Medicines & Healthcare products Regulatory Agency

BOARD MEETING HELD IN PUBLIC

10:30 – 13:00 on 26th October 2020

Chair: Stephen Lightfoot

	AGENDA ITEM	PURPOSE	PRESENTER
10:30	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
10:45	CURRENT CONTEXT		
	4. What are the current issues from the CEO point of view?	Discussion	June Raine
11:10	HEALTHCARE ACCESS		
	5. What is the assurance that the MHRA can regulate multiple COVID-19 vaccine applications in parallel with priority, rigour and independence?	Assurance	Sam Atkinson
	6. What is the assurance that the MHRA will be ready to operate on Day 1 of EU Transition?	Assurance	Jon Fundrey
11:50	PATIENT SAFETY		
	7. What is the MHRA doing to address the recommendations of the Cumberlege Review?	Assurance	June Raine
12:10	DYNAMIC ORGANISATION		
	8. What are the key responsibilities and assurance map of the new Unitary Agency Board and Committees?	Approval	Chair

12:20	ANY OTHER BUSINESS		
	9. What are the key items for discussion at the next MHRA Board Meeting?	Discussion	All
	10. Are there any other urgent items for discussion?	Discussion	All
12:30	EXTERNAL PERSPECTIVE		
	11. What questions do members of the public have for the MHRA Board?	Discussion	Chair
13:00	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board meeting of 21st September 2020

(13:00 – 15.50)

By Teams conference call

Present:

The Board

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

Others in attendance

Mr [redacted]	Secretary to the Board and Head of Directorate
Ms [redacted]	Executive Assistant to the Chair

Department of Health and Social Care (DHSC)

Dr Alistair Hardisty	Head of MHRA Sponsorship and EU Exit Medicines and Pharmacy Directorate, DHSC

Devolved Administrations

Mrs Cathy Harrison	Chief Pharmaceutical Officer, Northern Ireland

Item 1: Introduction

What are the priorities for this meeting?

1.1 The Chair introduced his expectations and priorities for the meeting, which was his first since being appointed as Chair of the Agency on 1st September 2020. He was keen to change the format of Board meetings to ensure the business of the agenda was strategically focussed with sufficient quality time for discussion. Information items and updates could be addressed separately as part of a monthly information pack of papers. The Board seminar, which had preceded the meeting, was an example of a new way of working. The Board supported the new approach.

1.2 The Chair welcomed all to the meeting, including Dr Samantha Atkinson, Mr John Quinn and Dr Christian Schneider, who were appointed to the Unitary Board as interim Chief Officers.

Apologies

1.3 No apologies were received from members of the Board.

Declarations of interest

1.4 Professor Campbell announced that he had agreed to consider joining a group being formed by a commercial company to focus on a treatment for varicose veins which has benefits for patients over other methods in common use.

Item 2: External environment

What can the Agency do to support the health system this winter?

2.1 Dr Alastair Hardisty outlined what the Agency can do to support the health system during the coming winter. Among the challenges set out were:
(a) the end of the transition period on 31st December 2020;
(b) preparing for winter seasonal flu, alongside the ongoing challenges around COVID-19, including preparing for a roll-out of a vaccine programme of work; and
(c) preparing for Government's response to the Independent Medicines and Medical Devices Safety Review.

2.2 The Board considered issues around the Northern Ireland Protocol and other challenges facing the UK such as the issues surrounding COVID-19 vaccines.

Item 3: Internal context

What are the current issues from the Chief Executive's point of view?

3.1 Dr June Raine presented the Chief Executive's monthly report which was divided into the four strategic priorities of the Agency:
(a) Dynamic Organisation – including updates on the return to work sites and the Change Programme;
(b) Market Access – COVID-19 diagnostics, vaccines and therapeutics, and international collaboration;
(c) Patient Safety - Review of UK Plasma, Patient Safety Day (17th September), Opioids; and
(d) Financial Sustainability – Spending Review and Day 1 Readiness (1st January 2021).

3.2 The Board noted the report and discussed the Agency's preparedness for a second wave of COVID-19, the redeployment of staff to support work on multiple vaccines at the same time, and Day 1 Readiness and, in particular, its impact on Northern Ireland.

3.3 Concerning vaccine development, the Board asked Dr Samantha Atkinson to give assurance at the next Board meeting that the Agency will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence.

3.4 As regards Day 1 readiness, the Board noted that the Agency will be subject to an audit by the Infrastructure and Projects Authority (IPA) about whether the Agency's systems are ready.

How is the Agency performing against its Balanced Scorecard?

3.5 As regards the Performance Scorecard, the Board noted this will be considered by the Audit and Risk Assurance Committee at its meeting on 2nd November.

- **Action:** Dr Samantha Atkinson to give assurance at the next Board meeting that the Agency will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence.

- **Action:** Jon Fundrey to give the Board assurance at its next meeting on 26th October that the Agency will be ready to operate on Day 1 of EU transition with actions on how gaps will be mitigated

Item 4: Market access

How is the Agency going to regulate COVID-19 In-Vitro Diagnostics (IVD) tests quickly and effectively?

4.1 The Board considered a paper on how the Agency has worked to address the regulatory challenges seen during the pandemic for COVID-19 diagnostics. The paper gave an overview of the Agency's work to address the challenges with COVID-19 diagnostics, and that it is meeting the objectives of both being an 'enabler' of new diagnostics reaching the market and as a protector of patient safety.

4.2 The Board noted how the pandemic has caused a major shift for Devices Division into pre-market activity. This has enabled high-quality diagnostics to enter the supply chain, thereby meeting Government objectives. Examples cited of such work were: derogations for exceptional use, and Target Product Profiles (TPPs), the latter of which the Agency established to support industry in their development of new IVDs to respond to the pandemic.

4.3 The Board discussed the complexity of this area and how the Agency can become an enabling regulator in this new and evolving area. The Board advised that NHS Procurement was a partner with which the Agency should engage. The Board also mentioned new genetic tests, known as polygenic risk scores. These have increased access to genetic risk information for a wide range of conditions.

4.4 [redacted]

4.5 The Board concluded by asking that the following actions be carried out:

- **Action:** John Quinn to present an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation.

Item 5: Patient safety

What are the Agency's priorities on the implementation of the Cumberlege Review?

5.1 The Board considered a paper on work by the Agency following the publication of the Independent Medicines and Medical Devices Safety Review (IMMDSR) Report, 'First Do No Harm'. The paper set out priority areas being addressed and outlined work being done with others in the healthcare system.

5.2 The Board noted that, while the Government's response to the IMMDSR is not due until the autumn, the Agency started work on next steps immediately after the IMMDSR's publication on 8th July 2020. The Agency has made a public commitment to act quickly where it can and to deliver IMMDSR's recommendation no. 6 ('MHRA needs substantial revision particularly in relation to adverse event reporting, medical device regulation, and the need to engage more with patients and their outcomes'.

5.3 The following examples were cited as actions that have been taken:

(i) *The Medicines and Medical Devices Bill (MMD*), which is currently before Parliament, will provide the Agency with the powers to update the current regulations for medicines, medical devices and clinical trials in the best interests of patient safety.

(ii) *Patient engagement* – The Agency is working to embed learnings from the IMMDSR into all planned communications, incorporating opportunities to consult with relevant patients' groups where possible ahead of publication.

(iii) *Overhauling safety systems* – the Yellow Card Scheme is being overhauled as part of a large-scale programme of technology improvements for the MHRA vigilance systems.

(iv) *Valproate* – The Agency is working across the healthcare system to reduce the number of women of childbearing potential exposed to valproate and to support compliance with the valproate Pregnancy Prevention Programme.

(v) *Mesh and registries* – While NHS Digital continue to work on the development of a mesh registry, DHSC have amended the MMD Bill to include a clause on Information Systems for all medical device implants.

(vi) *Chief Safety Officer* – work on recruiting for this new role has begun.

5.4 The Board noted the programme of work but added that a required shift in the culture and attitude of staff to patients was also needed. The Board went on to endorse a proposal by the Chair to hold a Board seminar in November on patient engagement. The Board also asked John Quinn to share information on the new patient safety IT systems.

5.5 The Board concluded by agreeing the following actions:

- **Action:** John Quinn to share information on the new patient safety IT systems that are being introduced in the next Board Information Pack.

- **Action:** The Chair to arrange a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations. The seminar will take place on 23rd November 2020.

Item 6: Financial sustainability

How is the Agency building a strategy to secure its financial sustainability?

6.1 The Board considered a paper on delivering financial sustainability following the Agency's formal exit from the European system on 1st January 2021. The paper considered the changes to the Agency's income from that date, including the implications of significant investments required to replace legacy systems and the impact of the Northern Ireland Protocol.

6.2 The Board discussed what needed to be done during the remainder of the calendar year, as well as to prepare for the next business plan and to consider what can be funded through existing fees. The Board noted the importance of having the correct sequence of activities to be reflected in an action plan that will come to the Board. As part of the Board's consideration, the Board discussed the current level of corporate overheads, future investments in digital and organisational design. The Board also highlighted the importance of the new skills required for the new Agency in 2021 and beyond.

6.3 The Board asked that the following actions be carried out:

- **Action**: Jon Fundrey to present a high-level action plan and deadlines of key activities to achieve MHRA financial sustainability for the next Board Information Pack.

Item 7. Dynamic organisation

What were the key issues discussed at the last Remuneration Committee?

7.1 Professor David Webb, Chair of the Remuneration Committee (REMCO), presented a report on the Committee's meeting of 25th June 2020. Professor Webb said the Committee's task was a difficult one, as the number of awards is limited, and many of the senior staff are doing extremely impressive work, particularly at this challenging time. Nevertheless, after receiving advice from the Director of Human Resources and reports from the Chief Executive, the Committee was able to come to a unanimous decision on the awards following an extensive discussion.

Item 8. Meeting administration

8.1 The Board adopted the minutes of the meeting of 24th August 2020 and asked that in future actions list be considered at the beginning of the meeting. The Board went on to have an initial discussion about agenda-setting for the next meeting.

