Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:10 on Tuesday, 20 April 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 Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
10:10	CURRENT CONTEXT 4. What are the current key issues from the CEO's point of view?	Discussion	June Raine
10:30	FINANCIAL SUSTAINABILITY 5. What are the priorities, accountabilities and key measures for the MHRA Delivery Plan 2021-2023?	Approval	Jon Fundrey
11.10	PATIENT SAFETY 6. What assurance can be provided by the Patient Safety and Engagement Committee?	Assurance	Mercy Jeyasingham
11:25	DYNAMIC ORGANISATION 7. What assurance can be provided by the Organisational Development and Remuneration Committee?	Assurance	Anne-Toni Rodgers
11:40	EXTERNAL PERSPECTIVE 8. What questions do members of the public have for the MHRA Board?	Discussion	Chair
12:10	CLOSE OF MEETING	-	Chair

Medicines & Healthcare products Regulatory Agency

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 16 March 2021

(10:00 – 12:00)

By Zoom Webinar

Present:

The Board

Stephen Lightfoot	Chair
Professor David Webb CBE	Deputy Chair
Dr June Raine CBE	Chief Executive
Dr Samantha Atkinson	Interim Chief Quality and Access Officer
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)

Kathryn Glover	Deputy Director, Medicines Regulation and Prescribing, DHSC

Devolved Administrations

Greig Chalmers	Interim Deputy Director, Chief Medical Officer's Policy Division, 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 Cathy Harrison, Chief Pharmaceutical Officer for Northern Ireland, and Alison Strath, Interim Chief Pharmaceutical Officer for Scotland.

2.2 Professor Bruce Campbell made a declaration of a personal nonspecific interest. Professor Campbell is providing advice on a consultancy basis to an organisation called PSC, who are working with NHS X on a project to develop and rollout an automated system to capture the details of all medical devices used in the NHS; this system will eventually link up with MHRA's devices database. The Chair noted the declaration.

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.

3.2 With regards to the action related to the Memorandum of Understanding with NICE; the Partnership Agreement with NICE was updated and renewed in order to support more collaborative working between the two Agencies, together with a refreshed workplan. The Board noted that a joint MHRA and NICE Board meeting will be held in October 2021.

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 a Regulatory Guideline which was published on adapting vaccines for Covid-19 variants, a GMP inspection of the Serum Institute India vaccine production site, Covid-19 tests, the lifting of the ban on the use of UK plasma, the first innovation passport under the ILAP project, the Partnership Agreement with NICE, a Regulatory Science Roundtable meeting held with the Academy of Medical Sciences, ongoing EU work, and international collaboration; (ii) patient safety – including updates on Covid-19 vaccines surveillance, use of real world data, drug safety issues, the valproate registry, suspension of the CE mark for B-lite breast implants, and patient safety and prescribing quality improvement; (iii) dynamic organisation – including an update on staff engagement sessions on the Future Operating Model; and (iv) financial sustainability – including an update on progress with the Delivery Plan 2021/22.

4.2 Dr Raine in particular noted that patient safety is our priority and it is in the spotlight at present; with weekly publication of all ADR reports associated with Covid-19 vaccines – intensive scientific review of an ongoing issue with clots associated with the vaccine is underway. Other key areas of patient safety include the valproate registry which was launched with NHS Digital to monitor compliance with current regulatory restrictions of the use of valproate during pregnancy; and CPRD participation in prescribing improvement initiatives with the RCGP. The Agency has been focusing on partnerships with NICE, the SMC, HRA, HTA and other organisations; better partnerships will mean improved access for patients.

4.3 The Board noted that thanked Dr Raine for her report and provided comments relating to the Access Consortium; working with GPs to improve prescribing safety and reporting rates; engaging with patient groups on specific issues such as valproate or antipsychotics safety; the use of real world data and how the Agency can be assured of the completeness of data. The Board noted that the data MHRA receives from GPs is very accurate; it was agreed that high quality data is essential to ensure patients and the public have this assurance from the MHRA. The feedback loop between MHRA and reporters is important to maintain high quality data.

HEALTHCARE ACCESS

Item 5: How is the Agency going to build on its scientific expertise and laboratory research to help achieve the vision of protecting and improving patient health?

5.1 The Board considered a paper describing how the Agency will adapt its laboratory science to ensure it can exploit its unique capabilities, act as an enabler to the Agency's innovation agenda and maximise impact on patient safety and healthcare access. The laboratory research activities perform the vital function of keeping the other scientific services at the forefront of life science technology developments and fit-for-purpose. The Board considered the proposals set out in the paper, which also underpin the Agency's continued and important role supporting UK government's ambitions for the life sciences sector.

5.2 The Board considered the report and commented that it will be important to focus on communication plans in relation to the proposed strategy; to increase public awareness of the vital work of the Agency. The Board emphasised the important work which NIBSC undertakes in many areas – including the safety of biological medicines in the UK, producing 90% of WHO standards, and playing a vital role in the handling of public health emergencies including Zika, Ebola, or Covid-19.

5.3 The Board provided further comments covering the increasing transparency and confidence the public will have with the Agency with increased communications; publication of good news stories in relation to health priorities, in scientific publications but also in other non-scientific publications such as magazines; ensuring that the strategy focuses on long term resilience and ensuring the MHRA remains as a global centre of scientific excellence; maximising international collaboration; how having the asset of the Agency's laboratories has enabled the MHRA to be able to react very quickly to public health emergencies or other issues such as defective or counterfeit products, establishing MHRA as a global leader in this area.

5.4 Further comments were provided highlighting the regulatory role of the strategy – reducing wasted effort by bringing science into the regulatory process early on will

be key. The Covid-19 pandemic has raised awareness of the Agency and the proposed communications strategy will bolster this. The Board agreed this strategy is vital to the future of regulation in the UK, and additionally the MHRA's role in enabling the supply chain.

5.5 The Board endorsed the proposal to develop and deliver an Agency Laboratory Strategy that will increase the impact of the Agency's research and scientific delivery. This strategy will form part of the Regulatory Science Strategy and will define the scientific functions that the Accommodation Strategy will need to support. The Board supported the recommendation to review the current approaches to communications and engagement and incorporate improved measures into the Laboratory Strategy so that the communications can be better coordinated with the scientific progress. A further request from the Board for an update on the overall Agency Communications Strategy was agreed.

Action 29: Present an Agency Laboratory Strategy to the Board as part of the Agency Science Strategy.

Action 30: Present the Agency Communications Strategy to the Board.

Item 6: What has been the impact of EU Transition on regulatory approvals and the work of the Agency in the first two months after leaving the EMA network?

6.1 The Board considered a paper which described the impact of EU Transition on regulatory approvals and the work of the Agency, two months after leaving the EMA network. This covered the Partnership Agreement between the UK and EU and the elements of this which now apply to regulation in the UK; deferral of some changes to the regulatory process e.g. for the Falsified Medicines Directive; the Northern Ireland Protocol; exchange of regulatory information for patient safety; MHRA's introduction of new routes to market including the Innovative Licensing and Access Pathway; and changes in working practices for the Agency and for industry due to restrictions in data sharing or receiving from the EMA, EC, EU competent authorities or notified bodies.

6.2 The Board noted the impact of EU Transition on the Agency's activities; a concern was noted regarding consequences from the lack of data sharing with Europe, however it was noted that the Agency continues to work to strengthen international relationships to make up for this loss of information. The Board provided further comments on ensuring MHRA is aware of EMA decisions; ensuring patient safety; monitoring the number of applications coming to the UK, and income from these; the positive feedback received from industry colleagues on the technology platforms which were implemented; reducing burden on staff; and new routes to market.

6.3 The Board noted that continued engagement with DHSC is ongoing in this area, in particularly in relation to new routes to market; ongoing regular interaction with industry is vital, and close monitoring of patterns of work going forward to carefully manage this area. The Board endorsed the recommendations in the paper: (i) As a priority, bring to a conclusion the areas of uncertainty in relation to EU discussions; (ii) Continue to advocate new routes to market in the UK to facilitate early patient access to medicines; (iii) Continue regular interaction with industry through the Trade Associations to identify issues in this early phase and help them to navigate solutions; and (iv) Continue to closely monitor the volume and pattern of work coming to the Agency together with resource requirements to enable demand to be supported in an agile way.

PATIENT SAFETY

Item 7: What are the proposed outcomes from the new Patient and Public Involvement Strategy and how are they going to be achieved?

7.1 The Board considered a paper which described the proposed outcomes from the new Patient and Public Involvement (PPI) Strategy, and how the Agency proposes to achieve these outcomes. The Board noted that the PPI strategy sets out a high-level strategic approach for the Agency, recognising that there is much work to be done once approved, in building a granular delivery plan. It was noted that the term "involvement" has been used in the title for brevity, as the Agency considers "engagement" a precursor to involvement.

7.2 The Board noted the update and provided comments including ensuring the importance of defining outcomes to measure success of the strategy; ensuring these outcomes meet the needs of patients; engaging with others in relation to design of regulatory practices; improving awareness and trust of the public via increased engagement and promotion of the Agency through culture change; embedding this in to regulatory systems rather than adding on top of the current systems; embracing opportunities for partnerships to improve patient and public involvement; and the importance of ensuring MHRA's systems are simple to use.

7.3 The Board provided a further comment that the Agency must facilitate two-way engagement; furthermore community engagement will be a useful tool to improve awareness. The Board endorsed the high level strategy objectives; Ministerial sign-off will be sought ahead of the public consultation.

Action 31: Seek Ministerial sign-off for public consultation on Patient and Public Involvement Strategy.

DYNAMIC ORGANISATION

Item 8: What are the key requirements in the new Unitary Board Conflicts of Interest Policy?

8.1 The Board considered the updated Conflicts of Interest policy for Board members, which has been updated to include all members of the Unitary Board. The Board noted that the ARAC previously reviewed and endorsed the policy. The Board approved the policy.

EXTERNAL PERSPECTIVE

Item 9: What questions do members of the public have for the MHRA Board?

9.1 The Board answered a range of questions from members of the public.

CLOSE OF MEETING

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 16 March 2021

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
13	Conduct review of CPRD. Further action 19/01/21: Include how to expand data sources for CPRD's role in safety surveillance.	Jon Fundrey	~~16/03/21~~ 20/04/21	On Seminar Agenda
15	Review Agency Fee structure to ensure closer alignment with costs of delivery	Jon Fundrey	15/06/21	
16	Produce a single 2-year Agency Delivery Plan to replace existing Corporate and Business Plans.	Jon Fundrey	20/04/21	On Agenda
21	ARAC to review governance and risks of the new medical devices regulatory framework	ARAC	18/05/21	
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	1~~8/05/21~~ 15/06/21	
24	PSEC to review opportunities for patient engagement and involvement in ILAP	PSEC	20/04/21	On Agenda
26	PSEC to review the opportunities for developing the Yellow Card Scheme and ensuring an equity of access across entire patient population	PSEC	20/04/21	On Agenda
27	ODRC to review Diversity and Inclusion to provide assurance to the Board	ODRC	~~20/04/21~~ 18/05/21	On Next Agenda
28	ARAC to confirm that actions have been taken on the limited assurance internal audit report on medical devices	ARAC	18/05/21	
New Actions				
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 / Rachel Bosworth	18/05/21	
31	Seek Ministerial sign-off for public consultation on Patient and Public Involvement Strategy	June Raine / Rachel Bosworth	20/04/21	Verbal Update at Meeting

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 April 2021

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

Medicines & Healthcare products Regulatory Agency

Chief Executive's Report to the Board
20 April 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

- MHRA's rigorous review of reports of thrombosis with low platelets associated with the AZ COVID-19 vaccine resulted in new advice for the public on this extremely rare risk
- An Artificial Intelligence tool is being utilised to help process reports of suspected ADRs to COVID-19 vaccine rapidly, for real-time signal detection
- CPRD is working in partnership with University of Birmingham on a major research project to evaluate Long COVID syndromes in non-hospitalised patients
- NIBSC has now tested 55.6 million doses of COVID-19 vaccines, well in advance of the Government target to have deployed 32.2 million doses by mid-April
- Applications for the Innovative Licensing and Access Pathway scheme now number over 20 with approximately one-third of these being Orbis products.
- The MHRA/NICE partnership agreement has been revised and was signed in March 2021, including a new work programme
- MHRA held a workshop with the Health Research Authority and National Institute for Health Research to discuss strategic objectives, alignments and explore areas for joint working to facilitate clinical trials in UK
- A scientific consultation with key stakeholders was held as part of the engagement strategy for the Yellow Card Biobank project, part of the Regulatory Science Strategy
- MHRA has been working with DHSC on the process and prioritisation of bringing forward Statutory Instruments to implement legislative changes for the MMD Act, including a new regulatory regime for software as a Medical Device
- International collaboration with the Access Consortium (Australia, Canada, Singapore and Switzerland), Indian regulator, EMA, TGA, Health Canada and WHO on vaccine safety has supported information sharing and alignment of regulatory approaches.

