Medicines & Healthcare products Regulatory Agency

AGENDA FOR BOARD MEETING HELD IN PUBLIC

10:00 – 12:30 on 19th January 2021

Chair: Stephen Lightfoot

	AGENDA ITEM	PURPOSE	PRESENTER
10:00	INTRODUCTION 1. What are the priorities for this meeting and how will the meeting run?	Information	Chair
	2. Are there any Apologies or Declarations of Interest?	Information	All
	3. What were the minutes and actions from the last meeting?	Approval	Chair
10:15	CURRENT CONTEXT 4. What are the current key issues from the CEO point of view?	Discussion	June Raine
	HEALTHCARE ACCESS		
10:40	5. How will the new Trade & Cooperation Agreement with the EU impact on the work of the agency and on the supply of medical products in the UK?	Discussion	Sam Atkinson
11:05	6. What are the plans to introduce a new registration system to improve the oversight of medical devices in the UK?	Discussion	Prof Bruce Campbell and John Quinn
	PATIENT SAFETY		
11:25	7. What are the short, medium and long-term deliverables on the agency recommendations from the Cumberlege Review?	Approval	June Raine
	DYNAMIC ORGANISATION		
11:45	8. What are the final proposed Terms of Reference for the three new Board Assurance Committees:	Approval	
	a. Audit & Risk Assurance Committee		Michael Whitehouse
	b. Patient Safety & Engagement Committee		Mercy Jeyasingham
	c. Organisation Development & Remuneration Committee		Anne-Toni Rodgers

12:05	EXTERNAL PERSPECTIVE 9. What questions do members of the public have for the MHRA Board?	Discussion	Chair
12:30	CLOSE OF MEETING	-	Chair

Medicines and Healthcare products Regulatory Agency

Minutes of the Board Meeting Held in Public of 23rd November 2020

(10:30 – 13:00)

By Zoom Webinar

Present:

The Board

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

Others in attendance

Rachel Bosworth	Director of Communications
{Name redacted: Section 40 – Personal data}	Secretary to the Board and Deputy Head of Directorate
{Name redacted: Section 40 – Personal data}	Executive Assistant to the Chair

Government Legal Department

Elizabeth O'Neill	Deputy Director, MHRA, Medicines & Pharmacy, GLD

Department of Health and Social Care (DHSC)

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

Devolved Administrations

Cathy Harrison	Chief Pharmaceutical Officer, Department of Health Northern Ireland
Alison Strath	Chief Pharmaceutical Officer, Scottish Government
Greig Chalmers	Head of Medicines Policy Branch, Scottish Government

Item 1: Introduction

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

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

1.2 The Chair welcomed all to the meeting, including the broad range of members of the public attending in the audience.

1.3 The Chair and the Board congratulated Professor David Webb who was made a Commander of the Order of the British Empire in the Queen's birthday honours.

1.4 The Board sincerely thanked the previous secretary to the Board, Aidan McIvor, for his unfailing readiness to offer help and advice to the Board.

Item 2: Are there any Apologies or Declarations of Interest

2.1 There were no declarations of interest.

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

3.1 The Board reviewed the minutes and actions from the last meeting and updates were provided on the outstanding actions. It was agreed to bring forward the action on Devices Registries for an update at the Board meeting.

CURRENT CONTEXT

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

4.1 Dr June Raine presented the Chief Executive's monthly report, which covered topics within the four strategic priorities: (i) healthcare access – including updates on Covid-19 vaccine, therapeutics and diagnostics, EU Exit, international work and CPRD support for new pragmatic clinical trials; (ii) patient safety – including updates on medicines and medical devices issues, MedSafetyWeek, and on the Medical Devices Safety Bulletin; (iii) dynamic organisation – including updates on inspections, mental health and wellbeing, staff meetings and Civil Service Awards; and (iv) financial sustainability – including updates on the Agency Change programme and the Finance Transformation.

4.2 The Board thanked Dr Raine for her report and provided comments relating to remote inspections and news ways of working; the safety and efficacy of hand sanitisers; the EU Exit web seminars and responding to uncertainty in industry, and stakeholder engagement in relation to EU Exit; and resources the MHRA has to undertake independent surveillance of covid-19 vaccines. The Board were assured on each of these points.

HEALTHCARE ACCESS

Item 5: What are the most promising scientific research projects within the Agency that could have the biggest impact on protecting and improving patient health?

5.1 The Board considered a paper describing the most promising scientific research projects within the Agency that could have the biggest impact on protecting and improving patient health. The Board noted that scientific research performed by the Agency, strategically aligned to a patient-centric Science Strategy, will create important outcomes

enabling medical products developing, licensing and surveillance, and evolve current regulatory frameworks.

5.2 The Board considered the areas of interest which should be considered for the Agency's portfolio which then can be further developed for the Agency's Regulatory Science Strategy. It was noted that the areas identified in the paper are not the only areas of interest, given the Agency's wide scientific portfolio. The Board commented that this paper focuses a lot on NISBC and CPRD; other areas of the Agency's portfolio could be brought in. The Board endorsed the proposal to establish a Centre for Regulatory Science.

