETING

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING IN PUBLIC – 20 April 2021

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
15	Review Agency Fee structure to ensure closer alignment with costs of delivery	Jon Fundrey	15/06/21	
21	ARAC to review governance and risks of the new medical devices regulatory framework	ARAC	18/05/21	On agenda
22	Present an update to the Board on how the short, medium and long-term deliverables from IMMDSR are being measured over time.	June Raine	20/07/21	
23	Review the operations, financial model, strategic outcomes and stakeholder feedback on ILAP	Sam Atkinson	~~18/05/21~~ 15/06/21	
27	ODRC to review Diversity and Inclusion to provide assurance to the Board	ODRC	~~20/04/21~~ ~~18/05/21~~ 15/06/21	
28	ARAC to review that actions have been taken being taken on the limited assurance medical device internal audit report	ARAC	18/05/21	On agenda
29	Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.	Christian Schneider	21/09/21	
30	Present the Agency Communications Strategy to the Board	June Raine	18/05/21	On agenda
New Actions				
32	The Board approved the 2-year Delivery Plan. Text and art-worked document to be finalised and published; engagement to be undertaken with partners; Key Performance Indicators and Balanced Scorecard to be finalised to monitor delivery.	Jon Fundrey	18/05/21	Verbal update on publication and engagement Balanced Scorecard on agenda
33	Consult members of the public on the branding of the Yellow Card Biobank.	Chief Safety Officer	21/09/21	
34	The MHRA had a commitment in the Life Sciences Sector Deal 2 to publish a new regulatory pathway for genomic medicines and genomic tests by March 2021. Provide an update on progress of this commitment.	June Raine	18/05/21	Verbal update
35	Answer specific question from member of the public	June Raine	18/05/21	Verbal update

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

Title	**What are the current key issues from the CEO's point of view?**
Board Sponsor	**June Raine**
Purpose of Paper	**Discussion**

Chief Executive's Report to the Board
May 2021

This report gives a brief overview of the current issues from the CEO's point of view. The Board is asked to consider and agree the priorities.

EXECUTIVE SUMMARY 'TOP 10' HEADLINES

- By April MHRA had received over 200,000 Yellow Card reports relating to suspected adverse reactions associated with COVID-19 vaccines and updated analyses relating to rare and specific types of blood clots with low platelets have been published weekly
- In April, NIBSC certificated 11 batches of COVID-19 vaccines, the equivalent of over 14.6m doses available to the UK vaccination programme
- Licensing Division is currently processing approval of Janssen-Cilag's COVID-19 vaccine, which has a single dose schedule, in light of review of international data on its safety profile
- Under MHRA's Early Access to Medicines Scheme a positive scientific opinion has been given for avalglucosidase, a novel treatment for patients with Pompe disease
- The first approval in the UK of an important anti-cancer product through FDA's Project Orbis has been awarded for Tagrisso (Osimertinib)
- We met with the Independent Medicines and Medical Devices Safety Review Patient Reference Group on 29 April and received a range of helpful insights into how our adverse event reporting system can work better for patients
- A Devices exploratory pilot is under way, seeking to gain a greater understanding of patient involvement in the medical device development process
- Drug Safety Update our MHRA drug safety bulletin, which also carries medical device alerts, has retained the NICE accreditation quality standard for another five years
- CPRD has secured additional NHSX funding for the MHRA's synthetic data research and development programme, resulting in a total funding allocation of £2,104,294 for the period 2020-2023
- A new performance development scheme 'My Progress Review' was introduced on 1 April 2021, bringing a fresh approach to performance development, underpinned by our values and behaviours and continuous, quality conversations with our staff.

HEALTHCARE ACCESS

COVID-19 Vaccine update

1. Following the publication of MHRA / ACCESS Consortium guidance on the studies required for the approval of 'updated' COVID-19 vaccines specifically designed for novel coronavirus variants, we have received requests for detailed scientific and regulatory advice meetings with companies developing updated vaccines. These meetings enable companies to plan their clinical trials and their manufacturing operations.

2. Janssen-Cilag's application for a single-dose COVID-19 vaccine is being processed under the 'EC Decision Reliance Procedure'. Under this procedure, when determining an application for a Great Britain Marketing Authorisations (MA), the MHRA may rely on a decision taken by the European Commission on the approval of a new MA in the centralised procedure.

COVID-19 vaccine Batch Testing by NIBSC

3. In April NIBSC certificated 11 batches of COVID-19 vaccines, equivalent to over 14.6m doses. Between December and the end of April NIBSC has performed laboratory testing and certificated a total of 63 batches of three different vaccines, equivalent to more than 68.5m doses. NIBSC completed the transfer of analytical methods to enable independent batch release testing of the Moderna vaccine to support deployment, and the testing and certification of these vaccines commenced shortly after the MHRA granted a conditional Marketing Authorisation. NIBSC has also completed technical transfer of the Janssen vaccine and is now in a position to test batches. NIBSC is responding to requests from national control laboratories to both advise on COVID-19 vaccine control tests as well as to perform contract testing.

COVID-19 therapeutics clinical trials

4. The pandemic has seen a large increase in the number of clinical trial applications. Overall,131 COVID related trials have been approved since the beginning of the pandemic with 23 completed. Of these, 22 new clinical trials were approved between January and April 2021, 11 of these in March and four in April. Major trials based in the UK including RECOVERY, Remap-Cap and Principle studies are continuing to provide valuable evidence for various therapeutics of interest such as monoclonal antibodies, budesonide and the IL-6 antagonists, tocilizumab and sarilumab. The Clinical Trials Unit recently approved a phase II trial of expanded allogenic γδ T-lymphocytes (TCB008) in patients diagnosed with COVID-19.

COVID-19 Test and Trace - Daily Contact Testing

5. We have continued to work collaboratively with DHSC/NHS Test and Trace to support the national testing programme. We have reviewed studies designed to establish the suitability of offering Daily Contact Testing (DCT) using lateral flow tests as an alternative to self-isolation providing feedback on study design. Daily Contact Testing refers to when close contacts of positive COVID-19 cases are provided with seven days' lateral flow tests (LFTs). Contacts are then required to test themselves each morning for 7 days. If they test negative, they can continue normal activities such as attending work - the usual requirements for social distancing apply. Led by science, we have focused on the test's safety and performance, with a possible view to a future application for an Exceptional Use Authorisation.

Use of UK plasmas for manufacture of immunoglobulins

6. On 21 April 2021, the MHRA's critical risk assessment report was published for use of UK plasma for the manufacture of immunoglobulins and the safety question of vCJD risk. Following this rigorous scientific review, the Commission on Human Medicines has concluded that the risk of vCJD cases arising from use of UK plasma for the manufacture of immunoglobulin medicinal products would be negligible.

Innovative medicines - Early Access to Medicines Scheme and Project Orbis

7. The MHRA gave a positive scientific opinion for avalglucosidase under the Early Access to Medicines Scheme. This is a novel product for the treatment of patients with Pompe disease, a rare genetic disorder caused by the deficiency of an enzyme that degrades

glycogen. Avalglucosidase is an enzyme replacement therapy that has benefits for patients with both late-onset Pompe disease and also infantile-onset Pompe disease.

8. On 6 May 2020, MHRA approved the indication for an irreversible protein kinase inhibitor, Osimertinib, for treatment of certain lung cancer patients (adjuvant treatment after tumour resection in adult patients with NSCLC whose tumours have EGFR exon 19 deletions or exon 21 substitution mutations). This is the first approval in the UK of an important anti-cancer product through the auspices of FDA's Project Orbis since January 2021 when MHRA became a full partner having participated in the pilot process between August to December 2020. The evaluation process was completed in record time to facilitate early access to patients and we are working with healthcare partners to establish equitable access across UK.

British Pharmacopoeia and Laboratory Services

9. Public consultations have been held with stakeholders for two new standards designed to enable innovation and lifecycle management. The first, in a new generation of standards, sets out best practice for the use of flow cytometry for the ATMP community, developed with experts across industry, academia, the NHS and in close collaboration with the Cell & Gene Therapy Catapult. The second focusses on the application of Quality by Design to analytical procedures and is a world first in this area of analytical science.

PARTNERSHIPS NATIONAL AND INTERNATIONAL

Health Research Authority collaboration

10. Devices Division has been working with the Health Research Authority (HRA) to pilot a new coordinated assessment pathway which will streamline the review of clinical investigations involving medical devices. The pilot involves sharing information between MHRA and HRA during the review process. The first application is mid-way through the pilot coordinated assessment pathway. Review of experience with the Combined Ways of Working pilot, which was successful in streamlining MHRA and HRA approval of medicines and vaccines clinical trials, has formed the basis for exploration of further improvements for developers which are expected to include National Institute of Health Research involvement.

International Coalition of Medicines Regulatory Authorities

11. The International Coalition of Medicines Regulatory Authorities (ICMRA) has a COVID-19 Working Group, which we co-chair. On 28 April 2021, we gave a deep dive presentation on the 'Digital transformation of GCP and GMP inspections and clinical trials during COVID-19'. A reflection paper on the global regulator experience has been prepared for comments will be shared with the Working Group for endorsement in May 2021. Overall, the group has provided a valuable resource for international collaboration, shared lessons, and harmonisation of approaches used for remote inspections during the pandemic.

NIBSC involved in joint research into SARS-CoV-2 variants

12. A joint research programme is underway between NIBSC, the Coalition for Epidemic Preparedness Innovations, and the WHO to confirm the suitability of current assays, the efficacy of candidate vaccines, and the suitability of WHO-endorsed International Standards against SARS-CoV-2 variants which appear to be serologically diverse from the original VIC-01 isolate. A call for partners has been issued for sourcing serum or plasma from vaccinated individuals and/or recovered patients for the development of working standards for each of the SARS-CoV-2 variants of concern. Such material will be evaluated in a multi-centre collaborative study in parallel with the first WHO International Antibody Standard. This will bridge between the WHO Standard and a possible replacement should one be needed. This initial outreach is focusing on the collection of B.1.1.7, B.1.351 and P1 variant serum collection, but will also be interested in collecting other emerging variant-specific serum/plasma.

PATIENT SAFETY

COVID vaccines and ADR reports

13. We have undertaken a thorough review into UK reports of an extremely rare specific type of blood clot together with low levels of platelets (thrombocytopenia) following vaccination with the COVID-19 Vaccine AstraZeneca. On the basis of this scientific review, we have concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is plausible, but more work is still needed. An announcement on 7 April 2021 gave information about cases received up to 31 March 2021. In this report we provided updated information on cases received up to 21 April 2021and advised that anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Overall, the MHRA's advice is that the balance of benefits and risks of the vaccine remains positive for the vast majority of people.

Parenteral and Enteral Nutrition Bags

14. Devices Division issued Targeted Devices Safety Information (TDSI) on Parenteral and Enteral Nutrition Bags. This provided advice to the healthcare system following the manufacturers Field Safety Notice (FSN) that bags may not have been sterilised to the correct standard caused by an issue with their third-party sterilisation provider. There were no identified safety signals and risk to patients was assessed to be very low. Devices also provided the manufacturer with an Exceptional Use Authorisation (EAU) for alternative Multilayer bags to assist in providing the health care system with suitable alternative products.

Valproate Stakeholder Network

15. The Valproate Stakeholder Network (VSN) met on 22 April 2021 and brought together patient groups, charities, professional bodies and healthcare system organisations. The VSN welcomed the first report of the valproate registry and supported involvement of VSN members in its development. A digitalised acknowledgment of risk form was agreed to be a priority as this will facilitate effective communication between healthcare professionals and patients and enable monitoring of compliance with the PPP. NHSE & I updated the VSN on plans to send a letter to women taking valproate to inform them of

the risks and a number of members of the VSN will be involved in ensuring that the language used in the letter is accessible to all.

Independent Medicines and Medical Devices Safety Review Patient Reference Group

16. A cross-Agency team attended a meeting of the Independent Medicines and Medical Devices Safety (IMMDS) Review Patient Reference Group (PRG) on 29 April 2021 to update on how the Agency is addressing the Review's recommendations relevant to MHRA. Members of the PRG discussed with MHRA key questions including the priorities for MHRA in moving to a more responsive ADR reporting system and where increased patient involvement can have most impact for the Agency, and provided many useful suggestions. The conclusion was that there is much to be done, and we will be contributing to the DHSC led co-ordination of preparations for the full government response before the summer recess.

Patient Involvement pilot for devices clinical investigations

17. Devices Division has initiated an exploratory pilot involving new clinical investigation applications. Applicants are asked for evidence of the patient involvement activities throughout development of the device and the study. During the pilot, the information provided by the applicants will be voluntary and will not alter the outcome of their application. However, the information gained from this pilot will lead to a greater understanding of current patient involvement in the medical device development process and highlight areas for future patient involvement.