HEALTHCARE ACCESS

Vaccine Batch Testing by NIBSC

1. By the beginning of April NIBSC had tested 55.6 million doses of COVID-19 vaccines, well in advance of the Government target to have deployed 32.2 million doses by mid-April. NIBSC has achieved a significant increase in testing capacity by both recruiting staff after receiving funding from DHSC to support COVID-19 Batch Release, and by reassigning testing tasks between teams. This included developing new Batch Release assays in response to two of the three COVID-19 vaccines using the novel and RNA vaccine technology. It is a testimony to the scientific skills, organisation and dedication of NIBSC staff that this Batch Release was performed without delays to the deployment of any batches of biological medicines, especially that of the COVID-19 vaccines.

Moderna COVID-19 vaccine

2. On 31st March a GB conditional marketing authorisation (cMA) was issued for the Moderna Covid-19 vaccine. This vaccine had previously received a temporary authorisation for supply on 8th January under Regulation 174 of the Human Medicines Regulations 2012. This GB cMA aligns with the EU cMA applicable in Northern Ireland and supports the deployment of the vaccine from April. A review of the pipeline of COVID-19 vaccines shows that further Covid-19 vaccine approvals are expected in the coming months. The MHRA is also in discussion with vaccine developers about vaccines targeted at virus variants that are expected to be approved later in the year.

COVID-19 Test and Trace

3. We are continuing to support DHSC/NHS Test and Trace through post-market surveillance of self-tests as part of the national testing programme as well as supporting a new pipeline of tests through reviewing performance and usability study applications from new manufacturers in advance of any applications for Exceptional Use Authorisation (EUA). One EUA has been granted at this time.

Innovative Licensing and Access Pathway

4. The Innovative Licensing and Access Pathway (ILAP) was launched on 1st January 2021. The ILAP has received 22 applications for the Innovation Passport (IP) from a variety of sponsors including large and small companies and in common diseases (e.g. community acquired pneumonia, chronic wounds, diabetes) as well as rare diseases (leukaemia, lymphomas). Of the 22 IP applications, 8 have currently expressed interest in entering Project Orbis, the US FDA project on approving oncology products in collaboration with countries such as Canada and Australia. We have started setting up a dedicated ILAP patient reference group, having agreed that patients will be part of the decision making for the Innovative Passport and will be included in further developing the specific patient engagement ‘tool’.

5. Work is also ongoing with NICE and the Scottish Medicines Consortium (SMC) on the ILAP which aims to accelerate the time to market, facilitating patient access by using innovative methods and tools to accelerate product availability, including the integration of novel clinical trial designs, enhanced collection of real-world data, and “strengthened regulatory oversight. In order to deliver this, we have reviewed our partnerships across the system, making SMC, as well as NICE, permanent partners of the ILAP process. This collaborative framework will enable the impacts of licensing routes on health technology assessment and commissioning to be considered prospectively to accelerate patient access.

Clinical Trials

6. The MHRA, the Health Research Authority (HRA) and the National Institute for Health Research (NIHR) met in March to discuss strategic objectives, alignments and explore areas for joint working. Discussions covered streamlining approvals and trial delivery, transparency, innovative regulation and technology enablers in the wider context of the research system-wide and UK-wide Clinical Research Recovery, Resilience and Growth (RRG) Programme. This Programme will drive the Government’s vision on the future of UK clinical research delivery published on 23 March 2021. Alignment of offerings by MHRA, HRA and NIHR was agreed at the workshop. MHRA and HRA will continue to develop and scale-up combined regulator/ethics review so that by the end of 2021 all trial applications will benefit from this streamlined process. In addition, a ‘fast-track’ process for certain trials will be implemented encompassing both approval and delivery support.

MHRA pilot aims to boost patient involvement in clinical research

7. On 23rd March 2021 a pilot project was launched that puts patient involvement at the heart of clinical trials and medicines development. When applications for new active substances and new indications are received, the applicant company is asked for evidence on patient involvement activities undertaken when developing their product and what impact these have had. For clinical trials, we will be documenting in medical assessment reports if there is evidence of patient involvement in clinical trial applications in order to better understand the scope of patient involvement. We will use this to improve the quality of clinical drug development and health outcomes. A successful pilot will lead to systematic patient involvement playing a greater role in the final assessment process when clinical trials are approved and medicines are licensed.

Medicines and Medical Devices Act

8. Since Royal Assent was given to the Medicines and Medical Devices (MMD) Act we have been working with DHSC on the process and prioritisation of bringing forward Statutory Instruments to implement legislative changes. There are a range of Agency proposals under the new powers in the Act aiming to support patient access to medicines and devices and strengthen our regulations to support patient safety. The first phase of statutory instruments includes new regulations to support access to innovative products e.g. products manufactured at the point-of-care, new regulations for Clinical Trials and new regulations for medical devices. We continue to develop these proposals, preparing for launching public consultations later this year, alongside developing the wider programme of future legislative changes.

PARTNERSHIPS AND INTERNATIONAL

UK Partnerships

9. The MHRA/NICE partnership agreement has been revised and was signed by Chief Executives in March 2021. This new agreement underpins a new, more collaborative way of working with NICE and capitalises on the new regulatory freedom that leaving the EU provides. It also includes a commitment to deliver on a number of joint workstreams, including safety and standards, timely access to medicines/healthcare products for patients, the promotion of innovation and growth, international partnerships and real-world data methods and standards. We are now following up on the governance arrangements underpinning the partnership agreement, including renewing the Core Strategic Group membership and terms of reference, with a view to holding the first official meeting in May.

International regulatory collaboration

10. The International Office has continued to coordinate our international effort working with regulators around the world on COVID-19 vaccines and therapeutics. We have collaborated closely with global regulators such as the EMA, Health Canada and the Australian Therapeutic Goods Association, as well as the WHO Global Advisory Committee on Vaccine Safety on the possible link between the AstraZeneca vaccine and thromboembolic events. We continue to lead the ICMRA COVID-19 Working Group work on vaccine vigilance and on the digital transformation on inspections.

11. The International Office hosted a bilateral call with the Central Drugs Standard Control Organisation (CDSCO), the Indian regulator, to discuss future collaboration options and development of a joint workplan to ensure implementation of the recently signed Memorandum of Understanding. We exchanged up to date information on vaccine pharmacovigilance and the possible link between the AstraZeneca vaccine and thromboembolic events with low platelets. We are working with Access Consortium partners (Australia, Canada, Singapore and Switzerland) on the development of a

strategic plan, to ensure the Consortium enhances efficiencies of our national regulatory systems, while optimising regulatory alignment and global work sharing.

International scientific collaboration

12. The MHRA participated in a roundtable discussion with the Alliance for Regenerative Medicines alongside the US FDA and the EMA. This was an opportunity to showcase the UK's new ILAP offer, in particular how the Agency engages and listens earlier with stakeholders. The outcome of the meeting was to define where stakeholders developing gene and cell therapies stand on their journey towards commercialisation of their developments, and how regulators can assist. It became obvious to stakeholders that the MHRA's offer is comprehensive and of value. The MHRA also contributed to a session on Complex Innovative Clinical Trials at the European Drug Information Association conference. This demonstrated the MHRA's internationally competitive position when it comes to complex innovative clinical trials, both as regards their conduct (see, for example, the RECOVERY or REMAP-CAP clinical trials) and their acceptance by the UK's regulator.

PATIENT SAFETY

COVID-19 vaccine ADRs

13. Two COVID-19 vaccines, Pfizer/BioNTech and Oxford University/AstraZeneca vaccines, are currently being deployed. By 28 March 2021, 43,491 Yellow Cards had been reported for the Pfizer/BioNTech, 116,162 have been reported for the Oxford University/AstraZeneca vaccine, and 418 have been reported where the brand of the vaccine was not specified. For both vaccines the overall reporting rate is around 3 to 6 Yellow Cards per 1,000 doses administered. For both vaccines, the overwhelming majority of reports relate to injection-site reactions and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally these happen shortly after vaccination and are not associated with more serious or lasting illness. These types of reactions reflect the normal immune response to the vaccines.

14. The MHRA's review of UK reports of rare and specific types of blood clots with low reported on 7th April that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed. The benefits of vaccination continue to outweigh any risks but the MHRA advised that careful consideration be given to people who are at higher risk of specific types of blood clots because of their medical condition. The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advised that this evolving evidence should be taken into account when considering the use of the vaccine. Updated guidance is being issued for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for four or more days after vaccination.

AI tool supporting ADR processing

15. An Artificial Intelligence (AI) tool to help process reports of suspected ADRs to COVID-19 vaccines has been in place since mid-December 2020. Since the initial release, additional 'models' have been made available, whereby more sections of the ADR report are able to be enhanced by the AI tool. These include event models to pick up reactions and past medical history as well as drug models to identify past drugs, concomitant drugs and co-suspects, including the drug indication. In addition, there have been improvements made to the accuracy of the AI enhancements. All models have now been successfully tested and we are now entering a continuous learning phase which will continue throughout the use of the AI tool; this will help to improve the accuracy of the tool further.

Improving our understanding of Long COVID

16. CPRD has been jointly awarded a £2.2 million 24 month award from the National Institute for Health Research in partnership with University of Birmingham, to evaluate symptoms and underlying pathophysiology of Long COVID syndromes in non-hospitalised patients. The CPRD team will search primary care electronic health records (EHR) and engage with the CPRD GP practice network, to identify and recruit into the study thousands of non-hospitalised patients with Long COVID who have had symptoms for 12 weeks or longer. Recruited patients will self-report symptoms, quality of life and work capability through a purpose-built app created by the Birmingham team. This patient reported data along with CPRD EHR data linked to hospital and COVID-19 registry data, will help characterise Long COVID. Ultimately these data will inform recommendations on therapies and health care management of affected patients.

Safer medicines in pregnancy and breastfeeding consortium

17. The Safer Medicines in Pregnancy and Breastfeeding Consortium, which brings together 16 leading organisations under a common pledge to meet the information needs of pregnant and breastfeeding women and healthcare professionals, through accessible, clear and consistent advice, met on 18 March. This was its eleventh meeting since it was set up in 2018 and the first since the launch of the information strategy on 11 January. Key topics for discussion were the women's health strategy call for evidence, led by DHSC, information on COVID vaccines in pregnancy or during breastfeeding, the valproate registry and the anti-epileptic drugs in pregnancy review. NICE colleagues provided a guidance update on shared decision making. The Consortium agreed on moving towards shared priorities and a joint work programme.

Regulatory Science

18. A scientific consultation workshop was held on the 23rd of March as part of the engagement strategy for the Yellow Card Biobank scoping project. The event was opened by Lord Bethell and included a range of experts in the fields of pharmacoepidemiology, pharmacogenomics and public health research. The aim of the meeting was to explore the opportunities and considerations for a potential Yellow Card Biobank and identify what would be required from a Yellow Card Biobank in order to be a useful asset for public health research. A report from the workshop is currently being prepared. Two introductory events for Yellow Card Biobank were also held in March for members of the public and health care professionals and the discussions from all three events are being fed into the development of our proposal for a Yellow Card Biobank as part of the year-long scoping project.

Medical Device Clinical Investigation transparency

19. Work has continued on greater transparency for Medical Devices regulatory systems. Following on from the transparency around Exceptional Use Authorisations, the team have been working on other key steps we can take within our current powers. On 25th March, for the first time we published the number of applications received, the number of withdrawals, number of objections and common reasons for objections. This is an initial step which will be developed as part of the Medical Devices transparency strategy, which will draw on the powers granted as part of the Medicines and Medical Devices Act. There will also be transparency for adverse incidents following a successful pilot in 2020.

Infusion pumps quality issue

20. The Devices team worked effectively across the healthcare system to develop and issue a National Patient Safety Alert (NatPSA) within 24 hours because of a potential supply disruption issue of Beckton Dickinson (BD) infusion sets/pumps and gravity

infusion sets following a quality issue with their third party sterilisation provider. The supply disruption occurred whilst the manufacturer moved to a new sterilisation provider and to minimise potential disruption the agency provided an Exceptional Use Authorisation (EAU) to BD for alternative IV kits.

DYNAMIC ORGANISATION

Mental Health and Wellbeing Campaign – 1 year since homeworking began

21. A year on from the original COVID 19 related lock-down for many of our staff, we took the opportunity of focussing on two related topics in the recent All Staff Meetings. There was an update on easing of lockdown and current thinking on related return plans and a session on signposting a broad range of support options available to staff, both reminders and new opportunities. This referenced specific sessions developed by Human Resources in relation to lockdown-related needs: facilitated Wellbeing sessions for teams to work through together, previous Remote Working sessions now available on video for those who had not accessed before or wanting a refresher, and re-launch of bookable Resilience training sessions for staff and for managers. Opportunities were highlighted to connect with and support others via various staff led, common interest networks and one to one networking, more formally organised via the 'Coffee Connect' initiative and less formally in terms of peer support and generally looking out for each other.