5.3 The Board commented that it is vital this work focuses on the particular strengths of the UK for regulatory science, and how to address any weaknesses; and provided additional comments regarding issues with real world evidence and secondary care data; the ability to translate data in to evidence and CPRD's role in recruitment for pragmatic trials. Mapping out future needs with regards to methodology and applications in the area of real world evidence will be key.

5.4 The Board requested more information on the work of CPRD; an action was taken to conduct a Board review of CPRD.

Action 13: Jon Fundrey to facilitate a Board review of CPRD.

5.5 The Board provided a range of additional comments on the topics including the growing number of tumour markers being identified and the requirement of genomic reference standards; ensuring the Agency has access to equipment at the cutting edge of science; development of medical devices; new sources of signals. The Board suggested the Agency should consider routine publication in scientific and medical journals; starting with the Covid-19 vaccines regulatory approval process.

5.6 The Board agreed it is important that the Agency communicates and collaborates across the UK in this work; the Board also agreed that consideration should be given on how to prioritise these projects internally, and also working with external stakeholders.

PATIENT SAFETY

Item 6: What is the assurance that the MHRA Enforcement Group can protect patient health by working with global partners?

6.1 The Board considered a paper providing assurance that the MHRA Enforcement Group can protect patient health by working with global partners. The Board noted that the work of the Enforcement Group directly impacts the security of the supply chain and the availability of unlicensed medicines and is therefore essential for public and patient safety.

6.2 The Board thanked the MHRA Enforcement Group for all the work they do to protect public health. The Board provided a range of comments regarding incentives and disincentives such as penalties; the enormous scale of this work and the importance of international collaboration; vaccine fraud; and the importance of taking a holistic approach to this work.

6.3 An action was taken to review the resourcing of the MHRA Enforcement Group as this is a key area of work the Agency does to protect public health. Performance indicators should also be considered.

Action 14: Samantha Atkinson to review the resourcing of the MHRA Enforcement Group and link with Business Plan as part of Size & Shape programme.

FINANCIAL SUSTAINABILITY

Item 7: What assurance can be provided by the Audit & Risk Assurance Committee on the current risks facing the MHRA and their proposed mitigations?

7.1 The Board considered a paper providing assurance by the Audit & Risk Assurance Committee (ARAC) on the current risks facing the MHRA and their proposed mitigations. The Board noted the Agency's likely end of year financial position and endorsed the need for sustained implementation of the necessary changes which the Shape and Size review is likely to recommend so that the MHRA remains an effective and highly respected regulator but also becomes financially resilient.

7.2 The Board considered the recommendations to strengthen further the Agency's approach to risk management. The Board agreed this work is vital to the future of the Agency, and agreed that is important that managers are fully engaged in the new governance system to ensure all risks are identified and there are no weaknesses.

7.3 The Board supported the project underway to better align fees to the Agency's costs and endorsed the need for a clear fee strategy which is periodically reviewed by the Board to enhance accountability and governance.

Action 15: Jon Fundrey to review Agency Fee structure to ensure closer alignment with costs of delivery

DYNAMIC ORGANISATION

Item 8: What are the strategic priorities for the new MHRA Corporate Plan (April 2021 – March 2024) and 2021/22 Business Plan?

8.1 The Board considered the strategic priorities for the new MHRA Corporate Plan (April 2021 – March 2024) and 2021/22 Business Plan. The Board agreed that a single 2-year Agency Delivery Plan should be produced instead of the existing Corporate and Business Plans. This should include specific details on change management, IT roadmap within realistic budget and prioritised Regulatory Science programme.

8.2 The Board agreed it is important to focus on deliverability, setting out the challenges and opportunities for the Agency from a public health and patient safety perspective, as well as from a scientific and regulatory excellence perspective. It was agreed that colleagues from the Devolved Administrations should be regularly consulted while the plan is in development.

Action 16: Jon Fundrey to produce a single 2-year Agency Delivery Plan to replace the existing Corporate and Business Plans. This should include specific details on change management, IT roadmap within realistic budget and prioritised Regulatory Science programme.

ANY OTHER BUSINESS

Item 9: What is the proposed membership of the Board Assurance Committees and the special responsibilities of the Non-Executive Directors?

9.1 The Board reviewed the proposed membership of the Board Assurance Committees so that each committee can finalise their Terms of Reference in line with the MHRA Governance Framework and Assurance Map approved at the MHRA Board Meeting on 26 October 2020. The Board endorsed the membership and also endorsed the proposed special responsibilities assigned to each Non-Executive Director. It was agreed that lay members should be seconded on to the Patient Safety and Engagement Committee until new lay members can be recruited.

Action 17: Second interim lay members on to Patient & Safety Assurance Committee until new lay members can be recruited

Item 10: What are the 2021 dates for Board Meetings to be held in public?