Drug Safety Update bulletin accreditation

18. The MHRA's drug safety bulletin, Drug Safety Update, has retained the NICE accreditation quality standard for another five years. The NICE Accreditation Programme recognises organisations which demonstrate high standards in the production of health or social care guidance. Drug Safety Update has been a member of the scheme since 2010 and has now successfully undergone two reaccreditation procedures. Accreditation means that Drug Safety Update articles will continue to be available through (National Health Service) NHS Evidence, a search tool for healthcare professionals to identify authoritative evidence in health, social care, and public health. Articles produced via an accredited process are displayed with the accreditation mark and appear near the top of relevant searches.

Medicines safety issues

19. Safety signals of adverse cardiac events and malignancies have been identified from a clinical trial to evaluate the safety of tofacitinib compared with TNF alpha inhibitor treatment in rheumatoid arthritis patients aged 50 years or older and with at least one additional cardiovascular risk factor. A Direct Healthcare Professional Communication has been circulated to communicate on the trial findings while further review of the data is ongoing and to recommend that healthcare professionals consider the risks and benefits when prescribing or continuing patients on treatment with tofacitinib.

20. The Commission on Human Medicines has considered a proposal to allow wider access to naloxone, an antidote for administration to people with opioid overdose. This proposal, which is aimed at reducing deaths from opioid overdose, will now be taken forward through a public consultation

Chief Safety Officer appointed

21. Dr Alison Cave has been appointed as our new Chief Safety Officer following a competitive recruitment process. This is a key appointment in the strengthened agency leadership and governance within our new Future Operating Model, as this appointment is another important example in our response to the Cumberlege Review. Alison will lead our safety and vigilance functions as a member of the Executive Committee and Board, so that we can continue delivering on our commitment to keep patients safe.

DYNAMIC ORGANISATION

Agency Transformation Strategy

22. Progress has been made with developing the Agency's future operating model, with detailed design work due for completion by end of June 2021. The process of ratification with Chief Officers and requirement to enable divisional engagement, has required changes to the sequence in which some of the detailed design work is being completed. The latest iteration of the new organisation design – now at 'Level 2' – has been agreed by the Executive Committee and shared with Directors and the Agency's Senior Leadership Group. The Human Resources (HR) plan of activities is progressing well and mobilisation for specialist additional HR resources is now underway to support delivery of the HR plan. Progress is also being made with front-runner pathfinder projects including the establishment of the Governance Office.

Staff engagement with the Delivery Plan 2021-22

23. The Board-approved Delivery Plan 2021-22 has now been shared with all staff and briefings held at All Staff, Senior Leadership Group and Directors' meetings. The material includes the more detailed version of the Delivery Plan with quarterly deliverables together with guidance on setting SMART (specific, measurable, achievable, relevant and time-bound) objectives. All staff have been asked to upload their objectives into Fusion by mid-May 2021. The branded version of the Delivery Plan is near completion and will be used as the basis for stakeholder engagement.

Performance Development

24. The agency's new 'My Progress Review' performance development scheme was introduced on 1 April 2021. The launch of this new scheme means a fresh approach to performance development, underpinned by our values and behaviours and with continuous, quality conversations. A quarterly check-in on goals during the year makes sure there is focus on delivering aligned outcomes and continuous development. We have discontinued end of year performance bonuses and moved to an in-year awards model including bonuses and other recognition opportunities. A focus of the new approach is that every member of staff will be responsible for investing in and sustaining an inclusive, effective and respectful working relationship in an environment where everyone is able to achieve their potential.

People Survey update

25. We recognise the importance of utilising the feedback from the 2020 People Survey, in parallel with what is a time of significant change for staff. Local action plans are now in place and being progressed and pan-agency we have selected the three priority themes of Leadership, Inclusion and Wellbeing. We are now focused on delivering the identified actions under each of these themes.

Return to work

26. The Government's COVID-19 roadmap identified June as a critical month. Managers are being supported to revisit return to work thinking in staff one-to-one meetings during April - May 2021. These conversations will include both timing of return and arrangements; with a need to balance the needs of the role and/or team with accommodation and facilities and alongside personal preferences.

FINANCIAL SUSTAINABILITY

27. The Agency three-year Business Case has been updated and re-baselined, with the latest data covering Agency operating costs, investment plans, and revenues. This has highlighted the affordability challenge for the coming financial year. The key focus is improving the completeness of data and review assumptions for investment costs and revenues. A further detailed review is being undertaken of the Digital Data and Technology roadmap focusing on opportunities to reduce technology investment and identify operational efficiencies.

Funding for synthetic data generation

28. The MHRA has been pursuing a programme of synthetic data research since 2018 when a joint application by Devices and CPRD to develop a proof-of-concept synthetic dataset that could be used to support the validation of machine learning algorithms, was funded by Innovate UK. This project demonstrated that it was possible to develop high-fidelity synthetic data which could be used to validate machine learning algorithms. Outputs included two synthetic datasets based on CPRD primary care data and four peer reviewed publications. Follow-up funding was provided by NHSX in 2020/21 to enable further work to refine the synthetic data generation methodology so that it could be applied to other types of data. The success of this project has led to NHSX confirming further funding this month for the MHRA's synthetic data research and development programme which will generate evidence for synthetic data applications such as its use for correcting biases, sample boosting, and in clinical trials.

June Raine
Chief Executive
May 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

Title	What is the current performance of the MHRA on the Balanced Scorecard?
Board Sponsor	Jon Fundrey
Purpose of Paper	Assurance

What is the current performance of the MHRA on the Balanced Scorecard?

1. Executive Summary

The Balanced Scorecard now has a set of 29 metrics which have been approved by the Executive Committee. Currently 17 of these include live data with a further 12 to be updated later.

The Board is asked to provide feedback on how the Balanced Scorecard can be used to provide assurance to the Board on agency performance and the implementation of the Delivery Plan and the Future Operating Model (FOM).

2. Introduction

The Board requested that the Agency performance is tracked regularly via a Balanced Scorecard. This required the design and production of a first-for-the-Agency Balanced Scorecard that translates the Agency's strategic objectives into a coherent set of performance measures.

A significant amount of consultation has taken place with stakeholders across the agency in arriving at the current version. We have considered the draft Key Performance Indicators (KPIs) from the Moments of Value workshops and have compared the Scorecard KPIs against the Delivery Plan (DP). While not all DP individual deliverables have a corresponding scorecard measure, the overall suite of KPIs on the scorecard in their entirety reflect the Agency's key strategic priorities. We are envisaging that the Balanced Scorecard along with the SMART measures for the 14 DP deliverables will form the core of the Agency's operational performance framework in 2021/22.

The evolving shape of the Balanced Scorecard has been reviewed several times at the Delivery and Performance Committee (DPC) as well as the Executive Committee (ExCo). While accepting there will still be some evolution of the KPIs as we gain access to better data, the current version has been approved and is therefore proposed to be used going forward.

Further work on the scorecard will now be focussed on defining the scope and methodology for each of the scorecard KPIs, especially those that are new for the Agency, setting targets and developing processes for data collection and reporting.

3. Proposal

3.1 Scorecard measures

The attached scorecard covers 29 proposed measures across six sections: Enabling Innovation, Accelerating Access and Ensuring Patient Safety to reflect the three core pillars of the Delivery Plan and the FOM, and three other sections on Involving Patients & Public, Dynamic Organisation and Financial Sustainability. The suite of measures gives good coverage of the key strategic priorities of the Agency and can be improved further through future iterations.

3.2 Alignment with Delivery Plan

The measures included in the Balanced Scorecard have been developed in accordance with the Delivery Plan priorities. Focus groups led by the Chief Officers were created to ensure we had sufficiently broad coverage of agency objectives where appropriate.

However, it is accepted that the Balanced Scorecard cannot include all activities of the agency. The scorecard development team along with the Delivery Plan group have an action to examine any gaps that still exist to ensure the delivery plan has a set of KPIs developed, in line with how the balanced scorecard has been developed. This will ensure a full set of KPIs for the Delivery Plan.

3.3 Frequency of reporting

Some of the measures included will only be available quarterly while others will show little movement on a month-to-month basis. The proposed frequency is a review of the full suite of quarterly measures at the Board in Public on a quarterly basis and review the smaller suite of monthly measures at Board Seminars in private in the intervening months. Creation and collection of data combined with paper submission timelines mean that reporting will be in arrears. We propose having full reviews at the Board meetings in September (Q1), November (Q2), February (Q3) and May (Q4). Monthly reviews will be based on scorecard data from two months prior to the Board meeting.

3.4 Status of live data

Currently 17 of the 29 measures have live data (those without are labelled and highlighted grey). Of the remaining 12 measures we should be able to have live data by next month. Some exceptions are:

- Indexed Productivity and Reputational index – both these measures will be hugely valuable, providing an insight into performance we will otherwise struggle to identify. However, they will both need significant planning and development of processes to be able to report on. These will likely take at least a quarter to develop.
- People Engagement Score – this requires the completion of quarterly pulse surveys
- Non-Pay Savings – this is a new KPI for 21/22, currently nothing to report.

The Balanced Scorecard will include a narrative to give insight, highlight key trends with support actions and recommendations.

3.5 Target setting

The next stage in development of the scorecard is to create targets and processes around data collection and reporting. Definitions of each measure will also be provided.

Target setting is key, as this will decide the standards of performance which the agency is measuring itself against. Some targets are self-explanatory, for example 'Cash Balance and Available Reserve' is an outcome of the budget. Others such as 'Generics – Net days to approval' will require consultation and decisions on our ambition. The scorecard development team will work with Chief Officers and stakeholders across the agency to submit a first set of targets to be approved by ExCo. These targets will be presented to Board to decide if the level of ambition has been set at an appropriate level.

We have already started to develop processes for data collection and reporting. For the majority of scorecard measures ownership and responsibility for providing the data to the reporting team will rest with the relevant business area. For cross-agency measures such as Productivity, the process and data output will be owned by the performance reporting team.

3.6 Future development of the scorecard

While it is important for reporting consistency to maintain a level of stability in the scorecard measures, we expect that these will continue to evolve. Currently the scorecard includes aspirational measures that we are currently not able to report on but wish to in the future. These include looking at the impact of inspections on industry players, public health actions resulting from safety signals and the pace of culture change at the agency.

4. Recommendation

4.1. The Board is asked to provide feedback on how the Balanced Scorecard can be used to provide assurance to the Board on agency performance and the implementation of the Delivery Plan and the Future Operating Model.

Jon Fundrey
Board Sponsor
May 2021

Medicines & Healthcare products Regulatory Agency

Balanced Scorecard v1.0

Accelerating Access

Variations - Net Days to Determination

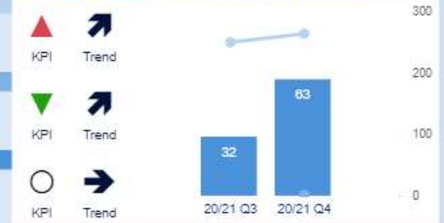
100
Target: 120

Generics - Net Days to Approval (inc Total Volume on Chart)

National MAs
263
Target: 210

EC Reliance
1
Target: 67

MRDC Reliance
(Blank)
Target: 67



NAS - Net Days to Determination (inc Total Volume on Chart)

EC Reliance
1
Target: 67

PL(GB)/Orbit/Access
42
Target: 210

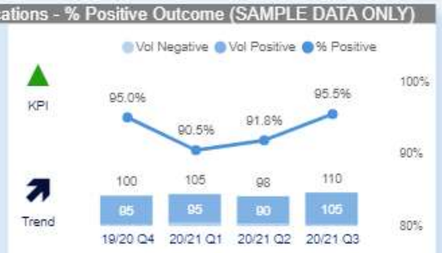
Standards Sales Volume

NIBSC (Non Flu)
37,677

BP
9,212

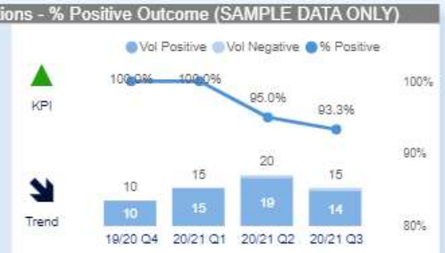
ILAP Passport Applications - % Positive Outcome (SAMPLE DATA ONLY)

95.5%
Target: 90.0%



EAM PIM Applications - % Positive Outcome (SAMPLE DATA ONLY)