Item 9. Any Other Business (AOB)

9.1 None was tabled.

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 21 September 2020

	ACTION	Who	When
1.	Present assurance at the next Board that MHRA will be able to assess and determine multiple licence applications for COVID-19 vaccines in parallel with speed, rigour and independence	Sam Atkinson	26/10/20
2.	Present assurance at the next Board that the MHRA will be ready to operate on Day 1 of EU transition with detailed actions on how any gaps will be mitigated	Jon Fundrey	26/10/20
3.	Present an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation	John Quinn	23/11/20
4.	Share information on the new patient safety IT systems that are being introduced in the next Board Information Pack	John Quinn	09/10/20
5.	Set up a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations	Stephen Lightfoot	23/11/20
6.	Present a high-level action plan and deadlines of key activities to achieve MHRA financial sustainability in the next Board Information Pack	Jon Fundrey	09/10/20

Medicines & Healthcare products Regulatory Agency

Board Meeting held in public

Chief Executive's Report to the Board

26th October 2020

This report gives an overview of the current issues from the CEO's point of view. Separate papers give more detailed information on capacity building for vaccines for COVID-19, the Agency's response to the Independent Medicines and Medical Devices Safety Review, and the preparations for the EU Exit transition. The Board is asked to consider and agree on the priority issues.

HEALTHCARE ACCESS

COVID-19 Vaccines, Therapeutics and Diagnostics

1. A key priority of the Agency is to enable the successful development, licensing and deployment of vaccines, therapeutics and diagnostics for COVID-19. In relation to COVID-19 vaccines, we are preparing to handle multiple applications to consistent high scientific standards and with regulatory independence. Work is ongoing at pace to put in place IT capability and adequate resources to support post-marketing surveillance once vaccine deployment begins. The COVID-19 Therapeutics Expert Working Group of the Commission on Human Medicines continues to review emerging data on various products, including remdesivir.

2. In conjunction with its work on standards for COVID-19, NIBSC is now undertaking work for the Coalition for Epidemic Preparedness Innovations (CEPI). The institute is one of seven partner laboratories that have been selected by CEPI to form a centralised laboratory to standardise the measurement of immune responses generated by multiple COVID-19 vaccine candidates. Samples from volunteers participating in phase I and phase II clinical trials will be tested in our labs as well as samples from preclinical studies. Additionally, NIBSC has received funding from CEPI to develop an International Standard for COVID-19 antibody. This will act as a 'gold standard' that can be used freely by regulators and vaccine manufacturers all over the world to calibrate their own tests.

3. The Agency continues to work to support the national COVID-19 Testing Strategy. There have been extensive developments in recent weeks as the government continues to increase its targets for mass testing. The Agency has participated in several stakeholder groups designed to support the UK In-Vitro Diagnostics (IVD) manufacturing industry to bring new technologies safety to market.

4. We are continuing to support the national Testing Strategy with the development of an expanded suite of Target Product Profiles (TPPs). This month we published a new Target Product Profile (TPP) for Laboratory-Based SARS-CoV-2 Viral Detection Tests on the gov.uk website. The TPPs are also an instrumental component of a joint working group with the DHSC and NICE, which is working to provide a list of validated and evaluated COVID-19 Tests which private sector organisations/employers can procure to provide testing services for their employees.

5. Global information-sharing in relation to COVID-19 vaccines and therapeutics continues through the variety of multilateral meetings in which MHRA participates. We are co-chairing the ICMRA working group with Health Canada and chairing an expert group on vaccine vigilance with the Therapeutic Goods Administration Australia. We are also actively contributing to multilateral discussions on requirements for COVID-19 vaccines in a group lead jointly by US Food and Drug Administration and the European Medicines Agency.

International work

6. In line with our vision of becoming an enabling regulator at global level, in September 2020 MHRA joined Project Orbis, a programme coordinated by the US FDA to speed up approval of the next generation of cancer treatments, new medicines which potentially offer significant benefit over existing cancer therapies. This programme, which includes the regulatory authorities of Australia, Canada, Singapore, Switzerland and Brazil, has already approved medicines for a range of cancers such as advanced endometrial cancer, chronic lymphocytic leukaemia or small lymphocytic lymphoma.

7. Since initiation, 27 products have been entered into the scheme by FDA including 9 new marketing authorisation applications. A further 7 products, including 2 new marketing authorisation applications, are scheduled for initiation through to January 2021. By pooling expertise and streamlining procedures, Orbis has reduced time to approval by several months. We are joining Orbis as an observer and look forward to full participation in assessing products that will conclude the licensing procedure in January 2021 onwards.

8. In October we gained UK membership of the ACCESS Consortium, working with the regulatory authorities of Australia, Canada, Switzerland and Singapore, which aims to ensure patients have timely access to high quality, safe and effective medicines via collaboration and work-sharing. The consortium has previously approved 9 innovative prescription medicines, including 5 new cancer treatments. The International Office also recently had a bilateral teleconference with the Japanese regulator preparing for the Heads of Agencies bilateral call scheduled for 15 December, which will focus on enhancing cooperation between regulators.

PATIENT SAFETY

9. **Opioids and risk of dependence –** We published an article on opioids and the risk of dependence and addiction in our bulletin for healthcare professionals, Drug Safety Update, which advised on the need to discuss the length of treatment to minimise the risk of dependence. This was accompanied by an information sheet for healthcare professionals to share with patients and families. At the same time there was a communication campaign to the general public to raise awareness of the stronger warnings and to highlight availability of the patient guidance.

10. **Warfarin and other anticoagulants (blood thinners) –** We issued advice on the monitoring of patients taking anticoagulants during the COVID-19 pandemic. Regular blood tests are required for patients who develop an additional illness while on anticoagulants in case the dose of anticoagulant needs to be changed.

11. Valproate (**Epilim) defect product withdrawal –** On 14th October a class 2 (pharmacy and wholesaler level) medicines recall was issued for 3 batches of Sanofi Epilim 500mg Gastro-resistant Tablets and we are working with the manufacturer to recall these batches from pharmacies. This was a precautionary measure due to out of specification results for disintegration testing during routine stability testing. The risk to patients who have taken the medicine from an affected batch is low and it is unlikely to affect the safety or effectiveness of the medicine. Patients can continue to keep taking their medicine and do not need to return any tablets which they have.

Patient and Public Engagement and Involvement Strategy

12. We continue to progress development of our strategy for Patient and Public Engagement and Involvement based on the results of last year's extensive survey and several meetings around the UK. We have sought comments from an External Reference Group (comprising a range of patient representatives and advocates) on our draft Strategy. The strategy will be published before the end of 2020 for public comment.

13. In parallel to developing the Patient and Public Engagement strategy, we have been progressing a number of actions to improve the 'patient-centricity' of the Agency. These include seeking input from patient groups on safety issues during the COVID-19 pandemic; seeking input from patients on our work on the Innovative Licensing and Access Pathway; exploring how Patient-Reported Outcomes can be built in to Agency processes; ensuring the importance of the Agency engaging with patients is built in to our induction process for new starters.

14. Our medical revalidation appraiser network now has a lay member and is working to provide more opportunities for medical staff who do not have a clinical commitment to receive feedback from patients. We intend to bring in a training programme for staff that will support them in engaging more effectively and earlier with patients and the public. These initiatives will help ensure patients and the public are embedded at the heart of all we do.

DYNAMIC ORGANISATION

Staff and Accommodation

15. An All Staff meeting on 23rd September was attended by around 500 staff and focussed on the MHRA's four main strategic themes – patient safety, healthcare access, dynamic organisation and financial sustainability. On October 4th an all-Managers' meeting was an opportunity for work in breakout groups on the leadership changes needed to become an outcome-focussed regulator. This meeting drew on the experience of regulatory delivery during the first wave of the COVID-19 pandemic, and the resulting actions will now be followed up.

16. Staff development remains a top priority, and on 6th October the senior managers held a Talent Management Workshop which reviewed development needs, plans and opportunities for those identified as having potential to progress further, along with the need to match these to Agency priorities. Agreement was reached on a range of development plans, including both formal training and developmental experience such as internal secondments, matrix working and project team roles.

17. With the onset of a second wave of COVID-19, staff based at the MHRA London office at 10 South Colonnade have been encouraged to continue home-working. At the NIBSC site in South Mimms, around 100 staff continue to work in the COVID-secure facilities on essential laboratory work. Work is progressing to determine how the Agency needs to develop their laboratory capabilities to allow the current work to continue and develop to support the Agency Science Strategy.

Diversity and Inclusion

18. At its October meeting the Executive Committee considered a range of recommendations to support the embedding of diversity, equality and inclusion within all key functions and services. These recommendations covered ensuring staff engagement sits at the heart of equality, diversity and inclusion planning and scrutiny; provision of opportunities for sharing, learning and development across functions; ensuring there is adequate scrutiny of current systems and models; ensuring recruitment and the staff 'journey' reflects a commitment to the public sector equality duty and ensuring customer experience and support reflects our duties under the public sector equality duty. We have welcomed a new Diversity and Wellbeing Lead who will enable the Agency to us deliver our commitments to further equality, diversity and inclusion development.

FINANCIAL SUSTAINABILITY

Agency Change programme

19. Our Agency Change programme is progressing with full roll-out of the new governance committee structure which aims to embed agile decision-making at this time of challenge and opportunity, and to enable decisions to be taken at the relevant forum and level in the organisation. The outputs of staff workshops on strategic priorities which took place over the summer have now been analysed and prioritised.

20. Phase Two of the Change programme is now at the mid-way stage of a twelve-week project that will deliver a design for our Future Operating Model which will determine the Agency's 'size and shape'. This is essentially the processes, skills, structures and ways of working we need in the future to deliver our vision and mission. The new Executive Committee is beginning to coalesce around the critical components of what it takes to create one Agency from the current 'three centre' structure and about the scope and scale of change that the Agency can manage and deliver. Plans for detailed design and implementation into 2021 are also under way.

Spending review bid

21. On 10 September 2020 MHRA submitted its 2020 Spending Review (SR) bid to DHSC. The SR bid is structured along three core pillars: (i) Innovative Regulation; (ii) Safety System Overhaul; and (iii) Transition and Regulator Reshaping. Additionally, the Agency has committed to efficiency savings for the current DHSC grant-in-aid funding for NIBSC and Devices. We are preparing to engage with Treasury officials on their questions relating to the policy intent and the quantum of the MHRA SR bid.