Accommodation update

22. It is recognised that there is still some way to go before any return to whatever normal will be in the future and so factoring in changes to accommodation and preferences and taking account of the experience and learning in lockdown adds to the complexity of planning and timing of this return. Managers are being asked to revisit these issues in one to one discussions during April and May. Whilst most staff continue to work from home in line with government guidance, planning is under way in readiness for staff to start to return to offices in late June, subject to guidance at that point. A programme of work to define the Agency's ways of working in the longer term was initiated last summer and continues with an aspiration to move to a hybrid working model.

FINANCIAL SUSTAINABILITY

Agency Change Strategy

23. The Agency Change strategy is gaining pace with the Director of Transformation's support team now in place. Progress with the Pathfinders (the range of initiatives which can be started immediately) is being driven forward: design principles work has been completed for the 'Spans & Spines' principles of the future Agency and transfer of responsibility has been completed for Corporate and Business Planning functions to the Chief Operating Officer's portfolio. Initial scoping sessions for bringing together clinical investigations and clinical trials have confirmed that a combined team is feasible for application submission, validation, and allocation of applications to specialist assessors. Emerging design principles for future regulation will require further engagement, testing, and agreement with colleagues in MHRA, DHSC, and Office of Life Sciences (OLS). Progress is on track to finalise an integrated design for safety signal detection across medicines and devices pathfinder by mid-April 202.

24. The overall lead for the Corporate Overhead Challenge and working co-leads have been identified and engagement is under way. The focus remains the target of 15% reduction in corporate overheads and next steps for the delivery team are to complete a review of accommodation, ICT, and other corporate overheads. This will produce specific opportunities to meet reduction targets.

25. The Transformation programme communications and engagement strategy is being refined and updated. The specific outcomes required are (i) engaging Agency employees and (ii) making sure that the Agency is ready for transformational change. The communications and engagement approach identifies the different channels that will be best suited to reach specific audiences with specific messages and content about the Agency's transformation work. An additional focus is aligning the leadership group around the communications approach and plan to ensure successful delivery of these messages. To support objective assessment of the effectiveness of the communications strategy, measures of success are being defined for Transformation-related communications and engagement.

June Raine
Chief Executive
April 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 April 2021

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

Medicines & Healthcare products Regulatory Agency

Chief Executive's Report to the Board
20 April 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

- MHRA's rigorous review of reports of thrombosis with low platelets associated with the AZ COVID-19 vaccine resulted in new advice for the public on this extremely rare risk
- An Artificial Intelligence tool is being utilised to help process reports of suspected ADRs to COVID-19 vaccine rapidly, for real-time signal detection
- CPRD is working in partnership with University of Birmingham on a major research project to evaluate Long COVID syndromes in non-hospitalised patients
- NIBSC has now tested 55.6 million doses of COVID-19 vaccines, well in advance of the Government target to have deployed 32.2 million doses by mid-April
- Applications for the Innovative Licensing and Access Pathway scheme now number over 20 with approximately one-third of these being Orbis products.
- The MHRA/NICE partnership agreement has been revised and was signed in March 2021, including a new work programme
- MHRA held a workshop with the Health Research Authority and National Institute for Health Research to discuss strategic objectives, alignments and explore areas for joint working to facilitate clinical trials in UK
- A scientific consultation with key stakeholders was held as part of the engagement strategy for the Yellow Card Biobank project, part of the Regulatory Science Strategy
- MHRA has been working with DHSC on the process and prioritisation of bringing forward Statutory Instruments to implement legislative changes for the MMD Act, including a new regulatory regime for software as a Medical Device
- International collaboration with the Access Consortium (Australia, Canada, Singapore and Switzerland), Indian regulator, EMA, TGA, Health Canada and WHO on vaccine safety has supported information sharing and alignment of regulatory approaches.

HEALTHCARE ACCESS

Vaccine Batch Testing by NIBSC

1. By the beginning of April NIBSC had tested 55.6 million doses of COVID-19 vaccines, well in advance of the Government target to have deployed 32.2 million doses by mid-April. NIBSC has achieved a significant increase in testing capacity by both recruiting staff after receiving funding from DHSC to support COVID-19 Batch Release, and by reassigning testing tasks between teams. This included

developing new Batch Release assays in response to two of the three COVID-19 vaccines using the novel and RNA vaccine technology. It is a testimony to the scientific skills, organisation and dedication of NIBSC staff that this Batch Release was performed without delays to the deployment of any batches of biological medicines, especially that of the COVID-19 vaccines**.**

Moderna COVID-19 vaccine

2. On 31st March a GB conditional marketing authorisation (cMA) was issued for the Moderna Covid-19 vaccine. This vaccine had previously received a temporary authorisation for supply on 8th January under Regulation 174 of the Human Medicines Regulations 2012. This GB cMA aligns with the EU cMA applicable in Northern Ireland and supports the deployment of the vaccine from April. A review of the pipeline of COVID-19 vaccines shows that further Covid-19 vaccine approvals are expected in the coming months. The MHRA is also in discussion with vaccine developers about vaccines targeted at virus variants that are expected to be approved later in the year.

COVID-19 Test and Trace

3. We are continuing to support DHSC/NHS Test and Trace through post-market surveillance of self-tests as part of the national testing programme as well as supporting a new pipeline of tests through reviewing performance and usability study applications from new manufacturers in advance of any applications for Exceptional Use Authorisation (EUA). One EUA has been granted at this time.

Innovative Licensing and Access Pathway

4. The Innovative Licensing and Access Pathway (ILAP) was launched on 1st January 2021. The ILAP has received 22 applications for the Innovation Passport (IP) from a variety of sponsors including large and small companies and in common diseases (e.g. community acquired pneumonia, chronic wounds, diabetes) as well as rare diseases (leukaemia, lymphomas). Of the 22 IP applications, 8 have currently expressed interest in entering Project Orbis, the US FDA project on approving oncology products in collaboration with countries such as Canada and Australia. We have started setting up a dedicated ILAP patient reference group, having agreed that patients will be part of the decision making for the Innovative Passport and will be included in further developing the specific patient engagement ‘tool’.

5. Work is also ongoing with NICE and the Scottish Medicines Consortium (SMC) on the ILAP which aims to accelerate the time to market, facilitating patient access by using innovative methods and tools to accelerate product availability, including the integration of novel clinical trial designs, enhanced collection of real-world data, and “strengthened regulatory oversight. In order to deliver this, we have reviewed our partnerships across the system, making SMC, as well as NICE, permanent partners of the ILAP process. This collaborative framework will enable the impacts of licensing routes on health technology assessment and commissioning to be considered prospectively to accelerate patient access.

Clinical Trials

6. The MHRA, the Health Research Authority (HRA) and the National Institute for Health Research (NIHR) met in March to discuss strategic objectives, alignments and explore areas for joint working. Discussions covered streamlining approvals and trial delivery, transparency, innovative regulation and technology enablers in the wider context of the research system-wide and UK-wide Clinical Research Recovery, Resilience and Growth (RRG) Programme. This Programme will drive the Government’s vision on the future of UK clinical research delivery published

on 23 March 2021. Alignment of offerings by MHRA, HRA and NIHR was agreed at the workshop. MHRA and HRA will continue to develop and scale-up combined regulator/ethics review so that by the end of 2021 all trial applications will benefit from this streamlined process. In addition, a 'fast-track' process for certain trials will be implemented encompassing both approval and delivery support.

MHRA pilot aims to boost patient involvement in clinical research

7. On 23rd March 2021 a pilot project was launched that puts patient involvement at the heart of clinical trials and medicines development. When applications for new active substances and new indications are received, the applicant company is asked for evidence on patient involvement activities undertaken when developing their product and what impact these have had. For clinical trials, we will be documenting in medical assessment reports if there is evidence of patient involvement in clinical trial applications in order to better understand the scope of patient involvement. We will use this to improve the quality of clinical drug development and health outcomes. A successful pilot will lead to systematic patient involvement playing a greater role in the final assessment process when clinical trials are approved and medicines are licensed.

Medicines and Medical Devices Act

8. Since Royal Assent was given to the Medicines and Medical Devices (MMD) Act we have been working with DHSC on the process and prioritisation of bringing forward Statutory Instruments to implement legislative changes. There are a range of Agency proposals under the new powers in the Act aiming to support patient access to medicines and devices and strengthen our regulations to support patient safety. The first phase of statutory instruments includes new regulations to support access to innovative products e.g. products manufactured at the point-of-care, new regulations for Clinical Trials and new regulations for medical devices. We continue to develop these proposals, preparing for launching public consultations later this year, alongside developing the wider programme of future legislative changes.

PARTNERSHIPS AND INTERNATIONAL

UK Partnerships

9. The MHRA/NICE partnership agreement has been revised and was signed by Chief Executives in March 2021. This new agreement underpins a new, more collaborative way of working with NICE and capitalises on the new regulatory freedom that leaving the EU provides. It also includes a commitment to deliver on a number of joint workstreams, including safety and standards, timely access to medicines/healthcare products for patients, the promotion of innovation and growth, international partnerships and real-world data methods and standards. We are now following up on the governance arrangements underpinning the partnership agreement, including renewing the Core Strategic Group membership and terms of reference, with a view to holding the first official meeting in May.

International regulatory collaboration

10. The International Office has continued to coordinate our international effort working with regulators around the world on COVID-19 vaccines and therapeutics. We have collaborated closely with global regulators such as the EMA, Health Canada and the Australian Therapeutic Goods Association, as well as the WHO Global Advisory Committee on Vaccine Safety on the possible link between the AstraZeneca vaccine and thromboembolic events. We continue to lead the ICMRA

COVID-19 Working Group work on vaccine vigilance and on the digital transformation on inspections.

11. The International Office hosted a bilateral call with the Central Drugs Standard Control Organisation (CDSCO), the Indian regulator, to discuss future collaboration options and development of a joint workplan to ensure implementation of the recently signed Memorandum of Understanding. We exchanged up to date information on vaccine pharmacovigilance and the possible link between the AstraZeneca vaccine and thromboembolic events with low platelets. We are working with Access Consortium partners (Australia, Canada, Singapore and Switzerland) on the development of a strategic plan, to ensure the Consortium enhances efficiencies of our national regulatory systems, while optimising regulatory alignment and global work sharing.

International scientific collaboration

12. The MHRA participated in a roundtable discussion with the Alliance for Regenerative Medicines alongside the US FDA and the EMA. This was an opportunity to showcase the UK's new ILAP offer, in particular how the Agency engages and listens earlier with stakeholders. The outcome of the meeting was to define where stakeholders developing gene and cell therapies stand on their journey towards commercialisation of their developments, and how regulators can assist. It became obvious to stakeholders that the MHRA's offer is comprehensive and of value. The MHRA also contributed to a session on Complex Innovative Clinical Trials at the European Drug Information Association conference. This demonstrated the MHRA's internationally competitive position when it comes to complex innovative clinical trials, both as regards their conduct (see, for example, the RECOVERY or REMAP-CAP clinical trials) and their acceptance by the UK's regulator.

PATIENT SAFETY

COVID-19 vaccine ADRs

13. Two COVID-19 vaccines, Pfizer/BioNTech and Oxford University/AstraZeneca vaccines, are currently being deployed. By 28 March 2021, 43,491 Yellow Cards had been reported for the Pfizer/BioNTech, 116,162 have been reported for the Oxford University/AstraZeneca vaccine, and 418 have been reported where the brand of the vaccine was not specified. For both vaccines the overall reporting rate is around 3 to 6 Yellow Cards per 1,000 doses administered. For both vaccines, the overwhelming majority of reports relate to injection-site reactions and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally these happen shortly after vaccination and are not associated with more serious or lasting illness. These types of reactions reflect the normal immune response to the vaccines.

14. The MHRA's review of UK reports of rare and specific types of blood clots with low reported on 7th April that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed. The benefits of vaccination continue to outweigh any risks but the MHRA advised that careful consideration be given to people who are at higher risk of specific types of blood clots because of their medical condition. The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advised that this evolving evidence should be taken into account when considering the use of the vaccine. Updated guidance is being issued for healthcare professionals on how to minimise

risks, as well as further advice on symptoms for vaccine recipients to look out for four or more days after vaccination.

AI tool supporting ADR processing

15. An Artificial Intelligence (AI) tool to help process reports of suspected ADRs to COVID-19 vaccines has been in place since mid-December 2020. Since the initial release, additional 'models' have been made available, whereby more sections of the ADR report are able to be enhanced by the AI tool. These include event models to pick up reactions and past medical history as well as drug models to identify past drugs, concomitant drugs and co-suspects, including the drug indication. In addition, there have been improvements made to the accuracy of the AI enhancements. All models have now been successfully tested and we are now entering a continuous learning phase which will continue throughout the use of the AI tool; this will help to improve the accuracy of the tool further.