93.3%
Target: 90.0%



Device Registrations

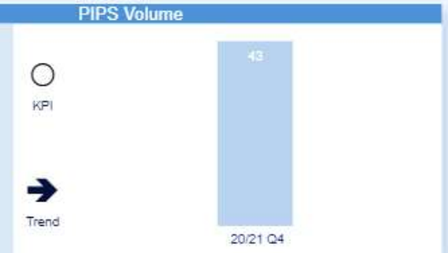
Deadline 01/05/21
536,459

Deadline 01/09/21
117,051

Deadline 01/01/22
235,833

PIPS Volume

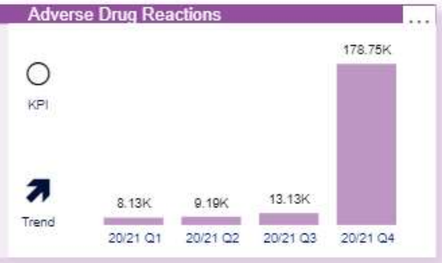
43



Ensuring Patient Safety

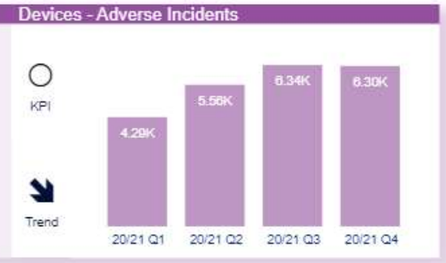
Adverse Drug Reactions

178,747



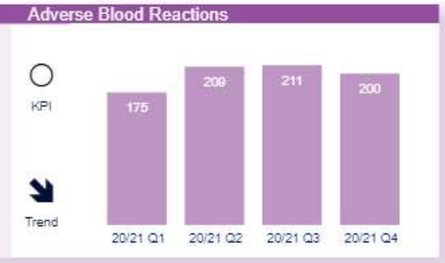
Devices - Adverse Incidents

6,298



Adverse Blood Reactions

200



Patient Safety Interventions

Major Signals
52,848

Manuf Safety Comms
13

MHRA Safety Comms
13

Medicines & Healthcare products Regulatory Agency

Balanced Scorecard v1.0

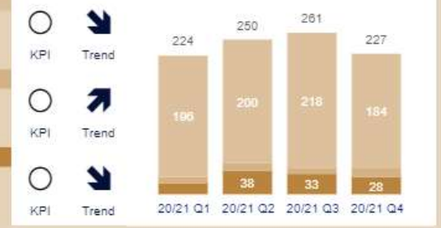
Enabling Innovation

Clinical Trials

Normal
184

Novel
15

FIH Approvals
28



Grants % Success Rate (SAMPLE DATA ONLY)

90%
Target: 90%

Research Papers - Impact Score / 100 (SAMPLE DATA ONLY)

100
Target: 90

CPRD UK Population Coverage (SAMPLE DATA ONLY)

24.6%
Target: 27.0%

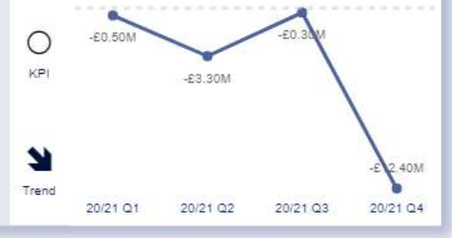
Publications using CPRD Data (SAMPLE DATA ONLY)

210
Target: 200

Financial Sustainability

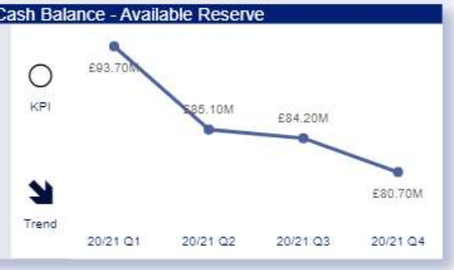
Projected Year End Operational Surplus/Deficit

-£12.40M



Cash Balance - Available Reserve

£80.70M



Corporate Overhead %

32.7%

Maintenance Costs
1.4%

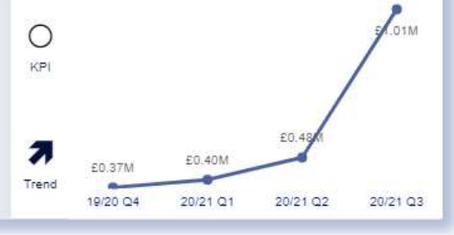
TD3
17.7%

Non Pay Savings (SAMPLE DATA ONLY)

£4.50M
Budget: £4.00M

Cashable Benefits (12m Rolling)

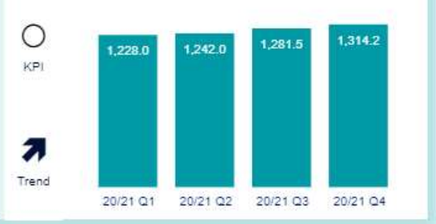
£1.01M



Dynamic Organisation

FTE

1,314.2



People Engagement Score (SAMPLE DATA ONLY)

72.9%
Target: 65.0%

Key Project Milestones Average Days Slipped

37

Indexed Productivity (SAMPLE DATA ONLY)

101
Target: 100

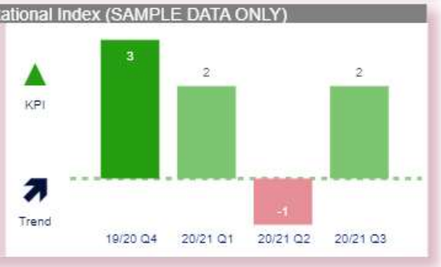
Involving Patients & Public

Public Communications Engagement (SAMPLE DATA ONLY)

175
Target: 150

Reputational Index (SAMPLE DATA ONLY)

+2
Goal: 0



Positive Media Sentiment (SAMPLE DATA ONLY)

94.0%
Target: 90%

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

Title	How can we build on the Combined Ways of Working with the Health Research Authority to accelerate the approval of clinical trials?
Board Sponsor	Christian Schneider
Purpose of Paper	Discussion

How can we build on the Combined Ways of Working with the Health Research Authority to accelerate the approval of clinical trials?

1. Executive Summary

1.1 The UK response to COVID-19 resulted in a level of cross-system collaboration desired but never fully realised before. The benefits of this cross-UK and cross-research-ecosystem collaboration will be embedded in our operations moving forward and collaborative working with the Health Research Authority (HRA) is the first step toward this goal.

1.2 The MHRA has been developing closer working practices with the UK research ethics services and the HRA for several years. Since 2018, we have offered trial sponsors a single application route, a coordinated review to set timeframes, and a combined UK decision on a trial via the Combined Ways of Working (CWoW) project. To date 283 initial applications, 592 amendments and 40 end-of-trial notifications have been received through CWoW. This streamlining of the approvals system for clinical trials has improved start up times by 30% according to a major contract research organisation (CRO).

1.3 This project is set to complete by September 2021 with an ambition for all UK trials to be submitted and assessed via this route by the end of the year. This paper describes the evolution of CWoW, the progress made to date, and the proposed future ambitions and opportunities afforded by more collaborative working.

1.4 This work links to the Agency Delivery Plan and broader Government ambition to ensure we continue to have a world-leading regulatory system that supports both UK and global trials.

2. Introduction

2.1 Objective 3 of the Delivery Plan "*Overhaul clinical trials system to support innovation and reduce time to approval*" includes a number of objectives for delivery over the next two years. These are outlined below:

- Enhance the research services of the Clinical Practice Research Datalink: launch our "SPRINT" service to assist in the recruitment of patients, with first contract in place by Q3, 2021/22; and offer "SPRINT" services to companies as standard by Q2, 2022/23; and by Q4, 2021/22 achieve 1 in every 4 UK GP practices signed-up to the Clinical Practice Research Datalink.
- Encourage a more innovative and pragmatic approach to UK clinical trials via an initiative to facilitate the uptake of novel trial designs and a communication effort to tackle the misperceptions that "traditional" clinical trials are always required for a licence by Q4, 2021/22.

- Consult on options for changing UK legislation to make conduct of trials generating real-world data easier by Q4, 2021/22.
- Publish guidance on points to consider when using trial designs with a real-world data element to support a licence application by Q4, 2021/22.
- Deliver NHSX funded synthetic data research project by Q4, 2021/22 and launch prototype synthetic data generation service by Q2, 2022/23.
- Promote the Innovative Licensing and Access Pathway Novel Trial Design Tool in partnership with the wider health ecosystem by Q2, 2022/23.
- Deliver a work package that ensures that artificial intelligence as a medical device is underpinned by robust evidence to enable safer innovation Q1, 2022/23.
- Develop our use of Patient Reported Outcome Measures via involvement in the "Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data" international initiative from Q1 through to Q4, 2021/22; then work up deliverables in 2022/23.

2.2 Objective 4 of the Plan: "*Develop and deliver the agency's future strategy and approach for access to medicines and devices*", sets out our intention to ensure the UK becomes an even greater place to develop, manufacture and supply products; and that we have continued access to safe new medical products. The deliverables specific to clinical trials are:

- Integrate with the Health Research Authority and National Institute for Health Research Clinical Research Network to provide a fast track approval for defined clinical trials - criteria approval agreed by end Q2, 2021/22; expand pilot process providing a single decision on research using both a medicine and device to a wider cohort of applicants and develop a process for the combined review of a product by Q1, 2022/23.
- Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via the ACCESS Consortium (ie the medical product regulators of Australia, Canada, Singapore, Switzerland and the MHRA) by Q4, 2021/22.
- Further develop the Innovative Licensing and Access Pathway concepts and tools, in collaboration with the National Institute for Health and Care Excellence and the Scottish Medicines Consortium to create a world-class first port of call for medicines development and access by Q3, 2021/22.

2.3 This paper focuses on the collaborative and streamlined working with the UK research ethics services and HRA to improve efficiency, as well as future ambitions for closer working with healthcare partners to support the broader Government priorities of supporting innovation and building a vibrant life sciences sector, as outlined in the Life Sciences Industrial Strategy and Sector Deals, the "Build Back Better: our plan for growth" policy paper, the "Integration and innovation: working together to improve health and social care for all" policy paper and, most recently, "The future of UK clinical research delivery" vision.

2.4 Currently in the UK and EU, regulatory and ethics approvals are applied for separately - either in parallel or in sequence. The maximum timeframe for a decision is 60 days following receipt of a valid application (which may be extended for certain types of product). In our current statutory instrument, MHRA splits this 60-day window into 30 days for an initial review, 14 days for the applicant to answer questions raised (if any) and a final decision by day 60. We offer an expedited 14-day initial review time for Phase 1 healthy volunteer studies. Ethics Committees instigate a 'clock stop' if questions are asked and so the sponsor response time does not form part of their 60-day timeline. The application forms and submission routes for MHRA and ethics review are different and the varying timelines means that if one organisation requires a change to a protocol when another has approved, a 'vicious cycle' of amendments taking up to 35 days is required before a final protocol is signed-off.

2.4 It should be noted that the new EU Clinical Trials Regulations (CTR) (expected in January 2022) provides for, in general, a maximum timeframe of 106 days between submission of a clinical trial application and a regulatory decision and, in practice, approvals will only be as fast as the slowest Member State involved. The UK therefore has an opportunity to gain a competitive advantage with competitive timelines and enhance the attractiveness of the UK as a research destination.

2.5 In comparison, in the USA the review time for initial submission of an Investigational New Drug (IND) application is 30 days. An IND automatically goes into effect in 30 days, unless the FDA notifies the sponsor that the IND is subject to a clinical hold. The clinical hold order may be made by telephone or in writing and then no more than 30 days after imposition of the clinical hold, a written explanation of the basis for the hold sent to the applicant. Once a complete response to the clinical hold deficiencies has been received, FDA will review the submission within 30 calendar days and determine whether the applicant's response to clinical hold satisfactorily addresses the issues. There is no defined regulatory requirement for a standard timeline for Institutional Review Board (ethical) review of a clinical trial.

2.6 The variability in Ethics / Institutional Review Board timelines make international comparisons of approval times very difficult, however; it is clear that overall start-up times in the UK are not as competitive as they could be largely as a result of the time for costing, contracting and local approvals. To address this aspect a National Contract Value Review is underway to streamline the process of setting-up multiple research sites in the NHS.

3. Progress to date

3.1 Collaboration and integration between MHRA and ethics has come a long way. It was only via legislation implemented in 2006 that actually allowed the MHRA and an Ethics Committee to disclose information to each other to help in carrying out our respective functions. The first step to a closer relationship was in 2015 when we began exploring how MHRA and Ethics Committees might work closer together, initially to prepare for a statutory requirement under the new EU clinical trials regulation.

3.2 CWoW offers trial sponsors a single application and submission route, a coordinated regulatory and ethics review to set timeframes, and a combined UK decision on a trial. This offers multiple benefits to sponsors in that they can prepare their application within a single system, upload and submit supporting documentation which gets routed automatically to the relevant organisation and a single communication route via the Integrated Research Application System (IRAS). By September 2021 a trial sponsor will be able to manage the complete lifecycle of their trial via IRAS.