June Raine
Interim CEO
October 2020

Medicines & Healthcare products Regulatory Agency

Board Meeting held in public

26th October 2020

Assurance Report - MHRA Review of COVID-19 Vaccine Submission Readiness

Issue:

This paper has been prepared to provide assurance to the Unitary Board that the MHRA can regulate multiple COVID-19 vaccine applications in parallel. The paper considers the MHRA's preparedness to deliver as a priority, while also ensuring scientific rigor and independence is maintained.

Action required by the Board and by when (timings):

The Unitary Board are asked to consider the MHRA's preparedness and comment on whether further work could be undertaken to ensure successful delivery of this important work.

Implications for patients and the public:

MHRA ability to deliver on vaccine assessments will have implications on vaccine deployment planning.

Which of the theme (s) in the Corporate Plan 2019/2023 does the paper support?

- We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products including through enhanced partnerships in the UK and internationally.
- We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences
- We will deliver robust proactive integrated vigilance for medicines and healthcare products and improve the way we share information to achieve measurable public health benefit
- We will ensure the safe production and supply of medicines and healthcare products through enhanced systems and strong international partnerships
- We will be an exemplar of organisational excellence and efficiency

Author (s): [redacted] Samantha Atkinson, Interim Chief Quality & Access Officer
Board sponsor: Samantha Atkinson, Interim Chief Quality & Access Officer

Assurance Report - MHRA Review of COVID-19 Vaccine Submission Readiness

What is the assurance that the MHRA can regulate multiple COVID-19 vaccine applications in parallel with priority, rigour and independence?

Introduction

The MHRA has prioritised the work it expects to receive over the coming months and has put all COVID-19 vaccine assessment and associated activities at the very top of the list. Assessment teams have been formed with lead assessors for each discipline to ensure consistency of decision making for all potential COVID-19 vaccines, and cross-agency groups have been formed to ensure the entire agency is informed of submissions received and actions required. A COVID-19 Benefit / Risk Expert Working Group (EWG) has been established specifically to advise on these vaccines and the EWG has already had several meetings. The MHRA is now ready to review the data relating to the quality, safety and efficacy of these vaccines that are expected to be received over the coming months.

Early Engagement and Scientific Rigor

Company Interactions

The MHRA has held productive discussions with companies seeking to supply COVID-19 vaccines to the UK. In some cases, this has included more detailed discussions on development plans to determine what data will be available and when. These discussions are ongoing and include all aspects of a regulatory filing.

Assessment Process

Marketing Authorisation applications will be assessed as national procedures using a rolling review mechanism. The MHRA cannot legally issue a Marketing Authorisation for a recombinant COVID-19 vaccine until the end of the Transitional Period on December 31st 2020, however we can accept data for assessment. In the event that a vaccine should have sufficient evidence of quality, safety and efficacy prior to December 31st 2020, procedures are being put in place to allow the temporary exemption to the requirement for a Marketing Authorisation using Regulation 174. However, any approval under Regulation 174 will require the same level of evidence of quality, safety & efficacy as appropriate for at least a conditional Marketing Authorisation. For public confidence in any vaccine authorisation or approval, the MHRA will need to maintain the same high standards of assessment irrespective of the legal procedure used.

It is worth noting that the vaccines for COVID-19 are novel products developed under expedited timelines. The length of the assessment process in each submission cycle has been significantly reduced by implementing robust prioritisation. Actual time needed for each assessment will depend on the quantity of the data submitted. While the review process will be expedited, for the avoidance of any doubt, the quality and robustness of the review will not be sacrificed for speed, and should the review take longer than 14 days (e.g. due to the volume of data submitted, or for any other reason) any regulatory decision will await the full completion of the review.

Rolling reviews

A rolling review is one of the regulatory tools available to speed up the assessment of a vaccine during a public health emergency. Normally all data on a vaccine's quality, safety and efficacy and all required documents must be submitted together at the start of the evaluation in a formal Marketing Authorisation Application to approve the use of a vaccine. With a rolling review, tranches of data are submitted when they are ready for regulatory review and before the entire data package is assembled by the company.

By reviewing the data as they become available, an opinion can be reached sooner on whether or not the vaccine should be licensed.

The rolling review mechanism will enable eligible population groups to have earlier access to COVID-19 vaccines while ensuring that the review process is as thorough and robust as for a conventional vaccine application.

Advice from External Experts

During August 2020 the MHRA established a COVID-19 Benefit / Risk Expert Working Group to advise the MHRA and the Commission on Human Medicines. This Working Group has met several times already and will meet regularly in the future. The group will also be available for ad hoc meetings to enable data to be assessed and commented on without any delay.

It is also expected that the MHRA will also seek the advice of other expert advisory group or working groups as appropriate. The final approval will be subject to Commission on Human Medicines (CHM) opinion as with other new products.

Patient Involvement

Vaccines will be given to healthy individuals and not to specific patient groups and therefore it will be particularly important to explain clearly how the benefit / risk evaluation was performed and what data was used to perform that evaluation. The MHRA will publish Public Assessment Reports for all COVID-19 vaccines detailing this information. The rapid turnaround of the individual tranches of data that will be submitted in the rolling submissions will not allow time for consultation with interested parties so that the availability of a safe and effective vaccine is not delayed. However, there are lay members within CHM that will represent a wider public view. Furthermore, the MHRA will publish in the public domain the outcome of its clinical assessments performed with each vaccine, each vaccine's benefits and risks, and the reasons why it received a positive recommendation for authorisation.

Independence

Vaccine Task Force

The Government established a Vaccine Taskforce (VTF) in April 2020 to support vaccine efforts in the UK, with formal governance in place from May 2020. MHRA has supported the VTF in multiple workstreams and on various boards and stakeholder groups from the beginning. Regulatory support was provided on a regular basis in meetings and through ad hoc advice requests. Such advice has been for clinical trials, licensing, manufacturing, pharmacovigilance and other policy aspects, including international queries.

As the pandemic progressed and clinical trials moved forward to the point of being closer to potentially providing data to submit to regulatory authorities, it became apparent there could be a perceived conflict of interest between the MHRA as a regulatory body and those in the VTF involved in non-regulatory activities such as vaccine procurement. As such, to avoid any misunderstandings and for absolute clarity, it became necessary for Agency staff to take a step back from the VTF, to protect the MHRA's independence and avoid any potential conflict which our participation in the VTF might create. At the end of September 2020 the Agency formally withdrew from VTF, but with a key message that the MHRA was still very much available to support the VTF whenever possible and in a prompt manner.

MHRA's Internal Vaccine Deployment Oversight Group (VDOG)

The independence of the Agency's assessment of Covid-19 vaccines can be additionally assured through the work of the MHRA's Vaccines Deployment Oversight Group, chaired by our Chief Scientific Officer Dr Christian Schneider. This group is made up of relevant independent representatives from all Agency Divisions to ensure

that, as required by Government Legal as well as the Agency, any authorisation or approval decision is entirely independent, both from industry influence and from any other stakeholder including government. VDOG has in its mandate to ensure this independence and to be part of the decision-making process on COVID-19 vaccines.

Capacity

Assessment Resource

In recognition of the short assessment timelines and parallel vaccine assessments, we have bolstered the vaccine assessment teams with assessors from other units within the Licensing Division (LD) and with safety assessors from the Vigilance and Risk Management of Medicines Division (VRMM) so that we can assess more than one vaccine submission in parallel. Some activities will be deprioritised to ensure that assessors will be able to review vaccine data submissions as soon as they are received, although any delays to the assessment of other new medicines will be minimised.

To ensure accountability and communication, the assessment teams will be coordinated by the application specific lead assessors and each aspect of the assessment (non-clinical, quality, clinical) will also be coordinated by a lead.

Batch Release

Official Control Authority Batch Release (OCABR) is a legal requirement for vaccines and blood products. This is independent safety and quality testing and certification for every batch that is intended to be marketed. The National Institute for Biological Standards and Control (NIBSC) is the UK's Official Medicines Control Laboratory (OMCL). After the end of the transition period, NIBSC will be a stand-alone OMCL and issue national batch release certificates, whereas NIBSC is currently operating as a member of the EU OMCL/OCABR network on the basis of mutual recognition of OCABR certificates issued by EU member states. NIBSC is working with manufacturers to establish the technical transfer of critical test methods and quality assurance documentation needed for batch testing (and approval). Early engagement with vaccine manufacturers has been encouraged through reach-out from NIBSC; further communication is being considered in order to highlight the need for OMCL activity particularly for those manufacturers whose products may be approaching authorisation soonest.

Inspections

The MHRA inspectorate monitors compliance of sites in the regulated supply chain and can provide assurance that it is able to manage multiple COVID-19 vaccines in parallel with the normal high standards and independence the Agency requires.

The inspectorate has and will continue to prioritise vaccine inspections, with additional slots being held to inspect these vaccines when required. Any future vaccine submissions to the Agency that require an inspection will be prioritised, with other lower priority inspections deferred in order to accommodate. The Agency is setting up steering group meetings for vaccine submissions to ensure that all relevant Divisions of the Agency have input to the approvals pathway as required, ensuring the speed, rigour and independence. This allows any pre-submission aspects to be flagged to inspectors as early in the process as possible, preventing any delays.

It should be noted that not all vaccine submissions will require a specific inspection, for example this may not be required where companies already have the required licenses or where there is sufficient inspection history of the company to provide regulatory and patient safety assurance.

A hybrid inspection approach has been adopted to flex resource to ensure it is used most efficiently, including both on-site and remote inspection elements where required and appropriate. As we enter the second wave of the pandemic, remote inspection approaches are being used as far as possible, with an on-site element only used in order to review areas that cannot be completed remotely, to ensure the personal safety of everyone involved.

Public and Patient Safety

Safety Reporting and Risk Management

The VRMM has in place a strategy for proactive and near real-time pharmacovigilance of COVID-19 vaccines, supported by advice from a CHM Expert Working Group on safety surveillance. This strategy links in with Public Health England, NHS England, NHSX and Digital, and the devolved health authorities, to enhance UK-wide surveillance. Our four-pronged approach to surveillance involves enhanced passive surveillance (comparing Yellow Card reporting rates to background incidence rates – 'observed vs expected' analysis), targeted web-based active surveillance (to characterise safety in specific cohorts excluded from clinical trials), 'rapid cycle analysis' of electronic healthcare records (proactive surveillance of pre-defined adverse events of special interest in Clinical Practice Research Datalink (CPRD) data to rapidly detect/strengthen safety signals) and ad hoc epidemiological studies of significant safety concerns.