Improving our understanding of Long COVID

16. CPRD has been jointly awarded a £2.2 million 24 month award from the National Institute for Health Research in partnership with University of Birmingham, to evaluate symptoms and underlying pathophysiology of Long COVID syndromes in non-hospitalised patients. The CPRD team will search primary care electronic health records (EHR) and engage with the CPRD GP practice network, to identify and recruit into the study thousands of non-hospitalised patients with Long COVID who have had symptoms for 12 weeks or longer. Recruited patients will self-report symptoms, quality of life and work capability through a purpose-built app created by the Birmingham team. This patient reported data along with CPRD EHR data linked to hospital and COVID-19 registry data, will help characterise Long COVID. Ultimately these data will inform recommendations on therapies and health care management of affected patients.

Safer medicines in pregnancy and breastfeeding consortium

17. The Safer Medicines in Pregnancy and Breastfeeding Consortium, which brings together 16 leading organisations under a common pledge to meet the information needs of pregnant and breastfeeding women and healthcare professionals, through accessible, clear and consistent advice, met on 18 March. This was its eleventh meeting since it was set up in 2018 and the first since the launch of the information strategy on 11 January. Key topics for discussion were the women's health strategy call for evidence, led by DHSC, information on COVID vaccines in pregnancy or during breastfeeding, the valproate registry and the anti-epileptic drugs in pregnancy review. NICE colleagues provided a guidance update on shared decision making. The Consortium agreed on moving towards shared priorities and a joint work programme.

Regulatory Science

18. A scientific consultation workshop was held on the 23rd March as part of the engagement strategy for the Yellow Card Biobank scoping project. The event was opened by Lord Bethell and included a range of experts in the fields of pharmacoepidemiology, pharmacogenomics and public health research. The aim of the meeting was to explore the opportunities and considerations for a potential Yellow Card Biobank and identify what would be required from a Yellow Card Biobank in order to be a useful asset for public health research. A report from the workshop is currently being prepared. Two introductory events for Yellow Card Biobank were also held in March for members of the public and health care professionals and the discussions from all three events are being fed into the

development of our proposal for a Yellow Card Biobank as part of the year-long scoping project.

Medical Device Clinical Investigation transparency

19. Work has continued on greater transparency for Medical Devices regulatory systems. Following on from the transparency around Exceptional Use Authorisations, the team have been working on other key steps we can take within our current powers. On 25th March, for the first time we published the number of applications received, the number of withdrawals, number of objections and common reasons for objections. This is an initial step which will be developed as part of the Medical Devices transparency strategy, which will draw on the powers granted as part of the Medicines and Medical Devices Act. There will also be transparency for adverse incidents following a successful pilot in 2020.

Infusion pumps quality issue

20. The Devices team worked effectively across the healthcare system to develop and issue a National Patient Safety Alert (NatPSA) within 24 hours because of a potential supply disruption issue of Beckton Dickinson (BD) infusion sets/pumps and gravity infusion sets following a quality issue with their third party sterilisation provider. The supply disruption occurred whilst the manufacturer moved to a new sterilisation provider and to minimise potential disruption the agency provided an Exceptional Use Authorisation (EAU) to BD for alternative IV kits.

DYNAMIC ORGANISATION

Mental Health and Wellbeing Campaign – 1 year since homeworking began

21. A year on from the original COVID 19 related lock-down for many of our staff, we took the opportunity of focussing on two related topics in the recent All Staff Meetings. There was an update on easing of lockdown and current thinking on related return plans and a session on signposting a broad range of support options available to staff, both reminders and new opportunities. This referenced specific sessions developed by Human Resources in relation to lockdown-related needs: facilitated Wellbeing sessions for teams to work through together, previous Remote Working sessions now available on video for those who had not accessed before or wanting a refresher, and re-launch of bookable Resilience training sessions for staff and for managers. Opportunities were highlighted to connect with and support others via various staff led, common interest networks and one to one networking, more formally organised via the ‘Coffee Connect’ initiative and less formally in terms of peer support and generally looking out for each other.

Accommodation update

22. It is recognised that there is still some way to go before any return to whatever normal will be in the future and so factoring in changes to accommodation and preferences and taking account of the experience and learning in lockdown adds to the complexity of planning and timing of this return. Managers are being asked to revisit these issues in one to one discussions during April and May. Whilst most staff continue to work from home in line with government guidance, planning is under way in readiness for staff to start to return to offices in late June, subject to guidance at that point. A programme of work to define the Agency’s ways of working in the longer term was initiated last summer and continues with an aspiration to move to a hybrid working model.

FINANCIAL SUSTAINABILITY

Agency Change Strategy

23. The Agency Change strategy is gaining pace with the Director of Transformation's support team now in place. Progress with the Pathfinders (the range of initiatives which can be started immediately) is being driven forward: design principles work has been completed for the 'Spans & Spines' principles of the future Agency and transfer of responsibility has been completed for Corporate and Business Planning functions to the Chief Operating Officer's portfolio. Initial scoping sessions for bringing together clinical investigations and clinical trials have confirmed that a combined team is feasible for application submission, validation, and allocation of applications to specialist assessors. Emerging design principles for future regulation will require further engagement, testing, and agreement with colleagues in MHRA, DHSC, and Office of Life Sciences (OLS). Progress is on track to finalise an integrated design for safety signal detection across medicines and devices pathfinder by mid-April 202.

24. The overall lead for the Corporate Overhead Challenge and working co-leads have been identified and engagement is under way. The focus remains the target of 15% reduction in corporate overheads and next steps for the delivery team are to complete a review of accommodation, ICT, and other corporate overheads. This will produce specific opportunities to meet reduction targets.

25. The Transformation programme communications and engagement strategy is being refined and updated. The specific outcomes required are (i) engaging Agency employees and (ii) making sure that the Agency is ready for transformational change. The communications and engagement approach identifies the different channels that will be best suited to reach specific audiences with specific messages and content about the Agency's transformation work. An additional focus is aligning the leadership group around the communications approach and plan to ensure successful delivery of these messages. To support objective assessment of the effectiveness of the communications strategy, measures of success are being defined for Transformation-related communications and engagement.

June Raine
Chief Executive
April 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 April 2021

Title	What are the priorities, accountabilities and key measures for the MHRA Delivery Plan 2021-2023?
Board Sponsor	Jon Fundrey
Purpose of Paper	Approval

Medicines & Healthcare products Regulatory Agency

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

1. Executive Summary

1.1. This paper contains a draft of the public version of new Delivery Plan (2021-2023) for approval. We also summarise the development process and planned next steps.

2. Introduction

2.1. The agency's new Delivery Plan (2021-2023) contains a focused programme of work that 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.

2.2. The Board approved the high-level structure of the 6 priorities and 14 objectives in its meeting in March. Since then, the Executive Committee (ExCo) has developed the underpinning detail and a standalone document, which can be published and used in stakeholder engagement. The content of this document is in Annex A.

2.3. Annex B (see page 18) shows a summary of accountabilities at ExCo level for the objectives in the plan. All objectives will require One-Agency working to ensure successful delivery. The ExCo is collectively responsible but with named leads for each objective or clear divisions of responsibilities on cross-cutting objectives. To ensure delivery of the plan is embedded in the business, a staff objective cascade will be issued from Chief Officer downwards.

2.4. Annex C (see page 19) shows the distribution of deliverables over 2021/22 and 2022/23. During development, we aimed to avoid front-loading to account for the impact on staff of Transformation Programme implementation. A degree of balance has been achieved but there are several change deliverables that must, unavoidably, be delivered early in 2021/22. We must also bear in mind the ongoing impact of COVID-19.

3. Proposal

3.1. The content for the standalone public-facing document contains the narrative about the change the agency is undergoing, and it is intended to be published and used for engagement. A branded and art-worked version of the plan has been briefed to designers and we are working on that in parallel.

3.2. This public document is supported by an internal document that has more detail on the deliverables and which will be used by the ExCo to track delivery and to support the cascading of objectives.

3.3. While we have shared some of the emerging material, we have not been able to undertake extensive consultation in advance of the Board given current wider pressures. However, the plan is based on a good understanding of the links with our key partners from ongoing dialogue. We propose to use the public version of the plan as a consultation tool and will be sharing it with our partners following the Board to raise awareness and seek commitment.

3.4. There will be regular monitoring of progress against delivery via our updated governance arrangements, and a review and refresh of the plan in quarter 4 of 2021/22 in line with normal business planning processes. To facilitate monitoring and assurance, we are enhancing our processes and doing further work on Key Performance Indicators to support the new Balanced Scorecard. This work will also address the recommendations in the recent MHRA Business Planning audit report that was discussed at the Agency's Audit & Risk Assurance Committee (ARAC) meeting on 14 April. The audit was commissioned to inform planned process updates; their report noted that progress has been made but there are a few areas where additional work is recommended to strengthen reporting and governance arrangements (eg finalising the Balanced Scorecard, developing further KPIs, defining a more robust prioritisation framework and monitoring process).

4. Recommendation

4.1. The draft Delivery Plan (2021-2023) is the product of an extensive development process lead by the ExCo. We recommend that the Board approves the draft plan and provides any comments on the content. We will then finalise and publish an art-worked document, engage more broadly with partners on delivery, and further develop Key Performance Indicators and the Balanced Scorecard and our ability to monitor delivery against them.

Jon Fundrey
20 April 2021

Annex A: Delivery Plan 2021-2023: A new era for the MHRA – putting patients first

1. Introduction

Today's world calls for a new MHRA driving forward a new era in enabling regulation, regulatory science and best evidence. Today's public and patients have rightful expectations of safety and involvement in decisions about their healthcare products. Today's brilliant Life Sciences industry demands an agile and supportive regulator. Today's health service deserves safe and speedy access to the most transformative products. The future MHRA starts today and this plan is the road map to our future Agency. It represents the beginning of a new era in the protection of patients and the improvement of the public's health through innovative regulation based on excellence in science.

This time of change is a generational opportunity to deliver a new era and transform our organisation. As such, we are committed to delivering this new, ambitious two-year Delivery Plan (2021-2023), which aims to build a new organisation that is fit for the future and underpinned by a robust long-term business model. Successful delivery of our plan will ensure that we put patients first, become a truly world-leading, enabling regulator and that we protect public health through excellence in regulation and science.

2. Our Purpose

Our 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.

We aspire to be a leading global example of delivering excellence in public health and patient safety, enabled through regulation and at the forefront of innovation. Delivering our vision relies on our ability to act as One Agency, making the most of every benefit our collective experience and expertise provides, and relentlessly pursuing ways to apply these benefits to delivering meaningful outcomes for the patients we serve.

That means drawing together our scientific rigour and regulatory expertise to drive a new approach to addressing the challenges faced by the life sciences sector – how best to quickly realise the benefits that new therapies, artificial intelligence and innovative devices can bring to patients, while still ensuring the right levels of safety, quality and efficacy. It means developing new regulatory frameworks, drawing from our experience, and our productive relationships with other health system partners domestically and other regulators internationally. It means a continued refinement of our processes, innovation in thinking and agility in our approach to ensure we deliver for patients.

Our response to the challenge of COVID-19 has shown what sort of Agency we can be. We have flexed our resources and demonstrated agility in our approach. We have facilitated and worked quickly and thoroughly to approve clinical trials which have generated a sound evidence base for effective treatments for those infected, and for the approval of vaccines to prevent infection. Our rolling reviews of the evidence in this emergency have enabled us to rapidly approve licences for these products, while maintaining high standards of safety, efficacy and quality – these actions have enabled a vaccine rollout that has directly saved lives. Finally, our new approach to interrogating high volumes of safety data from those inoculated means we can provide public health advice in real-time about the benefit-risk of the vaccines across the UK population.

One Agency, delivering for patients.

We know that this means we need to change, right across the agency, if we are to be successful in delivering our vision. In the Independent Medicines and Medical Devices Safety Review, Baroness Cumberlege exposed 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. Our plan addresses these with clear actions.

At the same time as embedding the needs and expectations of patients and the public throughout our organisation, we are also working to maximise the opportunities that follow our departure from the European regulatory system to support the UK life sciences sector. We can evolve our regulatory framework so that it looks to the future and keeps pace with fast-moving life science developments, from novel personalised medicines to software and artificial intelligence, whilst ensuring our regulation provides the utmost protection of patients.

As the UK regulator, we play a pivotal role in the health and social care system and a leading role internationally. Our remit is UK-wide and we are committed to maintaining our strong relationships with the Devolved Administrations. We are now working more closely than ever with our partners to deal with the challenges of COVID-19 and support the NHS with the technologies and therapies it needs. Many of the most important healthcare agendas, from encouraging innovation to ensuring patient safety, require this sort of cross-system working – and the need for better collaboration was also a key theme of the Independent Medicines and Medical Devices Safety Review. We are committed to building on recent best practice and delivering our objectives in collaboration with others within and beyond the UK health and social care system.