3.3 The initial CWoW pilot, launched in 2018, involved applicants providing their regulatory and ethics submission documentation via a Secure File Transfer System (EudraLink) which was picked up by MHRA who then distributed relevant documents to the Health Research Authority (HRA). The coordinated review was facilitated via emails between the organisations and to the applicant, with a final decision on the submission provided by day 30 (or day 60 if any questions were raised) following receipt.

3.4 The operational and strategic benefits of closer working between the regulator and Ethics Committees were quickly realised with the manual pilot, with closer alignment of ethics and MHRA assessments, and Ethics Committees taking assurance from the MHRA medical assessment report. Applicants reported elimination of duplication or contradiction in communication to researchers reducing the need for cycles of protocol amendments. Feedback from a major CRO involved in the project is that they have reduced start-up times by up to 30% on behalf of their sponsor organisations.

3.5 IT systems to support CWoW were developed in an uncertain political environment regarding the nature of the future UK relationship with the EU. Consideration had to be given to different EU Exit scenarios ranging from UK implementation of the EU CTR as part of the EU network (and therefore interfacing with the EU clinical trials information system) to the MHRA being a stand-alone sovereign regulator. This increased the complexity of the IT build from the outset.

3.6 As clinical trials of medicines constitute about 15% of the total research applications seen by HRA, it was agreed that a new part of the IRAS, developed by HRA on behalf of the IRAS Partners across the research ecosystem, would act as the UK entry point for applications in a sovereign system, and the updated MHRA case management system (Appian) would be

'fed' via this entry point. Updates to IRAS form part of a wider UK research systems replacement programme led by HRA on behalf of the IRAS Partners.

3.7 A planned IT release to support scale-up of the CWoW pilot in April 2019 did not go live as it did not meet agreed requirements. Remedial work was required which resulted in a minimum viable product going live in March 2020. This allowed a doubling of applications from 5.9 per month under the 'manual' process to 11.5 per month (from a potential of approx. 80/90 per month). A further improvement to the IRAS system in January 2021 has seen applications increase to 16 per month. Two further releases are planned (June & August 2021) which will provide full functionality to manage the lifecycle of a trial via the new systems: initial application, amendments, safety updates, end of trial declaration, submission of summary results.

3.8 Stakeholder engagement and communications have been well managed with a regular written update and fortnightly support teleconferences for pilot participants who ranged from NHS researchers, contract research organisations and large pharma. This regular feedback allowed us to understand stakeholder needs and priorities better, for example the ability to book a 'preferred' ethics committee rather than being assigned one as well as a wish for flexibility in response times when needed on the sponsors side. A company involved in the process has quoted: *"Overall we have seen a significant decrease in MHRA and REC approval timelines which has been welcomed by our clients; the pilot process was straightforward and fitted well into [the company] established processes"*

3.9 An example of the approval time saving using CWoW is illustrated below which shows both average time and ranges are improved (the range out to 114 days was at request of a sponsor rather than internal delays); however, it is critical to understand that the time saving benefits of CWoW go beyond the assessment timeframe. The streamlining in preparation of a single application, a single route of communication and removal of cycles of discussions and amendments all provide benefits to trial sponsors. As we scale up the number of applications coming into CWoW we will be gathering further evidence on the overall benefits of this process.

	Phase 2-4 CTIMP (days)		**Phase 1 CTIMP(days)**	
	Mean	Range	Mean	Range
CWOW applications (no request for information)	29.3	28-30	22.8	17-29
CWoW applications (with request for information)	58.5	34-114	41.0	23-56
Non CWoW application (REC)*	91	20-292	34	13-134

*Figures are elapsed end to end including applicant response time. * Non CWOW data relates to REC timelines only as these are usually the longer but do not take account to scenarios where applicants apply sequentially to MHRA and REC. REC data from comparison is from period 1.4.19 – 23.9.19 only*

3.10 Since CWoW was initiated to prepare for an EU statutory requirement, initial patient and public engagement was via the public consultation on the legislation. More generally, we have heard a clear message from patients that approvals should be made less complicated and at a Patient Group Consultative Forum in January 2020 (not specifically on CWoW) patient representatives with experience in trial applications and approvals welcomed more joined-up working between MHRA and HRA. It should be noted that our pilot project that puts patient involvement at the heart of clinical trials and medicine development that was launched in March includes CWoW applications and the IRAS application includes fields to capture patient involvement.

3.11 In preparation for scale-up of the CWoW process, a communications and change management plan is in place to support all clinical trials applications being processed via combined working by the end of 2021, including reaching out to the wider public.

4. Strategic Ambition

4.1 Combined working aligns closely with the government's vision for the future of UK clinical research delivery. A key theme in this vision is streamlined, efficient and innovative research so the UK is seen as the best place in the world to conduct fast, efficient and cutting-edge clinical research. A key short-term ambition is to make combined working business-as-usual for all applications by the end of 2021.

4.2 From a systems perspective, we want to refine the initial CWoW solution to provide further streamlining, for example by reviewing the application data set which is based on the EU application form and simplify to align with other UK research approvals, thereby reducing bureaucracy and duplication. This will form part of wider UK research system upgrades and establish IRAS as a world-class hub for health and social care research in the UK, offering smooth and intuitive access to research approval, study management, best practice guidance and lay-friendly information about the results of all health and care research studies taking place in the UK.

4.3 Streamlined approval is only useful in the context of streamlined delivery of research and therefore close integration with the National Institute for Health Research (NIHR) and NHS is needed. The costs to MHRA (and HRA) for incremental improvements in approval times will be disproportionate until the blockers to trial set up are addressed. Via the UK-wide clinical research Recovery, Resilience and Growth Programme, we are working with colleagues to develop a workstream that will explore how a rapid end-to-end delivery approach can be delivered sustainably and at scale. This work will help drive the MHRA Delivery Plan theme on leveraging UK healthcare system partnerships and integrating processes to drive better outcomes.

4.4 The Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access. In order to fully realise the value of this pathway we want to ensure that we integrate the benefits of UK combined working and streamlined research delivery into the 'pull through' ILAP provides for licensing and patient access.

4.5 A further ambition is to extend combined working beyond trials of medicines. The MHRA Delivery Plan for 2021-2023 includes an action to expand the MHRA pilot process providing a coordinated decision on research using both a medicine and device to a wider cohort of applicants. However, for this process to reach its full potential, integration with ethics approval and integration into the combined ways of working process is necessary. As part of this work we will also streamline the application data entry requirements to simplify the process and reduce duplication.

4.6 A key facilitator of the UK COVID-19 response has been our support for innovative trial designs. We provided early engagement and advice services on trial design and conduct as well as any proposed regulatory flexibilities to facilitate efficient delivery of research. The MHRA Clinical Trials Unit (CTU) has been supporting and advocating the use of innovative designs for a number of years, including running a 2-day workshop in October 2020 attended by over 500 participants including commercial and non-commercial sponsors, contract research organisations (CROs), investigators, universities, charities and other regulators. In 2018 and 2019 MHRA approved 20 and 19 innovative trial designs, respectively. In 2020 this figure increased to 42 approvals, 14 of which were for COVID-19 trials.

4.7 Moving forward, working in collaboration will help enhance this offer, not only with HRA and the NIHR but via ILAP to ensure that trials are designed up-front to deliver 'actionable' evidence and will support both licensing and health technology assessment requirements for patient access. This work should take account of ICH development work on new guidance for Adaptive trials (ICH E20) which is due publish the 1st draft in November 2021.

4.8 While extensively used for monitoring the performance of drugs and devices after approval, real world evidence (RWE) is utilised much less frequently when it comes to demonstrating the efficacy or effectiveness of an intervention to gain an initial approval or an extension of an indication for an existing product. However, there is great potential for the use of RWE to increase the speed and reduce the cost of development programmes, which would see effective medications being approved more quickly, or even programmes which were previously thought to be unfeasible becoming feasible, with the consequent benefit to public health. The MHRA has made initial moves to encourage greater utilisation of real world data (RWD) by publishing guidance on performing randomised trials using RWD. This will be the first in a series of guidelines which will make explicit the regulatory interest in trials using RWD to support approvals which should stimulate interest from Sponsors who may have wondered about the regulatory acceptability of such approaches.

4.9 Remaining a globally attractive centre for clinical trials will be essential moving forward. While we have ambitious and innovative plans for the future we do not propose to deviate from internationally recognised standards; rather, we have an opportunity to be more agile and risk proportionate in our approach to ensure we remain as a preferred location to place multi-national trials. We also have the opportunity to take a leadership role in facilitating international harmonisation of protocols and pragmatic regulation via our membership of the International Coalition of Medicines Regulatory Authorities and the ACCESS Consortium.

4.10 Some of our ambitions will need legislation to help realise them. Work is ongoing to develop proposals to improve and update the regulation of clinical trials, including legislative changes to the Medicines for Human Use (Clinical Trials) Regulations 2004, using powers under the Medicines and Medical Devices Act 2021. We are aiming to ensure better research transparency, risk proportionate requirements, greater accessibility for patients, as well as a legal basis for streamlined approvals. We are also looking to modernise the trial terminologies in our legislation to reduce any confusion or duplication for multi-country trials. The aim is to help drive more effective delivery of trials, informed by global best practice and harmonisation of key functions. We want to ensure flexibility and risk-proportionality to support innovation in trial design and streamlined processes to support rapid set up of trials, whilst maintaining the highest standards of safety for trial participants and ensuring reliability of trial results.

5. Recommendation to the Board

5.1 The Board is asked to consider the discussion paper and propose other opportunities to accelerate the approval of clinical trials in the UK.

Christian K Schneider
May 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

Title	How is SafetyConnect going to improve the safety monitoring of all medical products?
Board Sponsor	John Quinn
Purpose of Paper	Assurance

How is SafetyConnect going to improve the safety monitoring of all medical products?

1. Executive summary

1.1 This paper sets out the work of the SafetyConnect Programme which is delivering one of the Agency's key objectives to have a more responsive safety surveillance system for all medical products, to keep patients safe.

1.2 SafetyConnect is making a range of changes to improve how we monitor safety. We are:

- enhancing how patients report suspected adverse incidents to us and how we engage and provide feedback
- introducing new cutting-edge technology for all our incident management and signal detection utilising automation and machine learning
- creating a new world leading vigilance service by introducing common ways of working across all vigilance activities and medical products.

1.3 The Agency Board is asked to note this report for assurance and recommend any other opportunities to improve safety monitoring.

2. Introduction

2.1 The public and patients have rightful expectations of the safety of healthcare products and involvement in decisions about their use. The Agency's vision is clear: to protect and improve patient health by enabling the earliest access and high-quality supply of safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

2.2 In the Independent Medicines and Medical Devices Safety (IMMDS) Review, Baroness Cumberlege highlighted areas of vigilance which need strengthening and gaps in the health system but most important of all, a failure to listen to and respond to patients. Recommendation six of the IMMDS Review states: *The MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.*

2.3 Our response to the recommendation of the IMMDS is to embed changes into our everyday practices to ensure that our responsibility to patient safety is the frame for all our decisions.

2.4 The Agency has put patient and public involvement at the heart of its Delivery Plan (2021-2023), ensuring that we put patients first across the full range of things we do and lifecycle of the products that we regulate.

2.5 The Agency has been working on a large programme of work which is making improvements to how it undertakes safety monitoring (vigilance). Patients have been consulted from the beginning of the programme, and through workshops have helped us shape our deliverables, particularly regarding the Yellow Card scheme and issues relating

to transparency. The name of this programme - SafetyConnect - was chosen by these patients and it is this programme that will be help us deliver Objective 6 of the Agency's Delivery Plan, by implementing an enhanced and more responsive reporting system.

PATIENT SAFETY Objective 6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe	**How SafetyConnect will help deliver this objective**
Continually improving our systems for identifying and acting on public health risk is essential to ensure we respond swiftly, effectively, and appropriately to any emerging issues of safety. The need for an updated adverse event reporting and medical device regulation were areas identified by the Independent Medicines and Medical Devices Safety Review. We will deliver a more responsive system that detects and responds to signals of issues more quickly and enables greater interaction with reporters. Our efforts will ensure we keep patients safe and improve our service to patients and healthcare professionals.	Options appraisal for Yellow Card Biobank by **Q3, 2021/22.** Deliver enhanced signal detection process for medicines and devices by **Q4, 2021/22;** Service enhancement and international opportunities to be defined in **Q4, 2021/22** and delivered in **2022/23.**

Extract of the objectives being delivered by SafetyConnect from the 2021-2023 Delivery Plan

3. The solution

3.1 SafetyConnect is a comprehensive and transformative programme of work which will improve the Agency's ability to proactively monitor and act on patient safety concerns across the full-product lifecycle. This will be achieved through using common processes, ways of reporting, IT systems and data – creating a new integrated vigilance service.