In addition to this, we are co-leading an International Coalition of Medicines Regulatory Authorities (ICMRA) Network on COVID vaccine vigilance readiness to help build international linkage on safety surveillance, and have a developed guidance on a national core Risk Management Plan for industry, which we expect each manufacturer to use in developing and preparing for their UK regulatory submissions for product approval.

Communications

Public concern about the use of unlicensed or "fast tracked" vaccine development is becoming a global concern. As such, there is a high risk that any perception that a COVID-19 vaccine has not undergone rigorous development and assessment or is being authorised for use without following the usual standards and processes, will fuel public anxiety and anti-vaccine campaigning.

Given this, we wish to proactively communicate about the independence of the agency, its decision-making processes and the evidence underpinning its decisions, as well as any emerging safety signals.

Communications will primarily concentrate on tactics and materials to support public and healthcare professionals' confidence in the regulation and safety of COVID-19 vaccines. This will include continued patient and stakeholder engagement, proactive and reactive media engagement, social media, GOV.UK updates and content, handling enquiries and supporting campaigns led by other government departments.

Any materials or announcements planned will be coordinated with the Department of Health and Social Care (DHSC) and other government departments as necessary.

Board Assurance

The MHRA has taken learnings from the first wave of the pandemic and has also implemented necessary actions to ensure that it can manage the likely demand arising from vaccine submissions.

The MHRA is dynamically shifting its resource, within its current headcount and financial envelope, to provide increased capacity across the organisation to match the anticipated demand.

Scientific rigor and independence remain paramount to ensure that any vaccine approved is assessed with the same high standards of quality, efficacy and safety.

Patient safety is at the centre of decision making. A comprehensive communications strategy is being developed to maximise public trust in any vaccine approved by the MHRA.

The MHRA stands ready to act and deliver, in support of the wider fight against COVID-19.

Medicines & Healthcare products Regulatory Agency

Board Meeting held in public

26th October 2020

What is the assurance that the MHRA will be ready to operate on Day 1 of the EU Transition?

Issue: Transition programme - Paper for the Unitary Board on 26th October
Action required by the Board and by when (timings): The Board is asked to review this assurance report and to identify any areas which require further assurance or action."
Implications for patients and the public: The underlying objective of the Transition programme is to ensure that patients in all parts of the UK will continue to have access to existing and new medicines and devices for their healthcare needs from 1st January 2021.
Which of the theme (s) in the Corporate Plan 2019/2023 does the paper support? **If relevant, which Business Plan strategic activity does it support?**
Author (s): [redacted]
Board Sponsor: Jon Fundrey

What is the assurance that the MHRA will be ready to operate on Day 1 of the EU Transition?

Summary

This paper is to provide assurance to the Board on the state of readiness of the Agency for EU Transition on 31st December 2020, and on wider work to support industry readiness for EU Transition.

It draws substantively on the findings of a review conducted in w/c 12 October 2020 by the Infrastructure and Projects Authority of the Agency's Transition Programme: this review rated the overall readiness at AMBER, which noted that good progress had been made towards the key aims of the Transition Programme – that patients continue to get the products and that companies can conduct their regulatory business with the MHRA - but flagged the critical need to resolve outstanding blockages to supply into Northern Ireland from GB arising from the provisions of the Northern Ireland Protocol relating to the Falsified Medicines Directive and to certain technical rules applying to products that will legally be imported into the EU when they pass from GB into Northern Ireland.

The IPA review also highlighted that, now that the Government positions have been clarified and translated into legal text on a 2 year period of Standstill for GB regulation and 4 years of application of the Northern Ireland protocol in Northern Ireland, the programme needs to pivot towards operational readiness ensuring:

- An updated clarification of what will be delivered for Transition Day that ensures patient supply and the ability for companies to conduct immediate regulatory business;
- Clarity about the actions – both operational and legal – that will need to be completed or adjusted after Transition Day (notably actions relating to what will happen at the end of the 2 year period of GB standstill, and the need for a completing/amending set of statutory instruments)
- Ramp up of support to the sector the Agency regulates for their readiness for Transition
- Completing work in hand with DHSC to align understanding and risk assessment of readiness.

The remainder of this note sets out the state of readiness on the legal, operational, regulatory and industry fronts.

Legal Readiness

The critical legal readiness step relates to laying the relevant Statutory Instruments. This had involved a complex process of legal instructions, guidance and legal drafting to prepare Statutory Instruments and supporting documents to be laid before Parliament.

The Statutory Instruments (SIs) covering both NI and GB were laid on 15th October (for Devices) and will be ready for laying on 20th October (for Medicines).

The preparation of the Statutory Instruments is a cross-Government process requiring extensive clearance throughout the process. Completing Statutory

Instruments has been complicated as Central HMG policy work is still being concluded in some instances and as negotiations with the EU are still ongoing.

It is highly likely that there will need to be an amending/completing Statutory Instrument in early 2021, but this will not be related to work for January 2021 readiness and will relate to plans for the end of the 2 years' standstill or the 4 years Northern Ireland Protocol (NIP).

Operational Readiness

Operational readiness for a 'No Deal exit' from the EU was managed by the European Systems Contingency (ESC) programme from July 2017 - January 2020 which delivered technical solutions to enable MHRA to function as the single Regulator for the UK on leaving the EU. The Transition programme has built upon these tested and validated systems and processes to prepare for the end of the transition period where it will be required to Regulate NI under EU laws and regulations and the rest of GB as a Sovereign State.

Resources have been used from across the Agency to draw upon specialised knowledge that covers the full breadth of the Agency's responsibilities to mobilise the Transition Task Force (TTF). The TTF is supported by the Transition Readiness Group (TRG) which works to ensure the fundamentals of operational readiness such as adequate resources in place across business areas for day 1, contingency plans are ready and tested, Information Technology & Infrastructure is updated and ready to meet business needs, Divisions and business areas are updated on changes and business processes from 1st January, and undertaking 'business readiness' days.

The independent review by the Infrastructure and Projects Authority (IPA) made a number of recommendations about alignment with DHSC on risks, issues and assumptions as well as closer involvement of DHSC in operational readiness workshops and 'dry runs'. Broadly the IPA felt that the programme was being well managed with priorities given to ensuring operational readiness for 1st January 2021: it recommended a determined pivot towards the operational readiness preparations for the remainder of 2020, as was already planned. A wider view of system readiness across both the Agency and Industry was recommended and planning is already underway to have further engagement with Industry through webinars starting on 19th October which are currently fully booked with over 20,000 registered to attend. The IPA team acknowledged that there are critical issues around the Falsified Medicines Directive (FMD) and supply of medicines and devices into NI which required external answers to outstanding questions to enable the Agency to progress these areas.

Regulatory Readiness

The Agency continues to work at pace to ensure Regulatory readiness although there are a number of areas where definitive proposals are still under consideration. These include:

Falsified Medicines Directive (FMD) and supply from GB to NI which requires EU agreement or (probably) national over-ride; and

Issues relating to the 2-year limit to standstill and proposed Mutual Recognition Agreement (MRA) with EU, notably Quality Control (QC) testing.

It is undoubtedly the case that the Northern Ireland Protocol adds complexity to the challenge of regulatory readiness. However, the following points can also give confidence about readiness:

- In discussions with industry, the signals are that relatively few companies are preparing to make extensive use, at least initially of the provisions under which products can move from EU27, through Northern Ireland into GB under "unfettered access";
- The legal frameworks independent operations are not changing substantially at least in the short term;
- Significant amounts of pharmaceuticals regulation are already done on a highly national basis anyway – notably clinical trial authorisation, much of pharmacovigilance and considerable elements of decentralised licensing
- We have avoided, wherever possible, regulatory "cliff-edges" on Transition Day – CE marks for devices will remain valid, as will decentralised and centralised pharmaceutical licences.

Industry Readiness

MHRA has been engaging with Industry over the last 6 months through the regular meetings with Trade Association (TA) representatives.

Industry engagement webinars covering 9 subjects are to be held over a two-week period starting on 19th October 2020 and are oversubscribed in almost all cases with a total of 21,655 registrations of attendance across all the webinars. Additional webinars are being considered for the most popular subjects. We will be ramping up engagement with industry on preparations for "grandfathering" centralised licences into UK licences and registration onto the IT systems.

Engagement with Industry has highlighted:

- De-snagging and other engagements suggest there are very low levels of interest in NIP "unfettered access" due to the 4-year time period, the requirement to ship products through NI, and uncertainty about the definition of an NI trader.
- Industry are increasingly concerned about signals that, at end of 2 years' standstill and if there is no Mutual Recognition Agreement (MRA), they will need to duplicate Quality Control (QC) testing in the UK/GB.
- There are real concerns regarding the Falsified Medicines Directive (FMD) and supply from GB into NI.
- There are growing calls for further clarity about what happens from 2 years (pharma) and 2.5 years (devices) after the transition period ends.

Conclusion

So long as some critical, but specific questions relating to supply into Northern Ireland are answered, the Board can be assured, including by the IPA review, that the Agency will be ready and capable to regulate medicines and devices as the UK Regulator from 1st January 2021, and that patients will experience no regulatory-based interruption to supply. Fallback and contingency plans are either in place or being finalised to deal with various scenarios that could occur between now and 31st

December to mitigate risks and uncertainties. The Agency will continue to work with Industry to ensure Industry and the wider 'system' readiness.

A continuous programme to manage and deliver the immediate and short-term requirements from 1st January that were not delivered as critical day 1 readiness requirements will continue the work of the Transformation programme throughout 2021.

Annexed is further background information about the Transition programme, and its predecessor "No Deal" programme.

Background

Since the UK voted to leave the European Union (EU) in 2016 the Medicines and Healthcare products Regulatory Agency (MHRA) has been taking steps to prepare for the United Kingdom's (UK) departure from the EU.