3. Our Resources

We employ more than 1,200 people and have facilities in London, York and Hertfordshire. Our highly skilled staff are among the best medical, regulatory and scientific experts in their fields, worldwide.

Using that expertise, we undertake a range of important services to protect public health:

- Taking prompt action on safety issues and providing advice about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use.
- Bringing innovation safely to patients as rapidly as possible.
- Ensuring that the UK's supply chain is safe and secure.
- Undertaking the standardisation and control of biological medicines and promoting international standardisation and harmonisation.
- Supporting innovation and research and development.
- Influencing UK and international regulatory frameworks so that they're risk-proportionate and effective.
- Enabling up to the minute studies and trials by offering our anonymised NHS clinical data service, which has data encompassing 60 million patients, including 16 million currently registered patients.

The agency is an arms-length body of the Department of Health and Social Care. We are funded mostly by income from fee-charging activities and sales from the products and services we offer, with the remainder of funds coming from the Department of Health and Social Care as grant-in-aid for specific activities mainly related to medical devices regulation and scientific research. As a government trading fund our finances have been

separate from our sponsor department. In 2018 the Office for National Statistics assessed the economic status of the agency and concluded we should be classified to the central government subsector. Once the relevant statutory instruments for the revocation of the Trading Fund status are enacted, our finances will be consolidated within the department's accounting boundary.

The agency utilises the expert advice of the Commission on Human Medicines, the UK Government's independent advisory body on the safety, efficacy and quality of medicinal products. Chaired by Professor Sir Munir Pirmohamed, the Commission on Human Medicines advises ministers, is comprised of world leading experts, and has supporting advisory committees and working groups. This network of experts helps ensure that decisions are independent and based on robust evidence.

4. Our Plan

Until now, every five years, the agency has published a Corporate Plan that outlines longer-term aims and objectives. Much has changed since we published our Corporate Plan (2018-2023) and, as outlined above, we are seizing the opportunity to refresh our plan. We intend to deliver a new more focused plan to a shorter timeframe, reflecting the pace needed if we are to realise our aspiration to be a global leader in what we do.

It is vital that we respond to the opportunities we now face, and we must address several substantial and interconnected challenges, including:

- Capitalising on the creation of new international regulatory relationships, enabling collaboration in different ways now that we are no longer part of the European regulatory framework.
- Evolving and strengthening our regulatory framework so that it looks to the future and keeps pace with fast-moving life science developments, from novel personalised medicines to software and artificial intelligence, whilst ensuring our regulation provides for the utmost protection of patients.
- Embedding changes into our everyday practices to deliver the recommendations of the Independent Medicines and Medical Devices Safety Review and ensure that our responsibility to patient safety is the frame for all our decisions.
- Creating a new business model that provides a financially sustainable future and preparing for the end of our operation as a Trading Fund and inclusion within the Department of Health and Social Care's accounting boundary. This will limit the use of our existing reserves to fund our change programme and investments to the 2021/22 financial year. After that date, we will no longer be able to carry forward reserves and will need a new financial model that balances our budget in-year.

Much important work has been done on these areas. Our new Delivery Plan (2021-2023) is designed to bring together and prioritise our existing efforts into one place, and deliver a programme that focuses on delivering over the two-year period.

The new priorities and objectives are being supported by a Change Programme that will deliver structural changes to the organisation and a new operating model by the end of the two-year period of the Delivery Plan (2021-23).

We have also delivered a refresh of our internal governance from the top of the organisation via a refreshed unitary Board and Executive Committee, led by a new Chair and Chief Executive. The creation of a new committee structure will support decision-making and more efficient operation. We have put the product lifecycle for the products we regulate at the core of our new structure. This will break down silos and group our staff and expertise in a way that focuses our resources where they add most value. This will ensure we deliver what our customers want and focus us on delivering public health outcomes that benefit patients.

Our Delivery Plan (2021-2023) is the result of an extensive process of development. Our refreshed unitary Board and Executive Committee, led by our new Chair and Chief Executive, have worked together to agree the strategy that underpins the future of our organisation and the priorities that will shape how we deliver that future. We have developed this alongside an assessment of core activities that must be delivered by the business, and worked to identify interdependencies and trade-offs, which has culminated in the critical objectives that form this plan.

The priorities and objectives of our Delivery Plan (2021-2023) have been informed by our ongoing dialogue with our stakeholders. Partnership working is central to the plan and we intend to use the plan to engage our partners and strengthen relationships with detailed work programmes.

The impact of COVID-19

For as long as it is necessary, we will continue to prioritise efforts to combat COVID-19. As the regulator, we are responsible for continuously monitoring the safety of all medicines, including vaccines, and medical devices once they are approved for use. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

Vaccines are the most effective way to prevent infectious diseases and they save millions of lives worldwide. At the time of writing, over 37 million doses of vaccines against COVID-19 have been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in the UK. Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them. We continually monitor safety during widespread use of any vaccine. This is to ensure vaccines are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.

Our response over the last year has demonstrated our outstanding contribution to public health in the UK and internationally. This work will remain a priority while we deliver the wider objectives in the Delivery Plan (2021-23). We will continue to authorise the development of vaccines, facilitate clinical trials of new medicines, support the supply of safe medicines and healthcare products, and ensure prompt, clear public health communication to the UK population.

5. Our Goals

Our Delivery Plan (2021-2023) has one overarching goal - delivering for patients and the public is at the heart of our plan and is a priority for all staff. The Delivery Plan focuses our efforts on six strategic goals and 14 underpinning objectives. Delivering for patients and the public is at the heart of our plan and is a priority for all staff. Scientific innovation, healthcare access and patient safety are our three key business outcomes. These are enabled by ensuring we have a dynamic organisation, that we make the most of collaborative partnerships and that we are financially sustainable.

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6. Our Deliverables

A PRIORITY FOR ALL OF OUR STAFF

1. Deliver better patient and public involvement to ensure we put patients first

Our vision for a new agency puts patients at the heart of what we do.

The Independent Medicines and Medical Devices Safety Review clearly outlined the importance of more engagement with patients and their outcomes. This is why we have put patient and public involvement at the heart of our Delivery Plan (2021-2023). This is a cross-cutting priority: the majority of the objectives below have been developed with patients and public need in mind. This will ensure we put patients first across the full range of things we do and lifecycle of the products that we regulate, for example:

- Develop our use of Patient Reported Outcome Measures to make patient outcomes more central to clinical trials (objective 3).
- Making patient involvement more prominent in legislation following the Medicines and Medical Devices Act and a new Innovative Licensing and Access Pathway that aims to ensure that patients are involved meaningfully at every stage of the process (objective 4).
- Developing and publicly consulting on a new regime for medical devices that makes patient safety and engagement, and transparency more prominent (objective 5).
- Implementing an enhanced and more responsive reporting system (objective 6).
- Continued prompt public health action to protect patients (objective 6 and 7), supported by communication campaigns and more involvement, and an enhanced Customer Service Centre (objective 12).
- New digital self-service platform that will improve the service patients and customers receive (objective 14).

Accountability: All staff as per the accountability of specific objectives below

SCIENTIFIC INNOVATION

2. Deliver public health impact, world-leading research innovation and a unique proposition

We are recognised as a global leader in science and we will build on this reputation. Our new ambitious science strategy will draw from our deep expertise to ensure we capitalise on the unique selling points and differentiation of our science, research and data. It will allow us to keep pace with the changing needs of patients in the UK, and global trends in medicine and medical device innovation to ensure we prioritise and focus our efforts accordingly. This will ensure we deliver world-leading research innovation that focuses on protecting and improving patient health; and ensures we retain our global prominence.

- Agency Laboratory Standards strategy (biological and pharmacopoeial) and long-term plan developed and published, including public consultation by **Q4, 2021/22** and implemented from **Q1, 2022/23.** Publication of new standards during **2022/23.**
- Upgrade *Clinical Practice Research Datalink's* observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by **Q4, 2021/22;** produce business case to deliver infrastructure and define timescales for implementation of new systems by **Q2, 2022/23.**
- Scale up pilot version the *Clinical Practice Research Datalink's* Observational Medical Outcomes Partnership and release data for pharmacovigilance research by **Q1 2022/23.**
- Risk-based approach to batch release: guidelines drafted by **Q3, 2021/22**; begin implementation of approaches via pilot studies from **Q4, 2021/22.**

Accountability: Chief Scientific Officer

3. Overhaul clinical trials system to support innovation and reduce time to approval

Overhauling the Clinical Trials system will ensure we continue to have a world-leading regulatory system that supports both UK and global trials. We will drive the uptake of innovative trial design, patient focused outcome measures, data enabled recruitment, and real-world evidence collection and analysis. We will put the patient voice, and active patient participation, at the heart of the regulation of trials. We will keep up with international standards and emerging innovative therapies to ensure that those engaged in trials will continue to develop safe, innovative treatments, both benefitting patients and boosting growth. This will ensure we encourage more trials; greatly improve the time it takes for trials to be approved, started, and delivered; and ensure that outcomes are more patient focused.

- *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 **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 NHS X 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;** work up deliverables in **2022/23.**

Accountability: Chief Scientific Officer

HEALTHCARE ACCESS

4. Develop and deliver the agency's future strategy and approach for access to medicines and devices

Following the UK's exit from the EU, we intend 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 passing of the Medicines and Medical Devices Act (2021) brings with it the opportunity to evolve the UK's regulatory regime. We will develop our strategy for the products we regulate and ensure we encourage and enable developers to bring products to the UK market.

- Regulatory evolution post transition: policy development and public consultation, programme and timings agreed and shared **Q1, 2021/22**; resolution of any live regulatory issues following EU transition by **Q3, 2021/22;** consultation on a national scheme to replace the falsified medicines directive by **Q3, 2021/22** and formulation of final of post-standstill policy during **2022.**
- 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**.
- Reduce regulatory burden by identifying which flexibilities introduced in response to Covid-19 are safe to embed**,** working with stakeholders from **Q3**, **2021/22** to develop proposal.
- Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of International *Pharmaceutical* Regulators Programme from **Q3, 2021/22**; take forward discussion of UK Biosimilar guidance in the Access Consortium from **Q3, 2021/22.**
- Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access consortium 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.**

- Ensure integrated UK regulatory pathways for products that combine medicinal products and medical devices; consultation by **Q3, 2022/23.**
- Continued regulation of the Northern Ireland market, under the EU regulatory system, working closely with the Northern Ireland Executive to ensure continued access to life-sciences products.

Accountability: Chief Quality & Access Officer and Chief Partnerships Officer (for legislative change elements)

5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products

Levelling up the UK's medical devices regime will ensure changes in clinical needs, technologies and patient views are integrated into modern and effective legislation. We will design, consult on and implement a new legislative framework. This will support ongoing access to products with the aim of providing an environment in which to support safe innovation. It will build on the existing framework, taking into account international best practice. We will include the following areas in our public consultation: a Medical Device Single Audit Program and domestic assurance approval routes to market; and several areas where we will innovate the framework further, including: software and artificial intelligence, In Vitro Diagnostics, implantable devices and an innovative access pathway for critical novel/innovative devices. To address the recommendations of the Independent Medicines and Medical Devices Safety Review, patient safety and engagement, transparency, and our pre-market role will also be key considerations. In the design and implementation of the new framework, we will work with partners across the healthcare system, including the National Institute for Health and Care Excellence, the Health Research Authority, clinicians, NHSX and NHS Digital. Our efforts will ensure an ongoing supply of safe medical devices to patients, the public and the healthcare system.

- Publish public consultation covering all key aspects of proposed new market access framework by end **Q2**, **2021/22.**
- Publish a consultation response with finalised policy positions by end **Q4**, **2021/22.**
- Lay relevant statutory instruments by end **Q1**, **2022/23.**
- Publish key guidance documents by end **Q3, 2022/23** with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework.

Accountability: Chief Quality & Access Officer

PATIENT SAFETY

6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe

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. We will move towards better risk assessment and more impactful safety messaging. In addition to our own deliverables, we will work closely with NHS colleagues to support the development of the Medical Devices Information System. Our efforts will ensure we keep patients safe and improve our service to patients and healthcare professionals.