3.2 Through the SafetyConnect Programme we are investing £10.6m on revolutionising our safety reporting and will complete the most important changes by March 2022.

3.3 The Agency started work on these improvements during 2020. We are implementing changes that will improve our service to patients, how we perform and how we work in partnership.

3.4 We took the decision to deliver a number of the SafetyConnect improvements early to help with the Agency's response to the Covid-19 pandemic. This included the development of a vigilance pandemic portal (Coronavirus Yellow Card) which helped the Agency quickly meet the challenges of safety monitoring and reporting during the pandemic. It has delivered an enhanced passive surveillance system for reporting incidents for both medicines and medical devices.

3.5 We have introduced artificial intelligence and machine learning when we process reports relating to the Covid-19 vaccines. This has helped us manage the number of Yellow Card reports and monitor safety during the pandemic, which saw the Agency receive 250,000 suspected adverse drug reactions so far this year (Jan-Apr 21) compared to the usual volume of between 40,000 to 45,000 a year.

3.6 In December 2020, as part of the Agency's pharmacovigilance strategy for coronavirus, we started to actively follow up and monitor patients who had the Covid-19 vaccine. This was enabled by the introduction of an active surveillance platform which was created for patients to register prior to vaccination. This allows patients to later log side effects, for MHRA to request post vaccination follow up information over different time points and to analyse patient data. The technology was hosted on existing infrastructure and was delivered through the Coronavirus Yellow Card site project, but several specific enhancements were required. This included amended user journeys; to enable registration prior to experiencing side effects, which was delivered through the concept of 'partial reports' and by improving our communication channels; to facilitate follow up by email, SMS or push notification.

3.7 The Vigilance Hub, which is the yellow card back-end platform and enables the Agency to control features such as report configuration, news and content, has also undergone development. It offers the ability for content to be presented through multiple channels, whether app, web or integration to other systems. We have also developed the ability to customise report configurations and have introduced enhanced analytics.

3.8 This provided early delivery of some elements of the SafetyConnect programme, including the technical changes to our website front-end server and the introduction of a Contact Management System (CMS). This gives us some new features such as being able to customise reporting forms for different medicinal products, having a single CMS hub and allowing website content to be easily edited and modified.

3.9 We have also been researching new methods for signal detection for medicines and vaccines comparing a number of different approaches to identify potential safety issues. For each method we will be computing signal scores and conducting a qualitative evaluation of the methods to compare the balance of true and false positives returned for each method. We will be analysing vaccine specific methods and looking at custom groupings of adverse event terms in order to determine if we can identify novel issues we may not previously have seen before. From the analysis we will be able to identify our algorithms of choice as well as identify optimum settings for thresholds and parameters in order to enhance our signal detection capability and deliver significant improvement in early identification of adverse events across medicines and vaccines.

3.10 Similar signal detection research is being conducted into the best methodologies for medical devices. Once complete, the implementation of this work coupled with increasing data capture via device registries and other data sources will greatly improve our safety surveillance capabilities on medical devices.

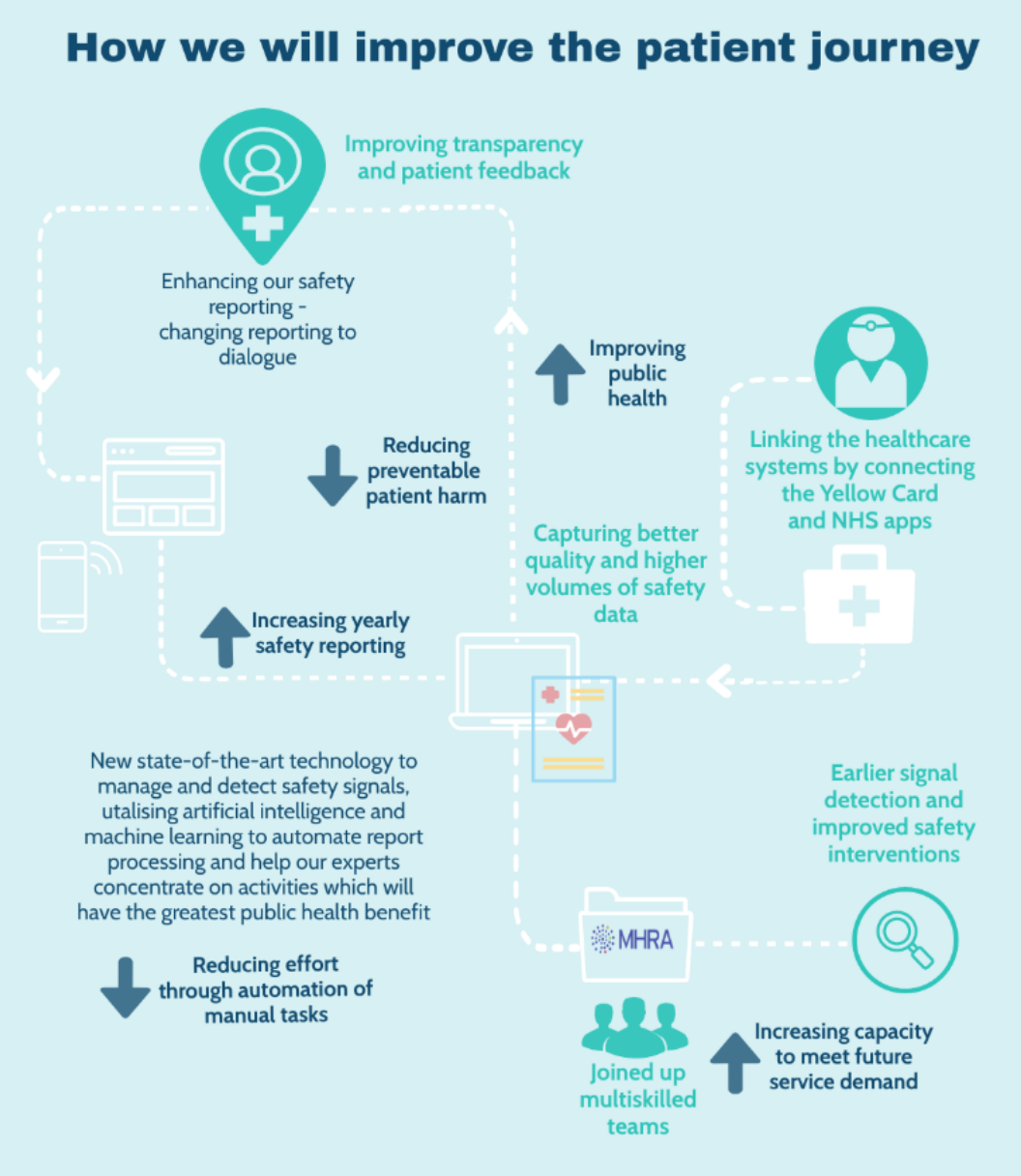
3.11 We have also now completed the procurement and are starting implementation of our new vigilance IT systems which will transform how we manage and detect safety signals. This new state-of-the-art technology will employ automation, more efficient processes and economies of scale as a result of integrating the management of vigilance for all products into the one system. This new system will help our experts concentrate on activities which have the greatest public health benefit.

3.12 Our work on ensuring medical products are safe is not limited to the UK, the Agency collaborates with a range of partners to improve safety internationally. We are working to assist regulators worldwide and are currently supporting the African Union Development Agency and the medicines regulatory agencies of Ghana, Nigeria, South Africa and Ethiopia to help them undertake signal detection and monitor vaccine safety during the pandemic. This is being done through our grant from the Bill and Melinda Gates Foundation. Through partnerships like this we are able to gather a wider range of data to identify safety issues earlier for the benefit of vaccinees wherever they are.

4 How SafetyConnect will improve safety monitoring from a patient's point of view

4.1 As part of the SafetyConnect Programme we are making a range of improvements to how patients engage with us, from how they report suspected adverse reactions and incidents, how we keep them informed, the technology we use and how we operate our service.

4.2 The diagram below illustrates the key changes we are making.



4.3 SafetyConnect will be implementing a new Yellow Card reporting system which will further improve the Agency's safety monitoring capability. It will focus on delivering enhanced reporting and patient-friendly forms for all medical products including medicines, devices, defective medicines, counterfeit medicines, E-cigarettes and blood products. This all being in one system will have the advantage of removing uncertainty for patients about what form should be selected for their issue as well as provide instant feedback and information about products of interest.

4.4 The reporting experience will be improved through the introduction of interactive smart forms; better processes for providing long term follow-up information and enhanced two-way communication. The information provided by patients will facilitate data driven regulatory action, allowing the MHRA to efficiently respond to safety issues that are of concern to patients.

4.5 We want a user-friendly, accessible, and transparent repository of adverse event reports and we are using feedback from patients and healthcare professionals to achieve this. Work has begun to make it easier for patients to report, make updates to their reports and to find out more information about products they are interested in. Enhanced features will include integration with other systems for example to look up postcodes and link to the NHS organisational information.

4.6 Our reporting forms will be improved to provide uniformity across all report types and medicinal products, better structuring of questions and improved visual impact. It will provide indicative timescales and show the percentage of the report completed at any given time, it will also offer the ability to add attachments and provide improved help functions.

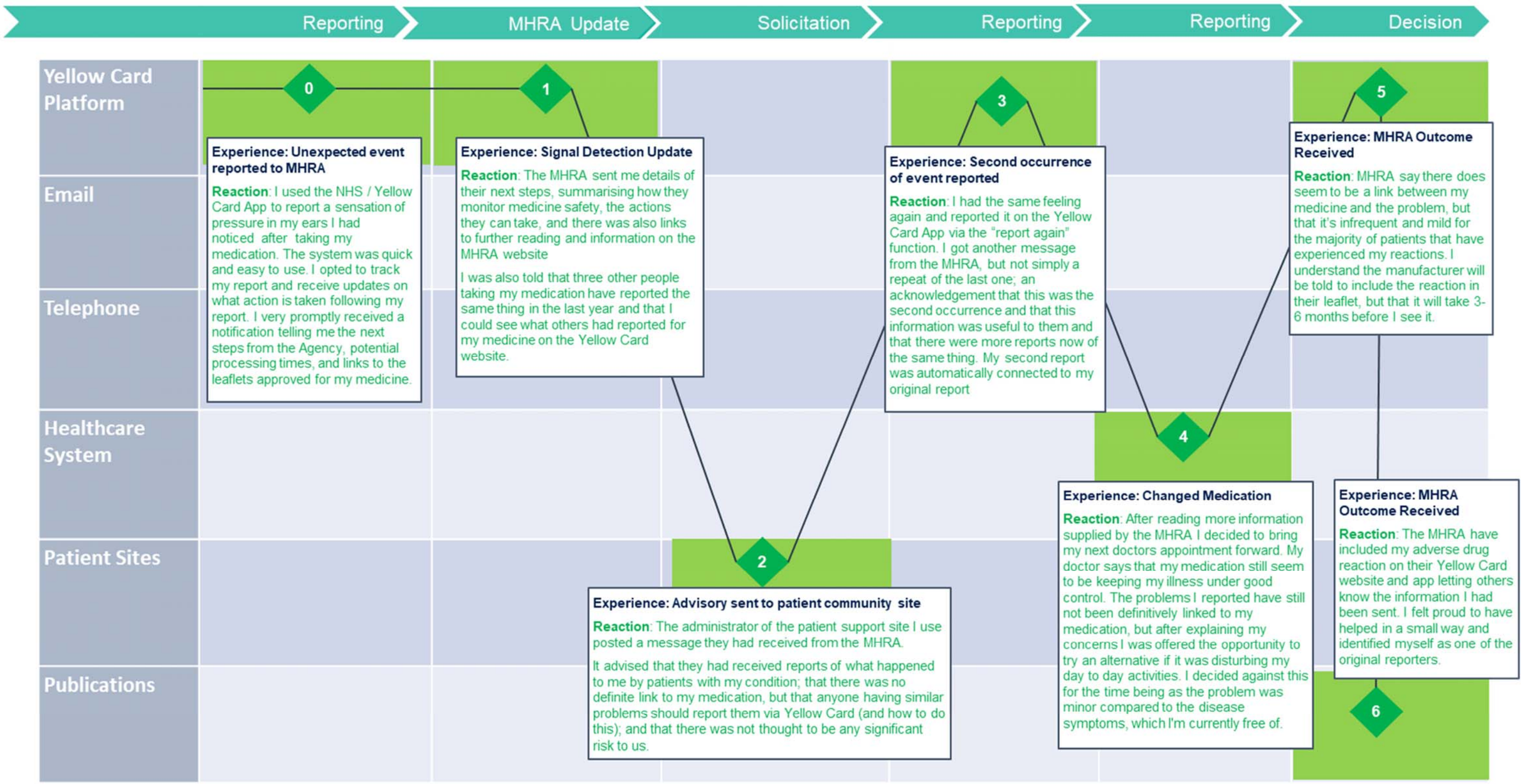
4.7 Engagement with patients and healthcare professionals has been a key area for development. There will be greater transparency for patients and healthcare professionals via two-way communication which will include visual displays of data of interest based on the forms they have submitted. It will focus on recognising the patient's contribution to the Yellow Card Scheme and will acknowledge their report, provide status updates as well as feedback with links to relevant safety communications and data. There will be an overall increase in access to useful information such as data for specific settings, signal summaries relating to reported products and devices transparency data.