Taking direction from Her Majesty's Government (HMG) through the Department of Health and Social Care (DHSC), initial preparations were made over the period July 2017 –January 2020 in case of a hard exit from the EU. Readiness was achieved through the mobilisation of the European Systems Contingency (ESC) programme to deliver the technical changes to ensure the Agency's ability to operate and through Policy Division led activity to ensure the legal, operational, regulatory and industry readiness of MHRA. With both the EU and UK agreeing terms and signing the Withdrawal Agreement on 19th October 2019 the deliverables of the ESC programme were placed on hold in January 2021 when the EU transition period started and trade negotiations began between the EU and UK to establish the working relationship between the UK and EU from 1st January 2021.

In June 2020 the Agency mobilised the necessary resources, under the Transition programme, to begin delivering the required changes to ensure the operational readiness of the Agency at the end of the EU transition period on 1st January 2021, noting the requirements of the Northern Ireland Protocol (NIP) and that trade negotiations between the UK and EU were still ongoing. The remit of the Transition programme covered the full scope of readiness including technical, legal, regulatory, operational and industry readiness. As negotiations were still ongoing between the UK and EU it was necessary to establish working assumptions to allow the programme team to plan the full delivery of the Agency's readiness.

The underlying objective of the Transition programme is to ensure that patients in all parts of the UK will continue to have access to existing and new medicines and devices for their healthcare needs from 1st January 2021.

Transition Programme Overview

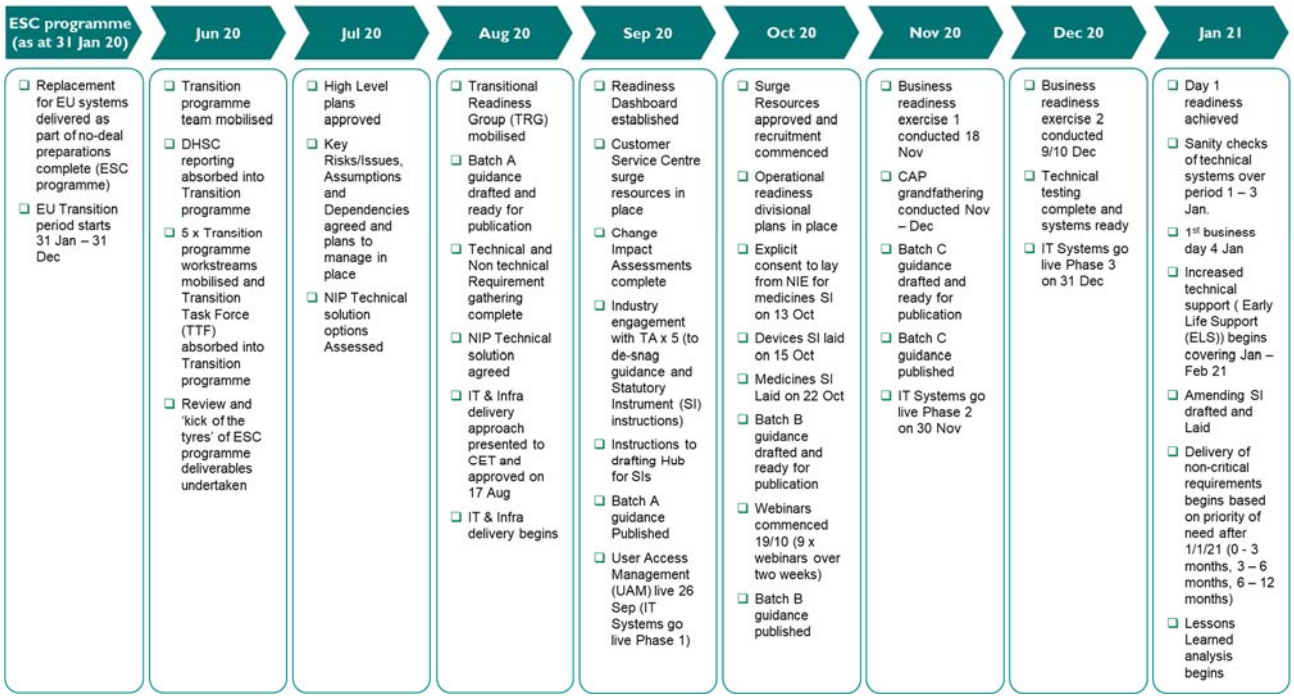
Led by the Director of Policy who acts as Senior Responsible Owner (SRO), the Transition programme sits within the wider EU and Trade portfolio of DHSC and consists of Programme Management professionals to plan and manage delivery of the programme, policy experts to develop new policies in collaboration with colleagues in DHSC, a communications team to co-ordinate engagement with internal and external stakeholders, a legal team to review legal guidance, Statutory Instruments (SIs) and other legal outputs of the programme; and operational leads drawn from across the Agency to act as Subject Matter Experts (SMEs) providing expert advice and leading on the operational readiness of Divisions and business areas.

The Transition programme has been set the following objectives:

- To ensure the Agency's readiness for 1st January and the end of the EU transition period basing delivery upon the Northern Ireland Protocol (NIP) for NI and "Standstill" for GB, managing the interfaces between GB and NI, and establishing reasonable assumptions where answers from HMG or the EU are still outstanding;

- To ensure operational readiness (people, processes and technology) across MHRA with systems and processes that work for 1st January itself and into immediate operations in 2021;
- To deliver the minimum viable products and solutions needed to meet the technical, legal and regulatory demands of adhering to the Northern Ireland Protocol (NIP) and GB "Standstill" in a way that is sustainable for a minimum of 12 months; and
- To manage and mitigate immediate political and financial risks to patient access to medicines and devices as a result of the end of the EU transition period.

The high-level delivery timeline for the Transition programme is detailed the diagram below.



INDUSTRY WEBINARS
AS AT 15th OCTOBER 2020

	Subject	Date	Comments
1	Guidance for manufacturers of biological medicines	19th Oct	1769 registered attendees
2	UK supply chain regulation from 1 January 2021	20th Oct	Registration full (2950), with a waiting list of 235
3	Clinical Trials	21st Oct	Registration full (2950), with a waiting list of 422
4	Regulation of medical devices from 1 January 2021	21st Oct	Registration full (2950), with a waiting list of 266
5	Post EU Transition: Pharmacovigilance requirements	22nd Oct	Registration full (2950), with a waiting list of 245
6	UK marketing authorisation & variation procedures	27th Oct	Registration full (2950), with a waiting list of 292
7	Conversion of Community Authorisations to GB	27th Oct	1890 registered attendees
8	PLPI – the legal framework of parallel imports	28th Oct	1463 registered attendees
9	UK paediatric requirements from 1 January 2021	29th Oct	1783 registered attendees

Medicines & Healthcare products Regulatory Agency

Board Meeting held in public

26th October 2020

WHAT IS THE MHRA DOING TO ADDRESS THE RECOMMENDATIONS OF THE INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW?

Issue:

To provide an overview of the action MHRA is taking in relation to the recommendations from the Independent Medicines and Medical Devices Safety (IMMDS) Review, led by Baroness Cumberlege.

Action required by the Board and by when (timings):

The Board is asked to:

- note the update on activities in response to the IMMDS Review report
- discuss the key areas of work and consider whether they agree these are the priority areas to address
- note that the Agency is working with DHSC and other healthcare partners in preparation for the government response and to improve working across the healthcare system.

Implications for patients and the public:

The Agency is carefully considering the recommendations and how we best listen and respond to patients and the public and taking action to address the issues relating to patient safety that have been highlighted.

Which of the theme (s) in the Corporate Plan 2019/2023 does the paper support?

All, particularly Public Health and Partnerships and Organisational Excellence / Efficiency.

If relevant, which Business Plan strategic activity does it support?

Responding to the IMMDS Review is a specific activity in the Business Plan.

Author (s): IMMDS Review co-ordination group

CET sponsor: Dr June Raine

Issue

1. On 8 July 2020, the Independent Medicines and Medical Devices Safety (IMMDS) Review, led by Baroness Cumberlege, published its Report, 'First Do No Harm'.
2. This paper updates on what the MHRA is doing to address the recommendations of the Cumberlege Review.

Background

3. Baroness Cumberlege was asked to lead the Review, which was announced in February 2018 by the then Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP in the House of Commons. He stated that it would examine how the healthcare system has responded to concerns raised by patients and families about three medical interventions; the hormone pregnancy test, Primodos; the anti-epileptic drug, sodium valproate and surgical mesh.

Review findings and recommendations

4. There are nine main recommendations made by the review (which can be found in Annex 1). In particular, Recommendation 6 states - *The MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.*
5. The IMMDS Review proposed high level changes to regulation to strengthen patient safety:
    - Establishing clear legal frameworks around safety decision-making which include the systematic involvement of patients and the public
    - Improving medical device regulation
    - Overhaul adverse event reporting to create a transparent, user-friendly system that recognises the contributions of those who make reports and engages with them throughout the analysis and decision-making process. There must be delineated obligations placed on manufacturers, healthcare professionals and the MHRA
    - Identifying risk profiles and teratogenicity for medicines used in pregnancy
    - Developing a protocol for a prompt system-wide co-ordinated response to safety decisions related to medicine or medical device

Response to the report and working with others in the healthcare system

6. The MHRA issued a statement on the day of the report publication, emphasising the importance of the review, our determination to put patients and the public at the heart of everything we do and committing to consider carefully the findings and recommendations. In communicating the report to our staff, we have emphasised that the recommendations relate to all areas of the Agency's activities.

7. Following the publication of the report, the Government has:
    - issued an apology for the time the system took to listen and respond
    - thanked Baroness Cumberlege, for carrying out her work with thoroughness and compassion
    - acknowledged that the response to these issues from those in positions of authority has not always been good enough
    - pointed out that while the review has been progressing, the Government and the NHS have taken a number of steps relating to the concerns it has raised

- committed to taking time to give the review the full consideration that it absolutely deserves.

8. MHRA is continuing to work with all system partners (including but not limited to the DHSC, NHSE&I, NHS D, NHS X, NICE, the GMC, CQC and Royal Colleges) to implement system improvements and improve collaborative working to ensure a more integrated approach to patient safety.

9. The Medicines and Medical Devices Bill provides the powers we need to be able to update the current regulations for medicines, devices and clinical trials in the best interests of patient safety. The Bill is currently progressing through the House of Lords.