- Complete review on new medical devices signals and risk management process, embed risk assessment template and identify opportunities for patient involvement by end **Q1, 2021/22.**
- Options appraisal for Yellow Card Biobank by **Q3, 2021/22.**
- Produce recommendations for improving the model of the Devices Expert Advisory Committee and its Expert Advisory Groups by **Q3, 2021/22**, to place it on a statutory footing and ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.
- Deliver enhanced signal detection process for medicines and devices by **Q4, 2021/22;** service enhancement and international opportunities to defined in **Q4, 2021/22** and delivered in **2022/23.**
- Deliver a significantly enhanced transparency regime for medical device regulation by **Q4**, **2021/22** with key elements being delivered over **2022/23**.
- Further action on sodium valproate to drive compliance with the Pregnancy Prevention Programme. Enhance the registry by extending the established England registry to include all antiepileptics by **end of Q2, 2021/22** and to make available a UK-wide digitalised annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by **end of Q4, 2021/22**.
- Review of teratogen use during pregnancy, and consideration of the strategies of other regulators (by **Q3, 2021/22**), with independent patient and stakeholder input and expert advice by **Q4, 2021/22**; and, if required, updated action and guidance by **Q2, 2022/23**.

Accountability: Chief Safety Officer

7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products

Delivering a secure supply chain for medical products, and to the highest internationally-accepted standards will help keep patients and the public safe. We will protect the UK's supply chain via pro-active management of poor compliance, a proportionate risk-based inspection programme and innovative interventions to disrupt serious criminal threats. Building on and learning from the agency's ongoing response to the COVID-19 pandemic, we will also look for ways to reduce any unnecessary regulatory burdens and increase the efficiency of our processes. This will help ensure that patients get access to medical products and that we protect public health.

- Process improvements: pilot voluntary 'pre-inspection' check prior to deploying inspectors and pilot use of consultants by **Q3, 2021/22** and roll out of automated inspection reports and identify new risk-proportionate approaches with our international partners by **Q4, 2021/22;** embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections in **2022/23**.
- Deliver the Great Britain Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain – delivery in partnership with the Department of Health and Social Care and to their timescales when finalised.
- Deliver a world leading approach to inspections and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats throughout **2021/22** and **2022/23.**

Accountability: Chief Safety Officer

DYNAMIC ORGANISATION

8. Deliver the Change Programme to make our agency a truly world-leading, innovative regulator

We have reached a pivotal point for the agency's development and have the opportunity to become a global exemplar in public health and patient safety, enabled through regulation and at the forefront of innovation. Our Change Programme will drive change across the agency, supporting the Delivery Plan (2021-23) and ensuring we deliver our objectives with greater accountability, focus on benefits and a systematic prioritisation of activities that add value and deliver better outcomes for patients. This will ensure the agency successfully adapts and becomes a truly world-leading, innovative regulator.

- Embed Delivery Plan (2021-2023) in staff objectives by **Q1, 2021/22;** monitor performance from **Q2, 2021/22** with an update reporting approach; and review and revise plan with the Department by **Q1, 2022/23** as part of annual business planning.
- Deliver accompanying Change programme and organisational redesign (staffing, governance, structures, processes) by **Q4, 2021/22** and post implementation support including benefits realisation from **April 2022** onwards**.**

Accountability: Chief Executive

9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change

Leadership and workforce planning are vital to supporting organisational change, maintaining high performance and attracting the expertise we need to remain a first-class regulator. We will deliver a programme alongside wider agency change to identify workforce and talent requirements, and the training our staff need. We will work to attract, retain and develop staff. This will ensure we have the right workforce and we empower our staff to put patients first and deliver the change needed to make our Delivery Plan (2021-2023) a success.

- Develop agency culture action plan by **Q1, 2021/22** and deliver associated actions; refresh plan in **Q1, 2022/23.**
- Launch staff leadership action plan from **Q2, 2021/22.**
- Deliver Human Resources support and guidance to support staff through agency restructuring throughout **Q1-Q4, 2021/22.**
- Identify agency future workforce and talent needs and deliver action to ensure the agency better embeds workforce planning by **Q2, 2021/22;** and review workforce in **Q1, 2022/23** to identify follow up actions.

Accountability: Chief Operating Officer

COLLABORATIVE PARTNERSHIPS

10. Leverage international partnerships to drive better outcomes

We are committed to excellent international relationships that deliver high standards of patient protection, prompt access to innovative products and that keep the UK an attractive market for developers and manufacturers of medical products. We will work with international partners to scope and deliver priority work programmes, particularly delivering interoperability of data and systems; strengthening the outputs of the Access Consortium, helping to make it competitive as a global regulatory pathway for companies;

and helping to maintain and establish new relationships globally following EU Exit. This will ensure make the most of the opportunities of EU exit and ensure the agency retains its leading role internationally.

- Development of an international strategy underpinning and aligned to the wider objectives in the Delivery Plan (2021-23) by **Q1, 2021/22.**
- Continuing our collaboration with the EU, through the establishment of the Medicinal Products Working Group, established under the Trade and Cooperation Agreement to as a forum for bilateral cooperation that can be built on in future. **Q2, 2021/22.**
- Collaborating with other country regulators, to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by **Q4, 2022/2023.**
- Full assessment of the linkages needed with the World Health Organisation, including in the context of the National Institute for Biological Standards and Control's standards work by **Q2, 2021/22.**
- Improve ability to capture and exchange data with partners by adopting international standards including "Identification of Medicinal Products" regulations by **Q2, 2022/23.**
- Engage with Access group and define options for approach to information sharing, joint inspections, interoperability of systems standards by **Q3, 2021/22** for delivery in **2022/23** (exact timings dependent on ongoing negotiations).
- Deliver refreshed inspection network that add strengths and international standing to the work of the MHRA's Inspectorate by **Q4, 2021/22.**
- Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation **throughout 2021-23 as per Department for International Trade timescales.**

Accountability: Chief Partnerships Officer

11. Leverage UK healthcare system partnerships and integrating process to drive better outcomes

The complex cross-cutting nature of issues facing a modern health and social care system means effective partnerships are vital to ensuring we deliver our objectives. We will enhance our relationships with key partners, with defined work programmes and impacts, and with a particular focus on NHS organisations, including the National Institute for Health and Care Excellence, the Scottish Medicines Consortium and the Health Research Authority. We will continue to deliver our commitments to the Department for Health and Social Care, UK Ministers and the Devolved Administrations. This will ensure we protect public health, maximise our impact and reach across clinical networks and more effectively share information to empower patients and the public to make informed decisions.

- Revised Partnership Agreement and a detailed package of work programmes, agreed with the National Institute for Health and Care Excellence, focused on safety and standards, improving timely access to medicines and healthcare products for patients and the promotion of innovation and growth by **Q1, 2021/22.**
- Deliver Agency data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by **Q3, 2021/22.**

- Map and identify the most important partnerships for delivery of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from **Q2** and in place by **Q4, 2021/22**.
- Partnerships meetings run with Devolved Administrations and wider stakeholder groups to inform and involve them on the delivery of their priorities quarterly throughout **2021/22** and **2021/22.**
- Continued delivery of our commitments to the Department of Health and Social Care and Government ministers throughout **2021/22** and **2021/22.**

Accountability: Chief Partnerships Officer

12. Build public and stakeholder trust in our organisation through a programme of pro-active and innovative communications

As a regulator, it is vital that we maintain trust in our approach, expertise, products and services. We will deliver a programme of pro-active and innovative communications to support the delivery of all relevant Delivery Plan (2021-2023) 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. This will help build public and stakeholder trust and support the delivery of wider objectives.

- Communications to support launch and ongoing service provision of wider plan actions across **2021/22** and **2023/23** (covers all communication deliverables in the wider plan).
- Ongoing prompt and responsive safety communication action (COVID-19, Yellow Card, Safety Connect, #FakeMeds, safer medicines and devices for women, drug safety issues, reclassifications and alerting / notifications) throughout **2021/22** and **2023/23.**
- Develop and deliver further communications to support the evolution of the agency's COVID-19 vaccines strategy **from Q2, 2021/22).**
- Enhance Customer Service Centre to support effective engagement with patients and customers, enabling them to access the information they need when they need it from **Q4, 2021/22.**

Accountability: Chief Executive

FINANCIAL SUSTAINABILITY

13. Establish a new business model for the future that increases income, reduces costs and improves productivity

We must create a new business model that ensures the agency has a financially sustainable future given the changing circumstances. We will conduct a full review across our sources of income and costs, adjusting fees and defining a new business model. This will ensure the agency is put on a robust footing for the future.

- Develop, consult on **(Q3, 2021/22)** and implement a new fee structure by **Q2, 2022/23.**
- Implement organisational design, creating a new, leaner structure for the agency and balancing our costs by **Q3, 2021/22.**
- Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at end **2021/22.**

- Reduce corporate costs by 15% by end **2022/23.**
- Reduce non-pay costs of £60m by £6m per a year through contract renegotiation & contract management by end **2022/23.**

Accountability: Chief Operating Officer

14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies

Modern digital, data and technology solutions are central to our new Agency and the services we provide. We will deliver simple, smart solutions using automation, artificial intelligence and digital self-service. We will build on established technology platforms so they support multiple services, improve interoperability across the UK health system and internationally and optimise costs. This will ensure we focus on meeting patients and our stakeholders' needs more completely and quickly than ever before. It will also improve our ability to share data and collaborate across the UK health system and internationally; provide opportunities to reduce costs and ultimately enhance our ability to protect public health.

- Finalise plan to overhaul costly legacy systems by **Q3, 2021/22** and start to deliver improved service and savings from **Q4, 2021/22,** and to have a new regulatory management core system in place by **Q3, 2022/23.**
- New digital self-service platform delivered in beta by **Q4, 2021/22** and live in **Q1, 2022/23** that will improve the service patients and customers receive.
- To support the revised regulations around medical devices, deliver the digital self-service, automation and data platforms required by **Q3, 2022/23**.
- Work with the Health Research Authority to deliver an enhanced clinical trials service by **Q4 2022/23.**

Accountability: Chief Technology Officer

7. Our Reporting

Each year, as part of the Department of Health and Social Care's annual planning process, our strategy, targets and plans are summarised and reported to the Department for scrutiny and review. Before the start of each financial year, we prepare, for endorsement by our Board and agreement with the Department, a plan that demonstrates how the Agency will deliver its objectives and the regulatory functions that the Secretary of State has instructed the agency to carry out on his/her behalf. Each plan sets out the intended activity for the following financial year and includes specific objectives and deliverables. Once approved by our Board and the Department, we publish a summary of the plan. Progress against delivery will be reviewed as part of our quarterly and annual accountability meetings with the Department. Progress will be monitored internally by the agency's new unitary Board and Executive Committee, supported by our new cross-agency Management Committees and a balanced scorecard with performance measures for our strategic objectives.

8. Back page material

We are an Executive Agency of the Department of Health and Social Care. The Department holds the agency to account for our performance, and we work in partnership to serve ministers and Parliament. Details on the relationship between the Department

and agency can be found in our Framework Agreement. As UK civil servants, all staff are committed to the Civil Service core values of integrity, honesty, objectivity and impartiality

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Office hours are Monday to Friday, 8:30am to 5pm. For real-time updates including the latest press releases and news statements, see our Twitter channel at www.twitter.com/mhragovuk

Annex B - The ExCo is collectively accountable for delivery with a named lead for each objective

Objective	**ExCo accountability**
1. Deliver better patient and public involvement to ensure we put patients first	All
2. Deliver public health impact, world-leading research innovation and a unique proposition	Christian Schneider
3. Overhaul clinical trials system to support innovation and reduce time to approval	Christian Schneider
4. Develop and deliver the Agency's future strategy and approach for access to medicines and devices (also includes COVID-19 regflex and new legal regime)	Sam Atkinson (operation) Chief Partnership Officer (new legal regime)
5. Establish a new medical devices regulatory framework to support safe innovation and ongoing access to products	Sam Atkinson
6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe	Chief Safety Officer
7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products	Chief Safety Officer
8. Deliver the Transformation Programme to make our Agency a truly world-leading, innovative regulator (includes Delivery Plan monitoring, business planning, work scoping the potential for automation, and improving our DDAT services)	June Raine
9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change	Jon Fundrey
10. Leverage international partnerships to drive better outcomes (x-cutting, input from others based on partner)	Chief Partnership Officer
11.Leverage UK healthcare system partnerships and integrating process to drive better outcomes (x-cutting, input from others based on partner)	Chief Partnership Officer
12. Build public and stakeholder trust in our organisation through a programme of pro-active and innovative communications (+ communication solutions for other objectives)	June Raine
13. Establish a new business model for the future that increases income, reduces costs and improves productivity	Jon Fundrey
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies (+ technology solutions for other objectives)	John Quinn

Annex C – Breakdown of deliverables by quarter to show the distribution of work over 2021/22 and 2022/23