4.8 The design and delivery of these changes involves patients and healthcare professionals in identifying what improvements are needed and to test prototypes and concepts as they are developed. Last year, we conducted webinars with patients to tell them about our ambitions, and to gain feedback about how we can improve our Yellow Card scheme.

4.9 We have conducted one-to-one sessions to get specific feedback about the active surveillance Vaccine Monitor prior to the go live of the system to ensure that it meets our user's requirements. Consultation and the involvement of patients affected by the changes we are making will be continuous throughout the design, development and user testing.

4.10 The Yellow Card enhancements have been completed in part via work carried out as part of the Agency's response to the pandemic but will be further developed with new the functionality being delivered in Q3 of 2021.

4.11 Patient journey for a new adverse reaction



5 How SafetyConnect will improve safety monitoring from an internal MHRA point of view

5.1 Through the SafetyConnect Programme we are redesigning our services and ways of working with the patients' journey at the core of what we do, accounting for the patient experience at all key stages. We will keep using feedback from patient groups and healthcare professionals to continuously improve and shape how vigilance activities are carried out.

5.2 We are improving our service to be able to detect signals quicker and be more responsive so we can provide a better service to our customers.

5.3 We aim to increase patient and public safety by having dedicated function to facilitate meaningful patient interactions and engagement, working with health system partners, sharing insights and resources.

5.4 We will integrate with other data sources and incident reporting systems; a key priority is PSIMS (Patient Safety Incident Management System) being developed by NHS Improvement. Successful data integration will mean one-time reporting of and real-time flow to the MHRA vigilance system.

5.5 There will be significant improvements in the Yellow Card and Vigilance Hub system's account management functionality which was one of the key areas of feedback from healthcare professionals. This will offer the ability to:

- update reports with further information,
- link accounts across teams for example doctors within a GP practice,
- provide enhanced visualisation of data,
- offer a report search functionality for frequent reporters,
- allow the management of data/products of interest,
- increased access to relevant safety communications and
- provide the ability to export and share their own reports within organisations.

5.6 We are changing how we manage our safety monitoring activities making sure our specialist teams can work together across all types of medical products to detect and respond to all safety signals, whether it relates to medicines, medical devices, electronic cigarette, blood or blood component, clinical trials or suspected defective or counterfeit products. This will result in improved patient safety through earlier signal detection and improved safety interventions and provide a consistent and trusted "one" voice on safety matters.

5.7 The main benefit of the improvements we are putting in place is how they help improve public health and reduce preventable patient harm but the programme is also expected to achieve £2.34m cashable benefits in cost savings, and £1.35m in non-cashable cost avoidance savings over its 7-year term.

	Programme term 7 years							
Benefit name	**19/20**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**25/26**	**Total**
Common integrated vigilance service	£0	£0	£0	£480,000	£480,000	£480,000	£480,000	**£1,920,000**
Proportionate approach to safety assessments	£60,000	£60,000	£60,000	£60,000	£60,000	£60,000	£60,000	**£420,000**
Total:	**£60,000**	**£60,000**	**£60,000**	**£540,000**	**£540,000**	**£540,000**	**£540,000**	**£2,340,000**

Summary of the cost savings cashable benefits

5.8 The cashable benefits are expected to be achieved through reducing, and in some cases eliminating, the effort needed to undertake manual case data entry by introducing automation in our new IT systems. This will reduce the resource required to carry out some functions and also enabled us to move resource to signal assessment. The non-cashable benefits have been achieved through avoiding most of the cost of additional surge resources that are needed to managed the large increase in reporting during the pandemic This was achieved by introducing artificial intelligence and machine learning technology to help process reports of suspected adverse reactions with COVID vaccines.

5.9 The Agency is already recognised as a world leader in detecting and responding to safety signals, but these changes will help us continue to respond to the changing world and product market and improve safety not only in the UK but internationally.

6 When will these changes be delivered?

6.1 We started this work in December 2019 and in 2020 we prioritised implementing the improvements that would help the Agency's response to the Covid-19 pandemic. We are now using this work as a blueprint that can be rolled out further.

6.2 We aim to have most of the improvements in place by March 2022 and are prioritising our public facing enhancements to the Yellow Card scheme earlier and are planning for these to be delivered in Q3 2021 after testing our prototypes of the changes with patients and the public.

6.3 Below shows a timeline of some of the key milestones in the SafetyConnect Programme.

SafetyConnect Programme key milestones

7 Recommendation

7.1 The Board is asked to note this report for assurance and recommend any other opportunities to improve the safety monitoring of all medical products.

John Quinn
Board Sponsor
May 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

Title	What are the communication priorities to build public and stakeholder trust in the MHRA?
Board Sponsor	June Raine (delegated to Rachel Bosworth)
Purpose of Paper	Approval

What are the communication priorities to build public and stakeholder trust in the MHRA?

1. Executive Summary

1.1 This paper sets out a high-level communications and reputation strategy for the Agency and proposes communications priorities to build and enhance public and stakeholder trust, for the Board to approve.

1.2 The Agency is transforming, and the Delivery Plan 2021/23 sets out a clear vision and road map that is a core driver for this strategy, putting the patient at the centre of everything we do.

1.3 The communication and reputation strategy aims to refocus the way the Agency communicates with all its stakeholders with a particular focus on patients and the public, building on our greatly increased profile and recognition during the COVID-19 pandemic.

1.4 Our insight tells us that we need a fundamental shift in the way we engage and involve patients and the public. We need to improve two-way communications and to speak consistently in a language and tone that is friendly, transparent and reassuring. We need to better recognise diversity and build trust across different communities and geographies. Investment in new digital services, underpinned by user service design, offers us more opportunities to achieve two-way communications using improved digital channels.

1.5 We have made progress with our public, patient and involvement strategy recently agreed and shortly to be published for final consultation. We are also about to consult healthcare professionals to develop a new strategy that focuses on how we communicate, engage with and involve them, including on the benefit / risk of the products we regulate. These strategies support our overall communications and reputation strategy.

1.6 This is a communications and reputation strategy for the whole Agency so every member of staff has a role and responsibility in ensuring that their day-to-day interactions at every level, with every audience, meet our aspiration and vision for communications, engagement and involvement. To help achieve this we will develop customer care training for all staff and back this up with a patient and public care charter, setting out the service levels we will aim for and expectations from all our staff.

1.7 COVID-19 has shone a light on the Agency and increased its public profile. Our name and our brands, such as Yellow Card, are becoming more familiar with the public. A challenge for us is to maintain this level of profile and relevance as the pandemic declines.

1.8 To achieve this we have set out an ambitious statement of what we want to be known for, and clear objectives and priorities which we are asking the Board to approve.

1.9 Key to this strategy is measuring whether outcomes are delivered, and we are putting in place robust mechanisms to do this. We recognise we need to do more to demonstrate how the Agency will achieve the patient and customer outcomes set out in this strategy. We aim to develop metrics to measure outcomes, and these will straddle other objective areas in the Delivery Plan 2021/23, which may also be reflected in the Agency's new balanced scorecard.

2. Introduction

2.1 This communications and reputation strategy has been developed to support the Agency's Delivery Plan 2021/23. We are grateful for the comments and input from the Patient Safety and Engagement Committee at an earlier draft stage.

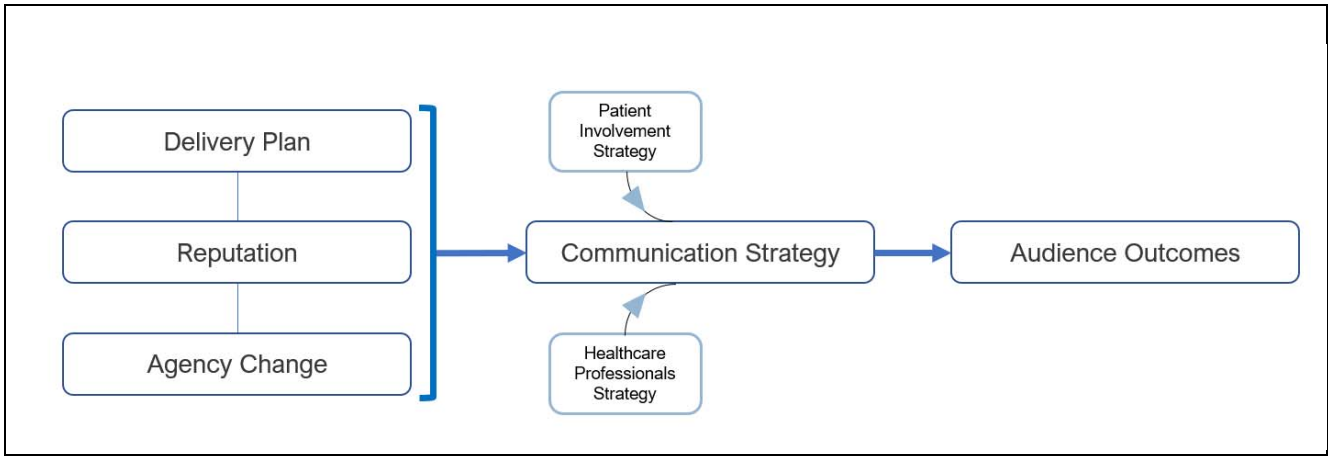
2.2 The strategy is set out in three sections: Where we are now; Where we want to be; and How we are going to get there.

3. Where we are now

3.1 The Agency's vision in our new Delivery Plan is '*to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits'*.

Drivers for our communication and reputation strategy

3.2 The chart below shows the key drivers for our strategy and how the patient involvement and healthcare professionals engagement strategies feed into the overall communications and reputation strategy, leading to audience outcomes.



3.3 The vision and Delivery Plan 2021/23 objectives are core drivers for this strategy. The strategy directly delivers objective 12 in the Delivery Plan to: *Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications*.

3.4 We will deliver a programme of proactive and innovative communications to support the delivery of all relevant Delivery Plan objectives. This will have a particular focus on ensuring we put patients first, ongoing COVID-19 communications, prompt communication of safety issues and enhancing the operation of our new Customer Service Centre. We will involve patients, the public and stakeholders in co-designing our new systems and processes.

3.5 This will help build public and stakeholder trust and support the delivery of wider objectives which are to:

- Develop and deliver communications to support the launch of new and ongoing activities (products, services, campaigns and issues) throughout 2021/22 and 2022/23 (this covers all communication deliverables in the plan).
- Publish our Public Involvement Strategy, which sets out how we can best include patients in our work by Q1, 2021/22
- Issue ongoing, prompt and responsive safety communication action (COVID-19, Yellow Card, Safety Connect, #FakeMeds, safer medicines and devices for women, drug safety issues, reclassifications, product alerts and notifications) throughout 2021/22 and 2022/23.
- Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from Q1, 2021/22.
- Enhance our Customer Service Centre to support effective two-way engagement with patients and customers, enabling them to access the information they need when they need it from Q1, 2021/22.

Within each of these objectives there are detailed plans and timelines.

Stakeholder insight

3.6 We have drawn insight from a range of sources to inform the priorities in this strategy. This includes:

- Interviews with key stakeholders, including patients' groups and industry bodies in April 2021
- Feedback on a working draft from the Patient Safety and Engagement Committee in April 2021, including two lay members
- The Independent Medicines and Medical Devices Safety review, 2020
- Brand and media sentiment reviews, 2020/21
- People Survey 2020 and transformation staff communications feedback, 2021
- Feedback from an extensive patient and public consultation in 2019 that informed the patient and public involvement strategy
- Evaluation and benchmarking of communications and marketing campaigns

3.7 The key insights are:

- We are generally seen by industry and partners as high-performing: expert and influential, open and collaborative, trusted to deliver and providing relatively good value for money, and becoming more open and outward-looking
- However, we are seen as cautious about change and as something of a 'black box'

- We need to demonstrate more clearly how we are putting patients and public at the centre of our work and taking their concerns seriously. *"If patients and public are to be involved in the Agency's work and decisions, there needs to be some evidence that the input from the patients… will be taken seriously and acted upon" (Patient verbatim from Public Consultation 2019)*
- We must build on the increased patient, public and healthcare professional profile through COVID-19 pandemic, both of MHRA generally and Yellow Card. *"From a public perception it may be unclear what the roles of NICE/MHRA are and how they are different… Generally, the public have a very limited understanding of medicines regulation and how it applies to them and the medicines that they are prescribed." (Patient verbatim from Public Consultation 2019)*
- We need to do more to ensure stakeholders are aware of the broad range of services the Agency provides
- We should focus on the UK being a good place to do business by building on our global reputation for excellence, to reach new markets and develop new services
- We should do more to join up and work in partnership with government departments and health providers
- We have high levels of staff engagement and commitment and are generally viewed as having done a good job in the pandemic
- Uncertainty around organisational change and transformation is concerning many staff.