Actions and priority areas of work for MHRA in relation to the Review

10. We are carefully considering the Review recommendations and actions for improvement and we are taking forward work to address the concerns raised.

11. The priority MHRA work in relation to the Review recommendations can be grouped into the following areas:
    - developing our patient and public engagement and involvement
    - developing a more responsive safety and reporting system
    - improve evidence for patient safety

Patient and public engagement and involvement

12. Building on our 2019 consultation asking patients how we can best engage and involve them in our work, we are developing a strategy to take this forward. This includes objectives to:

    - change our culture so that every member of staff considers the patient perspective in every decision they make
    - introduce new ways of working to ensure every team has a systematic means of engaging and involving patients in their work and that we publish how we do that, as well as creating opportunities for 'under-reached' groups and communities to interact with us
    - embed the 'patient voice' in the design and delivery of our services, to ensure that those services meet the needs of the patients and others who use them
    - ensure that all activity is under-pinned by patient-focussed communications and information

13. Our commitment to patient engagement is set out in the Agency's Corporate Plan 2018-23:

    The Agency is committed to delivering against public and patient expectations of engagement and transparency and to delivering real changes in the way we conduct patient and public engagement. This will include ensuring the patient voice is heard and listened to in licensing new medicines and medical devices, and in addressing safety issues.

    It is also reflected in the Agency's Business Plan 2020-21 as a key part of our strategic goals:

    We will engage proactively with the public, patients, health services and healthcare professionals, and gather insight from patients to aid our decision-making and communications

14. We aim to publish the draft strategy on GOV.UK for comment during Autumn 2020.

15. We have a monthly patient speaker programme, with patient advocates giving presentations to staff about the importance of engaging patients and involving them in our work. As of October, a section on patient engagement is now built into the corporate induction for all new starters, including a video of a patient talking about the importance of the Agency engaging with patients. Further patient videos will be incorporated in the coming months. We are also developing a programme of training for our staff to support them in engaging more effectively with patients. The Review will continue to be a key feature in many of our staff meetings.

16. Activities to improve the profile of the agency and an understanding of our work continues, with work underway to improve content and external communications channels. Specifically, several initiatives are underway to increase reporting to Yellow Card. We are running three reporting campaigns between now and end 2020: World Patient Safety Day was held on 17 September and there has been an increase in adverse event reports as a result; we are expecting to receive the 1 millionth Yellow Card report and will use this as an opportunity to highlight the benefits of reporting to patient safety; and Medicines Safety Week will be in November. We are also engaging with the public directly in gaining user feedback and perceptions on the Yellow Card transformation work (Safety Connect – see later) through user needs sessions.

17. A multidisciplinary team within the MHRA, with expertise in Patient Reported Outcomes (PROs), has formed a PROs Special Interest Group (PRO-SIG). The aim of this group is to gain an understanding of the level of knowledge and expertise of PROs within the Agency, to expand on that knowledge and raise awareness of the importance of good quality PROs in research and drug development that impacts the work we do for the benefit of patients.

A more responsive safety and reporting system

18. We are looking to revolutionise the way the Agency detects and responds to adverse incidents relating to medicines, medical devices, electronic cigarettes and nicotine containing products, and blood (haemovigilance) and in how it can better share and use information for the greatest public health impact.

19. A programme of work, SafetyConnect, has been established and we will be introducing a new vigilance service and new IT systems to detect and respond to safety concerns with any medicine, medical device or blood product more quickly and more comprehensively than ever before. It will have a significant impact in improving how the Agency monitors and acts on safety insights across the full product lifecycle, through joined up safety vigilance, reporting and information.

20. The SafetyConnect programme will help align available data and information, including real-world evidence, and will help to inform proportionate regulatory decisions on benefit-risk and safety throughout the lifecycle of a product, in order to benefit patients. The Agency will seek the views of patients and healthcare professionals to inform decision-making and the content of the guidance we publish. The Agency will adopt a risk proportionate approach to streamline regulatory procedures, the Agency will achieve this through the delivery of the strategic objective to embed state of the art surveillance across medicines and medical devices.

21. There are also a number of change themes this programme will follow or incorporate. These include:

    - **Importance of patient voice** – the importance of meaningful, systematic, real-time and proactive engagement with patients and healthcare professionals in response to

potential changes in benefit-risk profiles. This capability is as important as receiving safety issues.

- **Better cross system working** – as the regulator of healthcare products we must work closely with others across the healthcare system to effect change relating to safety issues. This includes improving how we collaborate and share data with healthcare system partners to inform decision making to improve patient outcomes.
- **Transparency and openness** – a need to be more timely, proactive and open on safety issues and other areas in the public's interest. This programme will aim to increase transparency and information sharing with the public to aid patient choices.
- **The need for regulation to follow science and continuously evolve** – a future proof vigilance service, able to respond to continuously changing science and technologies. Creating or utilising registries and other health data early to inform decision making.
- **Innovation and how to balance this with safety** – ensuring appropriate and effective mechanisms are in place and maintained to enable the safe introduction of innovation for the benefit of public health.
- **EU Exit** – the Agency should, regardless of the impact of the terms negotiated within the EU Exit withdrawal agreement be able to operate effectively.

22. The SafetyConnect programme will deliver three main outputs:

- Common ways of working which will lead to integrated and multiskilled vigilance teams across the Agency.
- A common improved technology platform for incident management and signal detection for medicines and devices. This is currently out for tender using the OJEU (Official Journal of the European Union) process and will conclude at the end of 2020 with contract award to begin delivery in early 2021.
- An improved engagement platform for reporting adverse incidents for both medicines and devices. Work on overhauling the Yellow Card reporting platform has already begun. New technologies have been introduced for the reporting of products used to treat Coronavirus and to develop our COVID-19 vaccine active surveillance system.

23. Under the SafetyConnect programme, the Agency has already initiated two projects. The first begins a programme of investment in the Yellow Card system and will deliver smart reporting forms, customised user centric follow up and transparency of vigilance activities. These enhanced services will not just be available through Yellow Card, will enable regulatory information to be embedded to third party platforms such as the NHS App. The second project will explore how novel analytics techniques can benefit surveillance of medicines and devices, including consideration of where artificial intelligence can add value and how multiple data sources can be used to identify and assess signal at the earliest possible point.

24. Being patient centric, SafetyConnect is designed to ensure the public, patients and healthcare professionals are at the very center of our delivery and vision for change. The programme has already been engaging with patients and during September we held two successful engagement session with Health Care Professionals which was well received by the 150 attendees.

Better Evidence for patient safety

25. In 2018, the NHS have paused the use of vaginally inserted surgical mesh for stress urinary incontinence until a set of conditions to ensure that patients receive safe and high-quality care are met. This pause was extended to include vaginally inserted surgical mesh for pelvic organ prolapse and will be implemented through a high vigilance programme of restricted practice. NHS Digital continues to work on the development of the mesh registry. MHRA provided NHSD with mesh UDI master data to facilitate the registry mesh registry pilots. Regular meetings are being held by NHSX with the main stakeholders, including MHRA.

26. Work is progressing on developing a valproate registry. A formal governance structure is being established to support the registry. We are discussing with NHSD how the registry could be expanded to cover all anti-epileptics as recommended in the report of the IMMDS Review and are exploring options to set up medicines registries key to public health.

27. A Commission on Human Medicines 'Expert Working Group on Optimising Data on Medicines used during Pregnancy' is considering how to make best use of real-world data on medicines exposure and pregnancy outcomes to facilitate research, improve the evidence base for regulatory and clinical decision making, and enable the provision of more individual patient-relevant information to allow informed decision-making. These data are also vital for measuring the impact and effectiveness of actions taken by regulators and healthcare professionals, for example in monitoring the success of a pregnancy prevention plan for a known teratogen. The Expert Working Group comprises key data holders and includes representatives from NHS Digital, the Clinical Practice Research Datalink (CPRD), Public Health England, individuals with expertise in statistics and epidemiology, data science and current clinical practice, and patient representative. The Group is developing a set of recommendations that can be taken forward by the relevant organisations with the goal of improving data collection, quality and access via enhanced capture of information and linkage of databases.

Actions for the Board

28. The Board is asked to consider the key work areas being progressed.

29. Note that MHRA has already taken steps to improve collaborative working with system partners to ensure a more integrated approach to patient safety and support that this work continues.

30. Note that MHRA continues to engage with and support other system partners in a co-ordinated system response to the IMMDS Review, overseen by the DHSC.

31. Note that resources will continue to be required for ensuring oversight, co-ordination and implementation of the MHRA-related recommendations. This work will continue to be treated as a priority. The Agency's Business Plan and Change Strategy will be reviewed and updated in light of the report.

October 2020

Annex A – Recommendations of the IMMDS Review

1. The Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.

2. The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.

3. A new independent Redress Agency for those harmed by medicines and medical devices should be created based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals.

4. Separate schemes should be set up for each intervention – HPTs, valproate and pelvic mesh – to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

5. Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy.

6. The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.

7. A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.

8. Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.

9. The Government should immediately set up a task force to implement this Review's recommendations. Its first task should be to set out a timeline for their implementation.

Medicines & Healthcare products Regulatory Agency

Board Meeting held in public

26th October 2020

WHAT ARE THE KEY RESPONSIBILITIES AND ASSURANCE MAP OF THE NEW UNITARY AGENCY BOARD AND COMMITTEES?

Issue: There is a need to map the roles and responsibilities of the new Agency governance structures, at both Board and Executive level, to provide clear leadership, direction and assurance that the Agency is fulfilling its multitude of responsibilities effectively.
Action required by the Board and by when (timings): The Board is asked to review the overall shape, key responsibilities and priorities of this revised governance framework so that it can discuss and agree whether these arrangements adequately provide clear routes of assurance in all directions across the Agency. The Board is also asked to provide recommendations on any areas of this governance framework that could be clarified or improved.
Implications for patients and the public: This revised governance framework strengthens the governance around patient safety and engagement at Executive and Board level with the establishment of a new Chief Safety Officer role and a new Patient & Safety Assurance Committee.
Which of the theme (s) in the Corporate Plan 2019/2023 does the paper support? All and particularly Organisational Excellence / Efficiency. **If relevant, which Business Plan strategic activity does it support?**
Author (s): [redacted] and Stephen Lightfoot
Board Sponsors: Stephen Lightfoot and June Raine

REVISED MHRA GOVERNANCE FRAMEWORK AND ASSURANCE MAP

Background

1. The Board will recall that a Governance Review was conducted earlier this year, which sought to review and transform the Agency's governance and leadership structures to enable agile and effective decision-making throughout the organisation. This review also confirmed concerns around how the Agency was operating, and about our ability to drive forward the necessary changes in response to a number of strategic challenges associated with the UK transition from the European Union, the recommendations of the Independent Medicines & Medical Devices Safety Review chaired by Baroness Cumberlege and the COVID-19 pandemic. At the same time the Agency also wanted to maximise the opportunities to support the life sciences innovation agenda and the wider health system in the UK by remaining a highly respected, responsive and world class regulator that puts patients at the centre of everything it does.