Objective	Time period 2021/22			
	Q1 2021/22	Q2 2021/22	Q3 2021/22	Q4 2021/22
1. Deliver better patient and public involvement to ensure we put patients first	Cross cutting – see other items below	Cross cutting – see other items below	Cross cutting – see other items below	Cross cutting – see other items below
2. Deliver public health impact, world-leading research innovation and a unique proposition			• Risk-based approach to batch release: guidelines drafted by **Q3, 2021/22**; begin implementation of approaches via pilot studies from **Q4, 2021/22.**	• Risk-based approach to batch release: guidelines drafted by **Q3, 2021/22**; begin implementation of approaches via pilot studies from **Q4, 2021/22.** • Laboratory Standards strategy (biological and pharmacopoeial) and long-term plan developed and published, including public consultation by **Q4, 2021/22** and implemented from **Q1, 2022/23.** Publication of new standards during **Q1-4 2022/23.** • Upgrade CPRD's observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by **Q4, 2021/22;** produce business case to deliver infrastructure and define timescales for implementation of new systems by **Q2, 2022/23.**
3. Overhaul clinical trials system to support innovation and reduce time to approval			• Enhance the research services of the CPRD: 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 CPRD.	• Encourage a more innovative and pragmatic approach to UK clinical trials via an initiative to facilitate the uptake of novel trail designs (eg cluster randomised trials) and a comms effort to tackle the misperceptions that "traditional" clinical trials are always required for a license **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 license 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.** • 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;** work up deliverables in **2022/23.**
4. Develop and deliver the agency's future strategy and approach for access to medicines and devices	• Regulatory evolution post transition: policy development and public consultation, programme and timings agreed and shared **Q1, 2021/22**; resolution of any live regulatory issues following EU transition by **Q3, 2021/22;** consultation on a national scheme to replace the falsified medicines directive by **Q3, 2021/22** and formulation of final of post-standstill policy during **2022.**	• 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**.	• Regulatory evolution post transition: policy development and public consultation, programme and timings agreed and shared **Q1, 2021/22**; resolution of any live regulatory issues following EU transition by **Q3, 2021/22;** consultation on a national scheme to replace the falsified medicines directive by **Q3, 2022/23** and formulation of final of post-standstill policy during **2022.** • Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of International Pharmaceutical Regulators Programme from **Q3, 2021/22**; take forward discussion of UK Biosimilar guidance in the Access Consortium from **Q3, 2021/22.** • Further develop the Innovative Licensing and Access Pathway concepts and tools, in collaboration with National Institute for Health and Care	• Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via ACCESS consortium by **Q4, 2021/22.**

			• Excellence (NICE), to create a world-class first port of call for medicines development and access by **Q3, 2021/22.** • Reduce regulatory burden by identifying which flexibilities introduced in response to Covid-19 are safe to embed**,** working with stakeholders from **Q3**, **2021/22** to develop proposal.	
	• Continued regulation of the Northern Ireland market, under the EU regulatory system, working closely with the Northern Ireland Executive to ensure continued access to life-sciences products.			
5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products		• Publish public consultation covering all key aspects of proposed new market access framework by end **Q2**, **2021/22.**		• Publish a consultation response with finalised policy positions by end **Q4**, **2021/22.**
6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe	• Complete review on new devices signals and risk management process, embed risk assessment template and identify opportunities for patient involvement by **Q1, 2021/22.**	• Further action on sodium valproate to drive compliance with the Pregnancy Prevention Programme. Enhance the registry by extending the established England registry to include all antiepileptics by **Q2, 2021/22** and to make available a UK-wide digitalised annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by **Q4, 2021/22.**	• Options appraisal for Yellow Card Biobank by **Q3 2021/22.** • Produce recommendations for improving the model of the Devices Expert Advisory Committee (DEAC) and its Expert Advisory Groups (EAGs) by **Q3, 2021/22**, to place it on a statutory footing and ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making. • Review of teratogen use during pregnancy, and consideration of the strategies of other regulators (by **Q3 2021/22**), with independent patient and stakeholder input and expert advice by **Q4 2021/22**; and, if required, updated action and guidance by **Q2 2022/23.**	• Deliver enhanced signal detection process for medicines and devices by **Q4, 2021/22;** service enhancement and international opportunities to defined in **Q4, 2021/22** and delivered in **2022/23.** • Deliver a significantly enhanced transparency regime for medical device regulation by **Q4**, **2021/22** with key elements being delivered over **2022/23**. • Review of teratogen use during pregnancy, and consideration of the strategies of other regulators (by **Q3 2021/22**), with independent patient and stakeholder input and expert advice by **Q4 2021/22**; and, if required, updated action and guidance by **Q2 2022/23.** • Further action on sodium valproate to drive compliance with the Pregnancy Prevention Programme. Enhance the registry by extending the established England registry to include all antiepileptics by **Q2, 2021/22** and to make available a UK-wide digitalised annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by **Q4, 2021/22.**
7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products			• Process improvements: pilot voluntary 'pre-inspection' check prior to deploying inspectors and pilot use of consultants by **Q3 2021/22** and roll out of automated inspection reports and identify new risk-proportionate approaches with our international partners by **Q4 2021/22;** embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections in **2022/23**.	• Process improvements: pilot voluntary 'pre-inspection' check prior to deploying inspectors and pilot use of consultants by **Q3 2021/22** and roll out of automated inspection reports and identify new risk-proportionate approaches with our international partners by **Q4 2021/22;** embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections in **2022/23**.
	• Deliver a world leading approach to inspections and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats throughout **2021/22** and **2022/23.** • Deliver the GB Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain – delivery in partnership with the DHSC and to their timescales when finalised.			
8. Deliver the Change Programme to make our agency a truly world-leading, innovative regulator	• Embed Delivery Plan (2021-2023) in staff objectives by **Q1 2021/22;** monitor performance from **Q2 2021/22** with an update reporting approach; and review and revise plan with the Department by **Q1 2022/23** as part of annual business planning.	• Embed Delivery Plan (2021-23) in staff objectives by **Q1 2021/22;** monitor performance from **Q2 2021/22** with an update reporting approach; and review and revise plan with the Department by **Q1 2022/23** as part of annual business planning.		• Deliver the Change programme and organisational redesign (staffing, governance, structures, processes) by **Q4 2021/22** and post implementation support including benefits realisation from **April 2022 onwards.**
9. Deliver a programme to enhance our leadership capability to attract, retain	• Develop agency culture action plan by **Q1 2021/22** and deliver associated	• Launch staff leadership action plan from **Q2, 2021/22.**		

and develop talent so that we can fuel innovation and drive change	actions; refresh plan in **Q1, 2022/23.**	• Identify agency future workforce and talent needs and deliver action to ensure the agency better embeds workforce planning by **Q2 2021/22;** and review workforce in **Q1, 2022/23** to identify follow up actions.		
	• Deliver HR support and guidance to support staff through agency restructuring throughout **Q1-Q4, 2021/22.**			
10. Leverage international partnerships to drive better outcomes	• Development of an international strategy for the MHRA, underpinning and aligned to the objectives of the Delivery Plan by **Q1, 2021/22.**	• Full assessment of the linkages needed with the WHO, including in the context of NIBSC standards work by **Q2 2021/22.** • Continuing our collaboration with the EU, through the establishment of the Medicinal Products Working Group, established under the Trade and Cooperation Agreement to as a forum for bilateral cooperation that can be built on in future. **Q1 2021/22.**	• Engage with ACCESS group and define options for approach to information sharing, joint inspections, interoperability of systems standards by **Q3 2021/22** for delivery in **2022/23** (exact timings dependent on ongoing negotiations).	• Deliver refreshed inspection network that add strengths and international standing to the work of the MHRA's Inspectorate by **Q4, 2021/22.**
	• Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation **throughout 2021 2023 as per DIT timescales.**			
11. Leverage UK healthcare system partnerships and integrating process to drive better outcomes	• Partnerships meetings run with Devolved Administrations and wider stakeholder groups to inform and involve them on the delivery of their priorities quarterly throughout **2021/22** and **2021/22.** • Continued delivery of our commitments to the Department of Health and Social Care and Government ministers throughout **2021/22** and **2021/22.**			
	• Revised Partnership Agreement and a detailed package of work programmes, agreed with NICE, focused on safety and standards, improving timely access to medicines and healthcare products for patients and the promotion of innovation and growth by **Q1, 2021/22.**		• Deliver Agency data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by **Q3 2021/22.**	• Map and identify the most important partnerships for delivery of our 2021 -23 objectives, and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from **Q2** and in place by **Q4, 2021/22**.
12. Build public and stakeholder trust in our organisation through a programme of pro-active and innovative communications	• Communications to support launch and ongoing service provision of wider plan actions across **2021/22** and **2023/23** (covers all communication deliverables in the wider plan). • Ongoing prompt and responsive safety communication action (COVID-19, Yellow Card, Safety Connect, #FakeMeds, safer medicines and devices for women, drug safety issues, reclassifications and alerting / notifications) throughout **2021/22** and **2023/23.**			
		• Develop and deliver further comms to support the evolution of the agency's COVID-19 vaccines strategy **from Q2, 2021/22).**		• Enhance Customer Service Centre to support effective engagement with customers, enabling them to access the information they need when they need it from **Q4, 2021/22.**
13. Establish a new business model for the future that increases income, reduces costs and improves productivity			• Develop, consult on **(Q3, 2021/22)** and implement a new fee structure by **Q2, 2022/23.** • Implement organisational design, creating a new leaner structure for the agency and balancing our costs by **Q3, 2021/22.**	• Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at end 2021/22.
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies			• Finalise plan to overhaul costly legacy systems by **Q3, 2021/22** and start to deliver improved service and savings from **Q4, 2021/22,** and to have a new regulatory management core system in place by **Q3, 2022/23.**	• New digital self-service platform delivered in beta by **Q4, 2021/22** and live in **Q1, 2022/23** that will increase the service patients and customers receive. • New digital self-service platform delivered in beta by **Q4, 2021/22** and live in **Q1, 2022/23** that will increase the service patients and customers receive. • Finalise plan to overhaul costly legacy systems by **Q3, 2021/22** and start to deliver improved service and savings from **Q4, 2021/22,** and to have a new regulatory management core system in place by **Q3, 2022/23.**

Objective	Time period 2022/23			
	Q1 2022/23	Q2 2022/23	Q3 2022/23	Q4 2022/23
1. Deliver better patient and public involvement to ensure we put patients first	Cross cutting – see other items below	Cross cutting – see other items below	Cross cutting – see other items below	Cross cutting – see other items below
2. Deliver public health impact, world-leading research innovation and a unique proposition	• Scale up pilot version of CPRD's Observational Medical Outcomes Partnership and release data for pharmacovigilance research by **Q1 2022/23.** • MHRA Laboratory Standards strategy (biological and pharmacopoeial) and long-term plan developed and published, including public consultation by **Q4, 2021/22** and implemented from **Q1, 2022/23.** Publication of new standards during **Q1-4 2022/23.**	• Upgrade CPRD's observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by **Q4, 2021/22;** produce business case to deliver infrastructure and define timescales for implementation of new systems by **Q2, 2022/23.**		
3. Overhaul clinical trials system to support innovation and reduce time to approval	• 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.**	• Enhance the research services of the Clinical Practice Research Datalink (CPRD): 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 CPRD. • Promote the Innovative Licensing and Access Pathway Novel Trial Design Tool in partnership with the wider health ecosystem by **Q2 2022/23.**		• Deliver NHSX funded synthetic data research project by **Q4 2021/22** and launch prototype synthetic data generation service by **Q2 2022/23.** • Enhance the research services of the Clinical Practice Research Datalink (CPRD): 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 CPRD.
4. Develop and deliver the agency's future strategy and approach for access to medicines and devices	• 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**.		• Ensure integrated UK regulatory pathways for products that combine medicinal products and medical devices; consultation by **Q3, 2022/23.** • Regulatory evolution post transition: policy development and public consultation, programme and timings agreed and shared **Q1, 2021/22**; resolution of any live regulatory issues following EU transition by **Q3, 2021/22;** consultation on a national scheme to replace the falsified medicines directive by **Q3, 2022/23** and formulation of final of post-standstill policy during **2022.**	
	• Continued regulation of the Northern Ireland market, under the EU regulatory system, working closely with the Northern Ireland Executive to ensure continued access to life-sciences products.			
5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products	• Lay relevant statutory instruments by end **Q1**, **2022/23.**		• Publish key guidance documents by end **Q3, 2022/23** with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework.	
6. Deliver a more responsive safety surveillance and risk management system for all medical products to keep patients safe		• Review of teratogen use during pregnancy, and consideration of the strategies of other regulators (by **Q3 2021/22**), with independent patient and stakeholder input and expert advice by **Q4 2021/22**; and, if required, updated action and guidance by **Q2 2022/23**		