Gathering audience insight is a constant effort and we will do this regularly through the evaluation of outcomes which we will feed into our communications and reputation strategy, adjusting where required.

4. Where we want to be

4.1 This part of the paper sets out where we want to be. It focuses on:

- Our reputation and what we want to be known for;
- Our analysis of audience needs so we have a clear view of what needs to change to build greater trust; and
- How we can recognise and be sensitive to the tone and language we use when communicating and involving.

Agency reputation – what we want to be known for by 2023

4.2 The Agency's vision is: *to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits*.

4.3 In delivering our vision, we will build on the increased awareness created through the COVID-19 pandemic and develop our reputation and profile to be recognised as:

- A trusted and transparent agency that delivers for patients: Relentless patient and public focus in all our work, involving patients, the public and stakeholders in the co-design of our services and in decision making, and speaking in a tone and language that is clear and engaging for diverse communities

- The trusted source and key provider of up-to-date information for decisions about medicine, vaccine and medical device use and safety, for patients, the public and healthcare professionals
- A proactive global leader in the regulation of medicines and medical devices, including biological medicines, vaccines, diagnostics, standards, blood and blood products, and data for research
- A key player in the UK health and social care system – an integral part of the health landscape, known for working collaboratively and in partnership with others and for our major impact on people's health
- A major contributor to UK life sciences and economic growth, through our support for innovation.
- An outward-facing agency which engages and keeps its staff informed and motivated; attracting and retaining the best talent.

Audience needs

4.4 We have segmented our key audiences and used the above insights to confirm their needs, understanding this is two way - what they want from us and we want from them – which enables us to better respond:

Audience	Needs
Patients	Easy, quick access to dynamic real-time information. Transparency around product use and safety, expressed clearly and simply so that patients can make informed decisions about their healthcare. Greater involvement and influence on decision-making. Assistance to navigate system.
Public	Trust, transparency, dynamic real-time information, confidence in regulated product use and safety in a language and tone that is clear and easy to understand.
Healthcare professionals	Information, guidance, clear and up-to-date advice to support patients to make informed decisions about their healthcare
Industry	Responsive, pragmatic, listening, clear guidance, signposting to products and services
Government, political and other regulators	Effective, transparent, working in partnership, part of the solution
Staff	Clear vision for One Agency, engagement and to feel valued
Health and social care system, NHS	Collaboration, joint aims and ambitions, partnership and joint working
Academia and research	Support, guidance, open dialogue and collaboration
Media (audience and channel)	More proactive, open, transparent, responsive

All of these audiences have a UK dimension, but some have international dimensions too. These audiences are segmented further as necessary in strategy implementation.

Channels and tone

4.5 A core outcome from our communications and reputation strategy is to create better two-way communication and engagement between us and all our audiences, and particularly with patients and the public. Two-way communication is a dialogue where messages are listened to, understood, responded to and the required action then taken by both involved in the dialogue. Using the right or preferred channel is important, as is the tone and language used. The tone needs to be suited to the receiver, and the language accessible and appropriate for the diverse audiences. This will include greater use of two-way digital communications, video and availability of information in different languages, etc.

4.6 We use a range of direct and indirect communication and engagement channels, depending on audience needs. We communicate directly with patients and the public through social media, websites (particularly gov.uk and the NHS website), our Customer Service Centre, the Yellow Card scheme and communications campaigns. Our Patient Group Consultative Forum is an important forum for engagement with patients and patient groups, and we are developing this further to broaden engagement and representation, and to work with us in co-designing our services. We will continue to communicate extensively through the media, healthcare professionals, charities and patient groups.

4.7 Our safety alerts and information for healthcare professionals are available digitally and via cascade systems through the health system, and our Yellow Card system enables healthcare professionals to report direct to us or via GP systems. Our conference programme for industry informs them of regulatory requirements and developments, and proactively markets relevant services such as the Agency's Innovation Office and the availability of biological and chemical reference standards for industry use.

4.8 We work in partnership and collaborate with other regulators, and other organisations in the health and care system, with Government and the Devolved Administrations, and with academic partners, where we are putting greater emphasis on joint scientific publications.

4.9 We use our effective internal communication and engagement channels to encourage staff engagement in the Agency's priorities.

4.10 The tone of and language used in our communications needs to be more audience specific. For patients and the public, the tone needs to be more welcoming, personal, understanding and listening. For healthcare professionals, we need to provide more of our information in a way that is able to be used for their direct communications with patients and the public. Regulatory communications with industry, including guidance on complex regulatory requirements, need to be clearer and more easily understood. For all audiences, we should communicate clearly and consistently, in a way that makes often complex requirements and issues more accessible, with a greater use of graphics and summaries to aid understanding.

Strengths, opportunities, benefits and risks

4.11 Understanding the strengths, opportunities and risks around how the Agency communicates with its audiences is important in helping us determine the communications priorities for the next two years, in support of the Delivery Plan 2021-23:

Audience	Strength	Opportunity/benefits	Risk
Patients	COVID led to greater awareness, improved in last 2-3 years, but more to do. Medicine or device specific awareness based on use/ experience	Greater involvement. Product safety assurance and transparency, build on brand recognition. Clarify difference between lay and patient agendas. Provide dynamic real-time information (eg COVID). Recognition and understanding of diverse needs and preferences. Accessible language. Introduce patient and public care charter. Change the way we handle and learn from complaints. Introduce greater two-way digital engagement including chat functions for contacting Customer Service Centre. Customer care training for all staff. Progress opportunities for services to be co-designed with patients.	Awareness will decline as the pandemic decreases. Need to focus on where we are relevant and not seen as just passing information on. May be seen as vaccine regulator.
Public	COVID led to greater awareness of Agency and Yellow Card	Confidence and transparency in the safety of the products we regulate. Build on brand recognition. Provide dynamic real-time information. Recognition and understanding of diverse needs and preferences. Accessible language. Introduce patient and public care charter. Customer care training for all staff. Use opportunity of digital investment to co-design services and create more opportunities for two-way engagement with public.	Awareness will decline as the pandemic decreases. Need to focus on where we are relevant and not seen as just passing information on. May be seen as vaccine regulator
Healthcare professionals	Good reputation with some professional areas	Use planned consultation to increase our understanding of requirements and channels, influence behaviour, build understanding of our role and relevance.	Our advice is not always acted on and our messages compete with other health agencies
Industry	Respected, good relationships	Market and promote commercial services/products, increase income, share our science.	Frustrations with regulations and market access post EU exit
Government, political, other regulators	Strong reputation, independence, especially since COVID	Build on higher profile to influence, enable greater partnership working across regulatory bodies.	Relevance declines post COVID. Ability and confidence to influence, still seen as a 'black box' by

			some key partners and stakeholders
Staff	High engagement and commitment to health and public service	Modernise culture and ways of working, employer attractiveness.	Lack of support for transformation and change, staff turnover
Health and social care system, NHS	Strong reputation, especially through COVID	Develop improved and more joined up communications and partnership, develop partnership management.	Ability and confidence to influence, still seen as a 'black box' by some key partners and stakeholders
Academia and research	Strong scientific reputation, collaboration	Sharing our science and collaborating.	Relevance of scientific research
Media (audience and channel)	Good contacts, greatly increased profile during pandemic	Need to be more proactive and promote more of our scientific work.	Relevance and media interest declines post COVID

Culture, values and behaviours

4.12 After extensive staff engagement, we launched our new values and behaviours in May 2020. These support our move to being One Agency – Delivering for Patients, with three values with supporting behaviours:

- We focus on patients and the public
- We work together with respect
- We take responsibility and are accountable.

4.13 Since the launch there has been a considerable amount of positive feedback from staff indicating a shift towards these new values. We are running a training and coaching programme for managers on the new values which has been attended by over 200 staff and this will be broadened further. The priority of focusing on patients and the public is important because this will help us build a more patient and public-centric culture which will support our plans for a patient and public care charter as we move forward.

4.14 The new values and behaviours are now ‘mainstreamed’ into our new performance scheme (appraisal), reward and recognition scheme and induction. Next year we plan to introduce an agency-wide 360 appraisal survey which will focus questions around the new values and behaviours, following a successful pilot this year. We are introducing a patient focused objective for all staff, and will consider broadening this to a communications objective too, recognising that effective communication and engagement is a responsibility for all staff.

Communication and message approval

4.15 The Agency's Communications division coordinates all the Agency's communications, sharing communications plans with the Department of Health and Social Care and Prime Minister's Office through the management of an established clearance process for all external communications across Agency. This applies to all announcements; campaigns; media engagement and consultations, which are cleared internally, with Ministers and then scheduled as part of cross-government planning, led by No 10. All new policy, guidance, events content and safety alerts must be cleared with the appropriate Minister; while generally local MHRA sign-off applies to business as usual regulatory communications.

5. How we are going to get there

Proposal

5.1 This part of the paper has proposals for the Board to consider, setting out how we are going to deliver this communications and reputation strategy. It includes high-level objectives, overarching priorities, tactics and how we will measure progress.

Communications objectives for 2021/23

5.2 We want to be the knowledge and decision-making partner for patients, the public, healthcare professionals and industry. To achieve this, we are proposing four ambitious high-level objectives that build on the Delivery Plan 2021/23, the audience insight and segmentation, and audience needs.

1. Proactively communicate, engage and involve, using the right tone, channel and tactics, with timely, clear, accurate, transparent and authoritative information which is recognised as important and acted upon, by patients and the public, healthcare professionals, and industry

2. Build brand and reputation awareness and understanding of the Agency as an independent, authoritative, trustworthy and efficient regulator and scientific and data expert which is focused on delivering for patients

3. Position the Agency as a global leader in the effective and efficient regulation of medicines and medical products, science and research, known for its collaborative approach

4. Ensure leaders and staff understand and align their efforts to the Agency's transformation, new vision and values, recognising that their interactions and communications with the public, customers and stakeholders directly influences the customer experience, our brand and reputation.

5.3 We will deliver these objectives through:

- **Patient engagement:** Deliver effective two-way engagement and involvement to embed patient input into and co-design our services – including user centred design for digital services - and decisions ensuring the patient is central to all the Agency's activities.

- **Safety communications:** Develop and deliver clear and effective safety communications to inform patients, the public, healthcare professionals, health system partners, stakeholders and charities about the use of medicines, vaccines and medical devices, and build trust in the Agency's advice.

- **Positioning the Agency as a global leader and managing reputation**: Develop marketing communications and branding that support positioning and marketing of the 'new' Agency, and its products and services, as a global leader, to support the building of income and development of global partnerships and collaborations.

- **Healthcare professional engagement:** Baseline healthcare professionals' understanding of the Agency and develop a proactive engagement plan to improve response to regulatory information and advice.

- **Internal communications and change:** Deliver staff engagement with the transformation programme through One Agency: Delivering for Patients communications and to communicate the benefits of One Agency change to external audiences.

- **Customer Service Centre**: Continue to build the Customer Service Centre to ensure the best services to patients, healthcare professionals and industry with a focus on new digital engagement mechanisms, greater consideration to tone, language and acting on feedback and complaints.

- **COVID-19 response**: Deliver the COVID-19 media and communications strategy and to manage issues regarding COVID-19 vaccines, diagnostics and therapeutics.

- **Consistently effective communication:** on a range of issues and topics, for all parts of the agency, including the effective handling of high-profile safety risks and issues, particularly those with the potential to attract media and public interest.

Summary of objectives and communications delivery

		Objective			
		1. Proactively communicate, engage and involve	**2. Brand and reputation**	**3. Global leadership**	**4. Staff comms**
Cross-cutting communications	**Patient engagement**	x	x		x
	Safety communications	x	x	x	
	Positioning the Agency as a global leader		x	x	x
	Healthcare professional engagement	x	x		
	Internal communications and change				x
	Customer Services Centre	x	x		
	COVID-19 response	x	x	x	
	Consistently effective comms	x	x	x	x

Implementation

5.4 The Communications Division leads the communications and reputation strategy but the whole Agency owns it.

5.5 At a strategic level, we will deliver the strategy by selecting the correct communications mix (channels, tactics etc) to:

- Achieve our communications objectives most effectively
- Gain the maximum impact with our target audiences for the resources available; and
- Deliver cost-effective results.