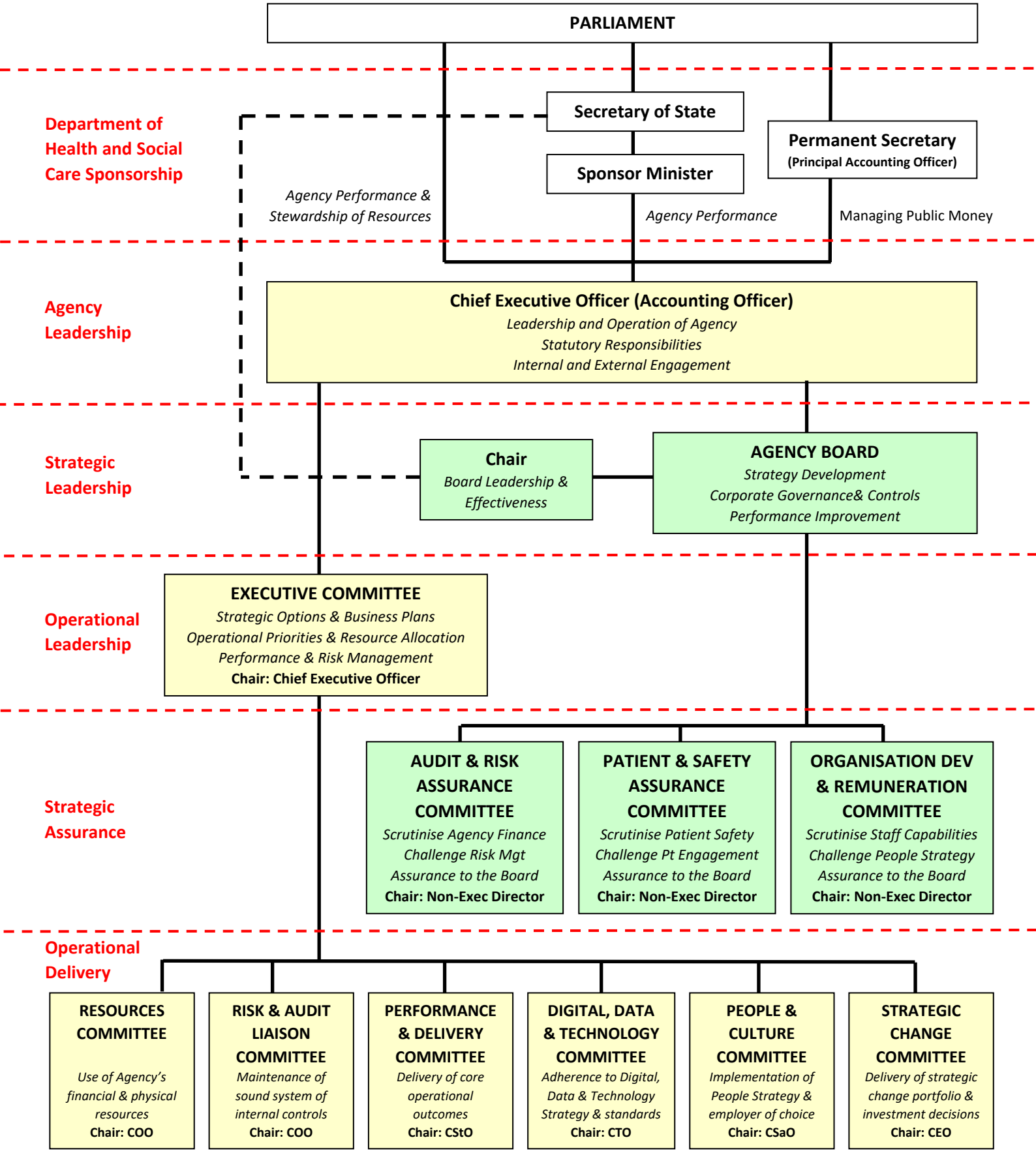
2. The Board committed to implement the recommendations of the Governance Review as quickly as possible to strengthen the Agency's governance structures and enable fast, effective decision-making in all parts of the Agency, cutting across existing siloed divisions/centres and filling any potential gaps. The outcome of these changes will be to drive delivery, hold people to account and make effective, intelligent choices about the future of the Agency's operations.

3. The first two fundamental governance decisions have already been taken:
   - the move to a Unitary Agency Board with an equal number of Executive and Non-Executive Directors, plus a Non-Executive Chair, supported by three Board Assurance Committees; and
   - the establishment of a new Executive Committee with a total of seven Chief Officers, including the Chief Executive as Chair, supported by a new set of six cross-agency, cross-divisional Management Committees.

4. This paper has been written to provide an overview of the revised governance framework and assurance map for the MHRA and this has been summarised with input from several sources including:
   - the Cabinet Office Public Bodies Handbook – Part 3 : "Executive Agencies: A Guide for Departments" published in 2018;
   - the Recommendation from the MHRA Governance Review, facilitated by independent consultants from EY and completed in June 2020;
   - considerable internal consultation and development led by [redacted], Deputy Director for the Agency Change Strategy; and
   - contributions from Board Directors individually, in working groups and at a Board Seminar in September 2020.

Revised MHRA Governance Overview

5. The diagram on the following page provides a highly simplified illustration of the overall governance structure for the Agency on one page. The yellow coloured boxes indicate Executive led functions and the green boxes indicate Non-Executive led functions :


PARLIAMENT
Department of Health and Social Care Sponsorship
Secretary of State
Sponsor Minister
Permanent Secretary
(Principal Accounting Officer)
Agency Performance & Stewardship of Resources
Agency Performance
Managing Public Money
Agency Leadership
Chief Executive Officer (Accounting Officer)
Leadership and Operation of Agency
Statutory Responsibilities
Internal and External Engagement
Strategic Leadership
Chair
Board Leadership & Effectiveness
AGENCY BOARD
Strategy Development
Corporate Governance& Controls
Performance Improvement
Operational Leadership
EXECUTIVE COMMITTEE
Strategic Options & Business Plans
Operational Priorities & Resource Allocation
Performance & Risk Management
Chair: Chief Executive Officer
Strategic Assurance
AUDIT & RISK ASSURANCE COMMITTEE
Scrutinise Agency Finance
Challenge Risk Mgt
Assurance to the Board
Chair: Non-Exec Director
PATIENT & SAFETY ASSURANCE COMMITTEE
Scrutinise Patient Safety
Challenge Pt Engagement
Assurance to the Board
Chair: Non-Exec Director
ORGANISATION DEV & REMUNERATION COMMITTEE
Scrutinise Staff Capabilities
Challenge People Strategy
Assurance to the Board
Chair: Non-Exec Director
Operational Delivery
RESOURCES COMMITTEE
Use of Agency's financial & physical resources
Chair: COO
RISK & AUDIT LIAISON COMMITTEE
Maintenance of sound system of internal controls
Chair: COO
PERFORMANCE & DELIVERY COMMITTEE
Delivery of core operational outcomes
Chair: CStO
DIGITAL, DATA & TECHNOLOGY COMMITTEE
Adherence to Digital, Data & Technology Strategy & standards
Chair: CTO
PEOPLE & CULTURE COMMITTEE
Implementation of People Strategy & employer of choice
Chair: CSaO
STRATEGIC CHANGE COMMITTEE
Delivery of strategic change portfolio & investment decisions
Chair: CEO

Revised MHRA Governance Responsibilities

6. The following section provides more information on the key responsibilities for each individual or component part of the governance framework so that the broad routes of assurance can be agreed by the Board before the final detailed Terms of Reference and Job Descriptions are produced.

7. Chief Executive Officer

The Agency is led by the Chief Executive Officer who is directly accountable to ministers for the operation and management of the organisation and for the delivery of its functions. The Chief Executive is also directly accountable to Parliament as the Accounting Officer for the Agency. The Chief Executive is supported by the Agency Board, which is led by a Non-Executive Chair.

There should be a formal, rigorous and transparent process for the appointment of the Chief Executive, led by the sponsoring department. This should be compliant with the Civil Service Commission's Recruitment Principles. The sponsoring department is also responsible for assessing the performance of the Chief Executive on an annual basis.

8. Agency Board

The Agency Board supports the Chief Executive in the effective delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring that controls are in place to manage risk. The Agency Board does not make any regulatory decisions on medical products and this remains an executive responsibility.

The new unitary Agency Board will consist of an equal number of Executive Directors (i.e. Chief Officers) and Non-Executive Directors, plus a Non-Executive Chair, when the recruitment processes for the substantive Chief Officer roles and some new Non-Executive Directors are completed in 2021. Board members will be recruited from a wide range of diverse backgrounds, with an appropriate balance of skills, experience, independence and knowledge.

The key responsibilities of the Agency Board are to:

- set the strategic direction for the Agency;
- provide assurance on the Agency performance in the delivery of its statutory duties and relevant corporate and business plans agreed with ministers; and
- agree the risk appetite and ensure effective controls are in place to manage risks.

Agendas for Agency Board Meetings will be prioritised around decision items and assurance items relating to the strategic priorities of the Agency. Other meetings will be used to discuss items which are still in development and information items will generally be shared by email to maximise the time for discussion on strategic decisions at Board Meetings. Participation in Agency Board Meetings will generally be limited to Board Directors, the Departmental Sponsor and Devolved Administrations to increase the accountability of the Chief Officers and Committee Chairs in presenting their own papers and to encourage more debate between Board members.