7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products	• Process improvements: pilot voluntary 'pre-inspection' check prior to deploying inspectors and pilot use of consultants by **Q3 2021/22** and roll out of automated inspection reports and identify new risk-proportionate approaches with our international partners by **Q4 2021/22;** embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections in **2022/23**.			
8. Deliver the Change Programme to make our agency a truly world-leading, innovative regulator	• Embed Delivery Plan (2021-2023) in staff objectives by **Q1 2021/22;** monitor performance from **Q2 2021/22** with an update reporting approach; and review and revise plan with the Department by **Q1 2022/23** as part of annual business planning.			
9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change	• Develop agency culture action plan by **Q1 2021/22** and deliver associated actions; refresh plan in **Q1, 2022/23.** • Identify agency future workforce and talent needs and deliver action to ensure the agency better embeds workforce planning by **Q2 2021/22;** and review workforce in **Q1, 2022/23** to identify follow up actions.	•		
10. Leverage international partnerships to drive better outcomes		• Improve ability to capture and exchange data with partners by adopting international standards including IDMP by **Q2 2022/23.**	Deliverables to be confirmed during 2021/22	• Collaborating with other country regulators, to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by **Q4 2022/23.**
	• Actively engage in ongoing trade negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation **throughout 2021 2023 as per DIT timescales.**			
11. Leverage UK healthcare system partnerships and integrating process to drive better outcomes	Deliverables to be confirmed during 2021/22	Deliverables to be confirmed during 2021/22	Deliverables to be confirmed during 2021/22	Deliverables to be confirmed during 2021/22
12. Build public and stakeholder trust in our organisation through a programme of pro-active and innovative communications	• Communications to support launch and ongoing service provision of wider plan actions across **2021/22** and **2023/23** (covers all communication deliverables in the wider plan). • Ongoing prompt and responsive safety communication action (COVID-19, Yellow Card, Safety Connect, #FakeMeds, safer medicines and devices for women, drug safety issues, reclassifications and alerting / notifications) throughout **2021/22** and **2023/23.**			
13. Establish a new business model for the future that increases income, reduces costs and improves productivity		• Develop, consult on **(Q3, 2021/22)** and implement a new fee structure by **Q2, 2022/23.**		• Reduce corporate costs by 15% by end **2022/23.** • Reduce non-pay costs of £60m by £6m per a year through contract renegotiation & contract management by end **2022/23.**
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies	• New digital self-service platform delivered in beta by **Q4, 2021/22** and live in **Q1, 2022/23** that will increase the service patients and customers receive. • New digital self-service platform delivered in beta by **Q4, 2021/22** and live in **Q1, 2022/23** that will increase the service patients and customers receive.		• To support the revised regulations around medical devices, deliver the digital self-service, automation and data platforms required by **Q3, 2022/23**. • Finalise plan to overhaul costly legacy systems by **Q3, 2021/22** and start to deliver improved service and savings from **Q4, 2021/22,** and to have a new regulatory management core system in place by **Q3, 2022/23.**	• Work with the Health Research Authority (HRA) to deliver an enhanced clinical trials service by **Q4 2022/23.**

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 April 2021

Title	What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?
Board Sponsor	Mercy Jeyasingham NED and Chair PSEC
Purpose of Paper	Assurance

Medicines & Healthcare products Regulatory Agency

What assurance can be provided by the Patient Safety and Engagement Committee (PSEC)?

1. Executive Summary

1.1 At the second meeting PSEC approved the Implementation Plan for CPRD data access and discussed three other areas of development. These were the Healthcare Professionals Engagement Strategy, the Yellow Card Scheme and the Innovation Licensing and Access Pathway (ILAP). The level of 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, 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.

2. Introduction

2.1 The second meeting of PSEC was held on 8 April 2021 and had four items on the agenda. The meeting started with a review of what the committee needs in terms of information and analysis from papers to enable it to assure the Board. The current format and content of papers did not provide the type of information the committee needed. Non -Executive members of the committee particularly needed more detailed information on what happens currently; how it is currently delivered; the proposed changes to enable greater patient and public involvement; improvements and the evidence on which proposals were based; and most importantly how the impact of changes will be measured and evaluated. Authors of the papers explained that the transition to new ways of working was underway and not yet complete, and two of the papers were exploratory and presented for an early orientation from PSEC. Overall it was agreed that having greater clarity in what was expected of papers from the committee was helpful.

3. PSEC then discussed each of the following items:

3.1 **CPRD Implementation Plan (Approved)**

PSEC was given the background to this issue. The process used by CPRD to allow researchers to access its data for public health studies was independently reviewed in 2019 and the recommendations were then supported by the MHRA Board. Delays to implementing governance changes were due to the pandemic. PSEC was now being asked to approve the plan. PSEC asked about the criteria used to select Lay Members of the proposed Central Advisory Committee (CAC), as well as their induction and training. It was noted that taking a risk-based approach might be more efficient in terms of use of resources,

but it was not clear what constituted high or low risk ("routine" and "non-routine") applications. It was agreed that specific decisions made by staff that were not reviewed by Expert Committees or the proposed CAC should be tabulated and presented to the CAC on a regular basis, so its members were aware of the type and volume of applications being approved in this way. CPRD was also aware of the consultation on the Government Code of Practice for Scientific Advisory Committees (CopSAC) The proposed changes were in line with this. CPRD was also asked to reflect on the outcome of the most recent 2020 Caldicott consultation. PSEC then approved the plan but asked CPRD to come back to PSEC at the end of the year for a review of how the new governance systems were working.

3.2 **Healthcare Professionals Engagement Strategy**

The proposed strategy for improved engagement with healthcare professionals was considered to be at an early stage. There was agreement that more research is needed to understand whom we are trying to engage with, and why. Prescribers (including doctors and pharmacists) are clearly important, both in their own right and also because they act as an information source for patients. A variety of other health professionals are also relevant. Raising the profile of the MHRA with a wide range of health professionals will help attract more people to apply to MHRA Committees to support the Agency in other work. Two-way engagement is important, but this needed to be strengthened. PSEC members suggested using members of the Agency's independent expert committees as ambassadors to promote the work of the MHRA and the wide remit it covers. Many issues raised in the discussion on engagement with health professionals were also relevant to the next item - Yellow Card reporting. More research including via focus groups is needed on who engages with us now, the nature of that engagement and the gaps. The strategy needs to set out clearly the aims of engagement with different professional groups, and the proposed methods of engagement. The urgency of working to build on our increased profile was important and the Agency needs to do this within the next 6 months. PSEC members offered their support in developing this strategy.

3.3 **Yellow Card Scheme**

Knowledge and use of the Yellow Card scheme (that records suspected adverse reactions to drugs and devices) has increased a great deal over the last year, mainly in the context of reporting reactions to COVID vaccination. However, the committee considered that more could be done to make reporting easier. It was encouraged by the work to incorporate Yellow Card reporting with other apps used by the NHS. More work on this would be an advantage because other apps seem easier to use and are better known. It was also pointed out that health professionals, such as hospital doctors, who under-report currently, are overwhelmed with administrative tasks, and linking to systems they already use would avoid duplication and encourage them to report. The committee discussed the under-use of Yellow Cards amongst some minority ethnic groups. There was support for community outreach for under-reached communities, and more research was needed on whether the 12 languages currently available are the right ones.

The committee favoured retention of the use of paper-based reporting because this suits some people who would be unable or reluctant to use other methods.

The Yellow Card scheme is a key area of patient engagement: the committee requested continued involvement and further updates on a regular basis.

3.4 **Innovative Licensing and Access Pathway (ILAP)**

The paper presented on ILAP focused on the Innovation Passport and the Patient Engagement Toolkit. PSEC questioned the real influence of patients through the process; whether patients had been "slotted into the process" or whether they were at the heart of the pathway – could they for instance define end points or veto Innovation Passports? Committee members also wanted to know how a diverse range of patient experience and expertise would be encouraged. MHRA assured PSEC that the input of patients was valued and suggested ways of engaging patients that would work in practice, for instance having discussions with manufacturers on why they have not engaged with patients if that was the case. Although PSEC accepted this it felt that the paper needed to be clearer and more detailed. PSEC would like to see how patients are influencing ILAP decisions and these needed to be audited and published.

3.5 **Amendment to the Terms of Reference for PSEC**

The terms of reference for PSEC under item 17 states *"Minutes of the committee will be provided to the Agency Board for information, consideration and, where relevant, action. The minutes of committee will be made available on the Agency's web page on GOV.UK."* In practice the regular assurance reports given to the MHRA Board summarise the business of the committee. These assurance reports are also in the public domain in a timely manner unlike minutes which await approval at the next meeting of the committee before they could be brought to the following meeting of the MHRA Board for information. The Board is asked to approve an amendment to the terms of reference to reflect the use of PSEC assurance reports to the Agency Board as the public document.

4. Conclusion

4.1 PSEC is developing the way it works so that it can assure the MHRA Board on the Agency's work in the context of patient and public engagement and involvement. The committee has already had an opportunity to provide advice on a range of issues, but members consider that much more work needs to be done to assure the MHRA Board. It is encouraged that greater clarity has been agreed on what it expects in the papers that the committee receives for its meetings.

Mercy Jeyasingham
Chair Patient Safety and Engagement Committee
Non-Executive Director MHRA
April 2021

Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

20 April 2021

Title	What assurance can be provided by the Organisational Development and Remuneration Committee (ODRC)?
Board Sponsor	Anne-Toni Rodgers NED & Chair ODRC
Purpose of Paper	Assurance

Medicines & Healthcare products Regulatory Agency

Organisational Development & Renumeration Committee Assurance Report

1. Executive Summary

1.1 The Organisational Development and Remuneration Committee (ODRC) provides independent and objective advice to the Agency Board and the Chief Executive on their responsibilities relating to workforce planning, development and rewards at the Medicines and Healthcare products Regulatory Agency (MHRA); with the aim of developing a regulatory organisation which effectively delivers for patients, the public and other stakeholders.

1.2 On a regular basis it provides Assurance Reports on these topics to the Board.

2. Introduction

2.1 Given the MHRA's ongoing change programme the ODRC continues to meet monthly. The Committee has recently considered the following topics and provides the assurance /recommendations to the Board as per Section 3.

- Transformation / Organisational Change - Progress to date
- Transformation / Organisational Change - Function and Scale
- Executive Remuneration Responsibilities and next steps.
- Focus for ODRC work.

2.2 Diversity will be discussed at the next ODRC meeting on 6 May 2020.

3. ODRC Assurance

3.1 Transformation / Organisational Change - Progress to date

The Committee considered the Agency's Organisational Change Timeline and progress to date. The committee was, in the main, assured that good progress had been made and that the Agency is on plan to deliver to its commitments by year end.

The committee was pleased to note that its request the Digital, Data and Technology (DDaT) plan be linked to the Agency strategy and plan had been actioned.

The committee pressed for early action on the Review of Core Capabilities and Behaviours for job descriptions, alongside the Agency's competency development framework. This should be focussed on a one agency approach, the new dynamics for expected behaviour with a clear understanding of requirements at each grade. The Committee also suggested a revisit of the Agency's Job Evaluation Scheme (JEGS) regarding scientific posts (Scientific Ladder).

The Committee considers communication of change within the organisation at each meeting. It was pleased to note that additional All Staff Meetings providing an update on thinking and progress in relation to the Transformation Programme and a session on a broad range of support available to staff were held in March and around 750 staff attended these sessions, with a video then being available to those who were not able to attend with around 250 views (we have a total of around 1300 staff). Feedback suggests that c60% consider transformation will deliver some or huge impact and an increasing percentage of staff and managers stated they believe that the changes will impact positively on outcomes, again c60%.

3.2 Transformation / Organisational Change - Function and Scale

The Committee considered this topic and whilst it was assured that appropriate progress had been made on the Functional Structure, including principles such as span of control and design principles, it felt that there was a requirement for a deeper dive and a clear report / data on the Future Scale of the organisation. It is critical that we understand the key principles and areas of activity which the Agency will complete in the future operating model. This Report will be presented at the next ODRC meeting on May 6. The aim is that the final structure will be considered by the Board in June.

3.3 Executive Remuneration Responsibilities & next steps.

It was agreed that the ODRC will only consider Executive Renumeration where there is an element of discretion. The result being that unless it is significantly out of the civil service or current agency scale the ODRC will play no role in agreeing the starting salaries of new Executive Directors. The ODRC will play a role in ongoing reward and recognition awards. It was noted that there is no Executive pay award this year due to the Civil Service pay freeze, the Committee will review end of year bonuses during June or early July.

3.4 Future work.

The Committee has identified the following as a future/continued focus for its work:

- Organisational Change (including: Principles for Change, Processes, Talent, Accountability, Diversity, Timelines and Managing Risk).
- People Strategy.
- Talent & Succession Planning.
- Executive Renumeration Decisions.
- Culture.
- Delivering One Agency.
- Executive /Management Mentorship.

- Sounding Board for specific challenges as they may occur
- Diversity.

4. Recommendation

4.1 The Board is asked to note and consider this report and provide feedback.

Anne-Toni Rodgers
Chair ORDC
13 April 2021.