We will do this in line with the Government Communications Services communications frameworks and approach.

5.6 At a delivery level, the strategy is owned by the whole Agency, as every member of staff has a role and responsibility in ensuring that their day-to-day interactions at every level, with every audience, meet our aspiration and vision for communications, engagement and involvement. To help achieve this we will proactively promote the strategy to staff and reinforce it with, for example, customer care training for all staff and back this up with a patient and public care charter that sets out the service levels we will aim for and the expectations from our staff. Our new appraisal and reward and recognition schemes are focused around our three values, one of which is to focus on patients and the public.

5.7 Once the strategy has been agreed, we will develop a plan setting out how we will deliver it. This will form part of how we measure our progress against outcomes and future performance, reporting to the Patient Safety and Engagement Committee and the Board.

Measuring progress against objectives

5.8 We need to do more to demonstrate how the Agency will achieve the objectives in this strategy, as well as the audience outcomes that we have set for all of the audiences we engage with. This builds upon the outcome measures in the Patient Involvement Strategy. This approach is in line with Cabinet Office/GCS guidelines on evaluation. There are three component parts to our approach:

1. Reputation (The level of trust in our brand)
2. Delivery Plan (Effective communications to achieve delivery plan objectives)
3. Audience Outcomes (The difference we make as an organisation)

5.9 We will create a reputation index to gain a deeper understanding of how our audiences think and feel about our brand, and whether they trust us to deliver. Delivery Plan objectives will be translated into more focused communication objectives to measure and demonstrate the role of communications in achieving our plan. Finally, the audience outcomes we have set, stretch far beyond what communications alone can achieve, and it will be important to incorporate this into our measurement.

5.10 All parts of the Agency play a role in delivering these broader audience outcomes. All three of these will be part of our balanced scorecard.

5.11 Below are examples of metrics we will use to measure success:

- Follow Government Communications Service/Cabinet Office evaluation framework approach
- Introduction of a quarterly reputation index tracker as part of the Agency's balanced scorecard which could include:
    - Patient engagement index as part of agreed Patient Involvement Strategy (Omnibus survey)
    - Ongoing brand awareness reviews which will include spontaneous and prompted awareness, as well as a small range of attitudinal statements. (Omnibus survey)
    - Data and insight from campaigns evaluation and digital analytics such as likes, shares, open rates, dwell time.
    - Insight from medicine and devices issues, reviews, reclassifications etc
    - Media and social media sentiment
    - Customer feedback and data from the customer engagement centre
    - Measurement against a patient and public care charter
    - Feedback from reporting systems such as Yellow Card
    - Feedback from events (industry) and meetings (eg Board meetings and patient forums)

5.12 We will review the progress in implementing the communications and engagement strategy against Delivery Plan 2021-23 priorities and update the Patient Safety and Engagement Committee and the Board quarterly or at a regular frequency to be agreed.

5.13 This is a strategy for the whole Agency. Every member of staff will play a role in delivering it as part of their day-to-day activity and interactions with stakeholders. The resources of the Communications division will be directed to delivering the objectives and priorities set out in this strategy, and to supporting the cultural shift needed across the whole Agency.

6. Recommendation

6.1 The Board is asked to approve the objectives and communications priorities set out in this strategy.

Rachel Bosworth
18 May 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

18 May 2021

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

What assurance can be provided by the Audit and Risk Assurance Committee?

1. Executive Summary

1.1 This report sets out the Audit and Risk Assurance Committee's (ARAC) response to two actions assigned to it at the February 2021 Board meeting and summarises key outcomes from ARAC's meeting on 14 April 2021.

2. Action: Confirm that actions have been taken in implementing the recommendations of the Internal Audit report on Medical Devices

2.1 An Internal Audit report considered by ARAC at its February meeting assessed the framework which the Agency has put in place to ensure the successful implementation of the recommendations of the Independent Medicines and Medical Devices Safety Review. Internal Audit awarded limited assurance because of the need for greater clarity over specific responsibility for ownership of the implementation of each recommendation, their coordination and how their impact in strengthening patient engagement and trust would be assessed.

2.2 We were assured that implementing all of the recommendations that fall within the remit of the MHRA is being given priority. Patient safety is very prominent on the Agency's risk register for which the Chief Executive Dr Raine is the senior risk owner. Overall governance is being strengthened by the recent appointment of a new Chief Safety Officer. A dedicated senior responsible officer who is a Board member is a welcome development to help ensure effective coordination. Overall, we are confident that recommendations are being implemented but it is too early to be totally assured until there is sufficient independent evidence on the impact of the improvements in strengthening patient engagement and trust. The Agency is committed to widening its evidence base which will become part of routine reporting to the Board.

3. Action: To review the governance and risks of the medical devices regulatory framework.

3.1 The Agency has significant work in hand to determine the route to market in the U.K. for products to ensure the supply of safe medical devices when all devices have to comply with domestic legislation from June 2023. The Agency has to manage this transition over a relatively short time scale while ensuring the ongoing access to and safety of medical devices. A Devices Working Group chaired by the Chief Access and Quality Officer and project team members are overseeing the design and implementation of these changes. Strong governance will be essential over the transitional period and the new framework from June 2023.

3.2 Four generic requirements are usually needed for governance to be effective: reliable systems and processes; appropriate culture; comprehensive, reliable and timely information to mitigate risks to access and safety; and clear transparent accountabilities. MHRA has action in progress to strengthen each of these and inevitably some are more advanced than others. The new Delivery Plan puts patient safety at the heart of the Agency's culture; systems are being strengthened underpinned by legislation; information reporting and patient access should be enhanced by SafetyConnect; and as outlined in paragraph 2.2, governance is being strengthened with the new executive Board member responsible for patient safety.

3.3 ARAC is assured that the Agency is taking sustained action to strengthen the medical devices regulatory framework and its effectiveness will ultimately depend on how well the different components operate together. Over the coming year, ARAC and the Patient Safety and Engagement Committee will work together to provide more substantive assurance, particularly on how risks to patient safety are being managed as the design of the new regulatory framework is developed.

4. Other issues covered by the Committee

Financial Performance

4.1 The Agency's financial performance for 2020-21 is broadly as expected with a small increase in the planned deficit. We were assured that there are no going concern issues. The Agency has reasonable financial reserves and after 31 March 2022, when it ceases to be a Trading Fund, the MHRA will for funding purposes come fully within the Department's financial regime.

4.2 Given the significant effort which the National Institute for Biological Standards and Control (NIBSC) has and continues to contribute to combating the pandemic we questioned why this was not reflected in increased NIBSC expenditure. It is important that the full cost incurred by the Agency in responding to Covid-19 is transparent to inform future budget and investment decisions. We asked Finance to provide further assurance that expenditure is being appropriately allocated.

4.3 We asked about the implications of the change in the Agency's status once it ceased to be a Trading Fund and how this would be reflected in the Framework Agreement between the Department of Health & Social Care and the Agency. We were assured that a revised Framework Agreement would be brought to the Board in due course.

4.4 In August 2020 a query from Finance as to why some universities were not charged VAT led to a review, undertaken by Finance, of all VAT exempt sales by CPRD. The Agency sought the advice of HMRC which determined that all CPRD sales should be within the scope of VAT and that fees to universities should include VAT. This ruling is retrospective and applies to the last four years. The total value of the tax liability is £1.7 million. CPRD are seeking to recover VAT for 2020/21 (circa £150,000) but consider it unrealistic to seek recovery for the previous three years. Finance has made provision for the full amount of VAT and

interest payable to HMRC in the Agency's 2020/21 financial statements. ARAC was assured that appropriate action has been taken to avoid a recurrence. The Agency's VAT guidance has been updated and includes specific reference to CPRD fees and pricing treatment for charities. A Tax & Compliance officer (appointed as part of Finance Transformation) now provides support on all tax related matters.

External Audit

4.5 The external audit timetable remains on track to ensure that the MHRA can, in compliance with legislation, present its audited financial statements and annual report before Parliament recesses for the summer. The Agency is currently on schedule to present its final audited accounts to the Board at its meeting on 15 June, prior to signature by the Accounting Officer. The NAO and KPMG have yet to complete their final audit, but at this point no issues were raised with ARAC that should prevent a clear audit opinion.

4.6 It was noted that there had been improvements in the control environment. This had been achieved through the roll-out of the Oracle Fusion System, improved processes and training including finance business partners.

Internal Audit

4.7 We discussed a further iteration of the internal audit plan for 2021-22 and emphasised that this should provide assurance in four broad areas: financial governance and control (including risk management); the operation of essential regulatory systems including digital; successful implementation of the change programme; and new emerging issues on which the Board needed additional assurance including for example changes in the Agency's fees. Taking account of the size of the MHRA and its inherent risk, we considered that eight substantive reviews a year were justified. This volume should be sufficient for Internal Audit to derive its annual opinion to the Accounting Officer and add value to the Agency. It is also important that Internal Audit's reviews are timed to ensure that there is sufficient substantive evidence on which to base a comprehensive opinion. The Agency had agreed a programme of Internal Audit work for the next three months. So that Internal Audit has sufficient time to plan and allocate specialist skills needed to provide added value to the Agency we asked that the annual programme for 2021-22 be now finalised (reflecting the above criteria) .We understand that this has now been done.

4.8 We considered three new Internal Audit reports all of which received moderate assurance. These are: the Agency's revised approach to business planning; the framework for implementing the recommendations of the Governance Review; and controls in place to support the health and safety of the Agency's Enforcement Group. Three reports for 2020-21 remain to be completed. These are: Cyber Security; Customer Service Centre; and Legacy Systems Replacement. We are holding an additional meeting at the end of May to consider these reports. We were assured by Internal Audit that these reports are near completion and together with those already agreed provide a sufficient body of evidence for the annual assurance to be provided to the Accounting Officer.

4.9 In 2019-20 the Agency asked Internal Audit to undertake a review to advise how the on-boarding and off-boarding of Non-Executive Directors could be improved following the identification by Finance of some control weaknesses. We considered a progress report and were pleased to note that all the recommendations of the review have been implemented.

Governance

4.10 We received an update on the incidence of Regulatory Fraud in the medicines and medical devices supply chain together with ongoing measures taken by the Agency to prevent this. We were updated on Non-Regulatory Fraud and the Agency's compliance with Cabinet Office guidance. We also approved the Agency's Anti-Fraud and Bribery Policy. No whistle blowing was brought to our attention.

4.11 We are impressed by the Agency's approach across the board in minimising the risk of fraud and we had no issues of major concern. We have however identified a wider systemic issue over which further assurance is needed. The effective exercise of the full range of the MHRA's regulatory responsibilities is highly dependent on the quality, comprehensive and independence of data available to assess risk, understand the impact of regulatory decisions in terms of access and patient safety, prevent fraud and more generally to identify emerging trends. We have not seen evidence to suggest that at present lack of data is a significant issue, but as the Agency continues to develop as a standalone national regulator sources of primary evidence and its accessibility are changing. We have agreed with the Chief Executive that a more detailed "deep dive'' by ARAC and the Patient Engagement and Safety Committee would be beneficial to understand how data sources are changing and how the Agency is ensuring it has access to the information it needs.

Risk management

4.12 The Agency's Risk Register continues to improve significantly. Currently the register has 15 strategic risks all of which are linked to the themes of the Agency's Delivery Plan. The number of risks is high but justified given the degree of change which the Agency is undergoing and external factors such as responding to Covid. We could not identify any risk that was omitted and therefore were assured over the completeness of the strategic risk register. Patient safety, security of supply of medicines and devices, supporting innovation and financial resilience all feature prominently in the register. Each risk has its own schedule setting out the member of the Executive responsible for ensuring management of the risk and the mitigating actions. There is evidence of how risk management is becoming more embedded in the Agency. More work is planned to develop risk indicators and performance measures. We also advised that residual risks after the impact of mitigating action should be clearer. Overall, however, we commend the progress which the Agency has made. The intention is that the Risk Register will be considered by the full Board in the early summer.

5. Recommendation

5.1 The Board is asked to note this report and agree to the proposed more detailed "Deep Dive" reviews by ARAC together with the Patient Safety and Engagement Committee into: (i) the new Medical Devices Regulatory Framework as it is finalised specifically from the perspective of managing risks to patient safety; and (ii) how the data and evidence sources of the Agency are changing and how the Agency is ensuring it has access to the information it needs to discharge its responsibilities.

Michael Whitehouse
May 2021