The Agency Board wants to improve its engagement and transparency with patients and the general public. Agency Board Meetings held in public will be broadcast live online and will also be recorded so that patients, members of the general public and staff can observe these meetings during and after the event at their own convenience. Board agendas and Board papers will be published on the MHRA GOV.UK website and the opportunity will be provided for patients and members of the public to ask questions at specific points during these Board Meetings.

9. Chair

The Non-Executive Chair is responsible for the leadership of the board and for ensuring its overall effectiveness. The Chair should ensure that new members undergo a proper induction process and is responsible for:

- ensuring that the Board, in reaching decisions, takes proper account of guidance provided by the sponsoring department or ministers;
- ensuring that the Board carries out its business efficiently and effectively;
- developing an effective working relationship with the Chief Executive and other senior staff; and
- undertaking an annual assessment of Non-Executive Directors' performance.

There should be a formal, rigorous and transparent process for the appointment of the Chair, led by the sponsoring department. This should follow the principles of the Governance Code on Public Appointments in as far as these are proportionate and applicable. The sponsoring department is also responsible for assessing the performance of the Chair on an annual basis.

10. Non-Executive Directors

As part of their role, Non-Executive Directors provide independent and constructive challenge. All Non-Executive Directors must be properly independent of management and must allocate sufficient time to the Agency Board to discharge their responsibilities effectively. This includes ensuring that high standards of corporate governance are observed at all times and ensuring that the Agency operates in an open, accountable and responsive way.

There should be a formal, rigorous and transparent process for the appointment of Non-Executive Directors, led by the sponsoring department. This should follow the principles of the Governance Code on Public Appointments in as far these are proportionate and applicable. The Chair is responsible for assessing the performance of each Non-Executive Director on an annual basis and regularly reviewing individual training and development needs.

Non-Executive Directors will be expected to become a member of at least one Assurance Committee and take on at least one special interest role on behalf of the Agency Board. The Chair will propose these responsibilities to the Agency Board for endorsement so that the workload and external experiences of the Non-Executive Directors can be shared.

11. Deputy Chair and Senior Independent Director

The Chair will nominate one of the Non-Executive Directors to be Deputy Chair of the Board and nominate another Non-Executive Director to be Senior Independent Director for endorsement by the Agency Board. The Deputy Chair should be able to deputise for the Chair so that Agency Board business can continue if the Chair is not available for any reason. If the Chair is not a clinician, the Deputy Chair should normally be a clinician (and vice versa) to provide a good balance of clinical and non-clinical leadership experience for the Board. The Senior Independent Director should have a strong background in financial and/or risk management and should normally be the Chair of the Audit & Risk Assurance Committee. The Chair will consult the Deputy Chair and Senior Independent Advisor on the operation and effectiveness of the Agency Board on a regular basis, as well as consulting them on any urgent issues which require attention.

12. Assurance Committees

Three sub-committees of the Agency Board will be set up to strengthen the independent scrutiny of core activities of the Agency so that robust assurance and recommendations for improvement can be reported back to the Agency Board. The Chair will nominate a Non-Executive Chair for each Assurance Committee and at least two Non-Executive Directors as members of each committee for endorsement by the Agency Board.

13. Audit & Risk Assurance Committee

The Audit & Risk Assurance Committee will be chaired by a nominated Non-Executive Director with financial and risk management experience to advise the Agency Board and the Chief Executive as Accounting Officer on their responsibilities relating to risk, controls and governance by:

- scrutinising the processes, systems and structures within the Agency to ensure financial probity, value for money, integrity and effectiveness with the support of internal and external audit;
- providing challenge to the executive on the identification and management of key risks; and
- providing assurance to the Board that the Agency has appropriate procedures in place to discharge its financial and audit responsibilities in line with public sector requirements

14. Patient & Safety Assurance Committee

The Patient & Safety Assurance Committee will be chaired by a nominated Non-Executive Director with a specific interest in patient safety to advise the Agency Board and the Chief Executive on their responsibilities relating to patient safety and patient engagement by:

- scrutinising the processes, systems and structures within the Agency to ensure that patient safety and patient engagement is paramount in regulatory outcomes;
- providing challenge to the executive on the aspects of the regulatory systems that could be modified to improve patient safety and patient engagement;
- providing assurance to the Board that the Agency has appropriate procedures in place for preventing, detecting and addressing any safety or quality issues with medicines, medical devices or blood products.

15. Organisational Development & Remuneration Committee

The Organisational Development & Remuneration Committee will be chaired by a nominated Non-Executive Director with recent organisational change experience to advise the Agency Board and the Chief Executive on their responsibilities relating to workforce planning, development and rewards by:

- scrutinising the processes, systems and structures within the Agency to attract, retain, and develop staff capabilities in a changing environment;
- providing challenge to the executive on the development and implementation of the People Strategy;
- providing a formal and transparent process for determining executive remuneration; and
- providing assurance to the Board that the Agency has appropriate procedures in place for managing and developing its workforce capabilities.

16. Executive Committee

The driving rationale for the introduction of the new Executive Committee (ExCo) and new Management Committees is to ensure that the decisions which are critical to the Agency are taken in a timely way, at the right level in the organisation, by the right people with the right evidence. This will ensure that we have clear accountability for delivery, strong management of risk, transparent priorities and that business is conducted in a smooth and predictable fashion. In so doing, we will free up staff to get on with delivering outcomes for patients, rather than spending time serving internal processes that do not add value.

The key responsibilities for the Executive Committee are:

- generating strategic options and refining forward strategies (for discussion with the Board and for inclusion in Corporate and annual Business Plans as appropriate);
- deciding operational priorities and allocating resources accordingly;
- ensuring performance against strategic and operational objectives, through the identification and removal of barriers and through holding business units to account;
- managing key strategic risks to the successful operations of the Agency; and
- setting and driving an enabling culture which centres patients at the heart of the Agency's responsibilities.

17. Management Committees

Everyone's work across the Agency will be touched by the new Management Committees in some way. Each of the Management Committees now has an agreed member of ExCo who will chair, designed in part to help reinforce the importance of working as 'One Agency' and to break down traditional silos. Each Chief Officer is working to hold the first meeting of their new committees by the end of October. Old committee structures are being stood down, and in a few specific cases repurposed as a supporting structure to the six new Management Committees. We are building Terms of Reference that work for the Agency's specific purpose and are prioritising what we want committees to be able to do straight away and where we see them developing over the longer term.

18. Resources Committee

The Resources Committee will be chaired by the Chief Operating Officer and the key responsibilities are to:

- hold senior budget holders to account for their use of the Agency's financial and physical resources to achieve the strategic objectives;
- approve operational financial requests which fall outside of the change agenda; and
- monitor compliance with the Agency's statutory requirements relating to financial affairs.

19. Risk & Audit Liaison Committee

The Risk & Audit Liaison Committee will be chaired by the Chief Operating Officer and its key responsibilities are to:

- support the maintenance of a sound system of internal control to achieve the Agency's policies, aims and objectives.
- provide challenge and assurance of the Agency's approach to mitigation of all major risks; and
- be responsible for Executive scrutiny of policies relating to conflict of interest and quality management

20. Performance & Delivery Committee

The Performance & Delivery Committee will look at how we are achieving against our strategic objectives and, if performance is not where it should be, will be able to have an objective discussion about the reasons for that and consider any action that may be necessary. The Performance & Delivery Committee will be chaired by the Chief Strategy Officer and its key responsibilities are to:

- monitors the performance of the Agency in delivering on core operational outcomes (non-corporate) and hold divisions to account for that performance;
- reports to ExCo on operational performance and escalate serious delivery issues; and
- be responsible for Executive level scrutiny of patient safety outcomes.

21. Digital, Data & Technology Committee

The Digital, Data & Technology (DDaT) Committee will be chaired by the Chief Technology Officer and its key responsibilities are to:

- hold the organisation to account for adherence to the DDaT strategy, and to architecture and standards;
- be responsible for Executive scrutiny of compliance with government data and technology controls (e.g. NHSX) and management of organisational security; and
- operational oversight of DDaT performance across the business and an escalation route for resolution of issues with existing applications.

22. People & Culture Committee

The People & Culture Committee will be the place where we consider how we are delivering on our strategy for staff and what more needs to be done to enable the delivery of outcomes by people right across the Agency. This Committee will be chaired by the Chief Safety Officer and its key responsibilities are to:

- be responsible for driving implementation of the People Strategy agreed at ExCo throughout the business, holding the HR function and unit leaders to account against their respective roles;
- be responsible for supporting ExCo to make the Agency an employer of choice on diversity and inclusion grounds; and
- provide oversight of risk management in relation to implementation of the People Strategy and workforce planning.

23. Strategic Change Committee

The Strategic Change Committee will be the place for challenging the rigorous prioritisation of change programmes, to avoid repeating past mistakes of overcommitting on what we can deliver and to ensure quality delivery across projects of all sizes. This Committee will be chaired by the Chief Executive and its key responsibilities are to:

- hold the Agency to account for delivery of the strategic change portfolio through monitoring progress, deciding priorities and escalating the most serious delivery issues to ExCo;
- take decisions on which projects/programmes should proceed, stop or delay under the change strategy; and
- provide final approval of investment in new projects and programmes.

24. Review

Once the Management Committees are in place, we will conduct a short, informal review to ensure they are delivering as intended and taken together, provide the necessary direction and executive assurance to enable the Agency to operate effectively.

This will be followed up by an annual self-assessment of each Board Assurance Committee and Management Committee to ensure continued alignment with the strategic priorities of the Agency, challenge the robustness of assurance provided and to identify opportunities for improvement from the practical experience of implementing this governance framework.

25. Conclusion

This revised governance framework of the new unitary Agency Board, Executive Committee, Assurance Committees and Management Committees will strengthen individual accountabilities and provide greater and more consistent organisational assurance on the delivery of strategic outcomes throughout the Agency. It will be simpler going forward for committees, now clearly orientated around specific issues and deliverables, to access appropriate information and understand responsibilities and accountabilities as they seek the necessary assurance that the Agency is delivering credible outcomes. This transparency, built on the appointment of the Chief Officers and the fulfilment of the commitment to a fully unitary Agency Board will also mean that, over time, we are better able to maximise the opportunities and mitigate the risks around the delivery of those credible outcomes.