10.1 The Board reviewed and endorsed the 2021 dates for Board Meetings to be held in public.

Action 18: Directorate to send out meeting invitation for agreed Board Meeting dates in 2021

Item 11: Are there any other urgent items for discussion?

11.1 The Board noted that there were no other urgent items for discussion at this time.

EXTERNAL PERSPECTIVE

Item 12: What questions do members of the public have for the MHRA Board?

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

SUMMARY OF ACTIONS FROM MHRA BOARD MEETING – 23 November 2020

Action Number	Action	Owner	Date	Status
Carried Forward from previous meetings				
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~~ 19/01/21	On agenda
5	Arrange a Board Seminar to discuss how the MHRA could engage patients more widely, building on existing engagement activities by other organisations, and involve patients systematically in our regulatory decision making	Stephen Lightfoot	~~23/11/20~~	Delegate to PS&E Committee
7	Provide an update to the Board on the Memorandum of Understanding with NICE	June Raine	~~23/11/20~~	Chair & CEO Meeting in February
8	Hold a Board Seminar discussion on diversity and inclusion	Stephen Lightfoot	~~18/12/20~~	Delegate to OD & R Committee
12	The Terms of Reference of the Board Assurance Committees need to be finalised and agreed by the Board	~~Stephen Lightfoot~~ Committee Chairs	~~18/12/20~~ 19/01/21	On agenda
New Actions				
13	Conduct a Board review of CPRD	Jon Fundrey	16/03/21	
14	Review the resourcing of the MHRA Enforcement Group and link with Business Plan as part of Size & Shape programme	Sam Atkinson	18/12/20	Included in Size & Shape programme
15	Review Agency Fee structure to ensure closer alignment with costs of delivery	Jon Fundrey	15/06/21	
16	Produce a single 2-year Agency Delivery Plan to replace existing Corporate and Business Plans.	Jon Fundrey	20/04/21	
17	Second interim lay members on to Patient & Safety Assurance Committee until new lay members can be recruited	Mercy Jeyasingham	19/01/21	Completed

18	Send out meeting invitation for agreed Board Meeting dates in 2021	Directorate	18/12/21	Completed

Medicines & Healthcare products Regulatory Agency

Chief Executive's Report to the Board

19th January 2021

This report gives a brief overview of the current issues from the CEO's point of view. Separate papers give more detailed information on the EU Exit transition, plans to introduce a new registration system for medical devices in the UK, progress in delivering on the Agency recommendations from the Cumberlege Review; and the new Board Assurance Committees. The Board is asked to consider and agree the priorities

HEALTHCARE ACCESS

Covid-19 Vaccines and Therapeutics

1. A key Agency priority is to enable successful development, licensing and deployment of vaccines, therapeutics and diagnostics for Covid-19. In relation to vaccines, we have completed the rigorous review of three Covid-19 vaccines to date, enabling UK deployment as appropriate batches become available. The Covid-19 Vaccine Benefit Risk Expert Working Group of the Commission on Human Medicines continues to review the emerging data. Clinical trials of other vaccines are ongoing, and the Agency is providing support to these companies including via 'rolling' reviews.

2. NIBSC is working with the Coalition of Epidemic Preparedness Innovations (CEPI) to monitor the new Covid-19 viral strains globally and evaluate their impact on vaccine candidates. This follows recent identification of new variant coronavirus strains in UK and from South Africa.

3. The CHM Covid-19 Therapeutics Expert Working Group continues to review emerging data on various products, including on tocilizumab and sarilumab, for treatment of Covid-19. Emerging data from ongoing clinical trials is also reviewed as soon as it becomes available in order to provide advice and support to researchers and DHSC.

4. It is estimated that over 1.2 million first doses and over 21,000 second doses of the Pfizer/BioNTech Covid-19 vaccine have been administered in the UK. The Agency continues to review emerging data for these vaccines and has a proactive pharmacovigilance programme in place in the form of a four-pronged approach which consists of enhanced passive surveillance with observed versus expected analysis, rapid cycle analysis and ecological analysis including that of adverse events of special interest and any other topics which arise, targeted active surveillance and formal epidemiological studies.

5. The most frequently reported ADRs are in line with the known safety profile of the vaccine and largely reflect reactogenicity that is expected post-vaccination or relate to vasovagal reactions associated with administration. Overall, there are no new

significant safety concerns raised based on the ADR data available. Anaphylaxis is being kept under close review following two initial reports shortly after the introduction of the UKs Pfizer/BioNTech Covid-19 vaccination program.

Covid-19 tests

6. The Agency continues to work to support the national Covid-19 Testing Strategy. We are working in partnership with the Variations of Concern (VOC) group on virus mutations. We contact manufacturers of PCR and antigen tests on the UK market to remind them of their regulatory responsibilities to report performance issues with assays within 48 hours.

7. In December we provided an Exceptional Use Authorisation to DHSC/Track and Trace for self-test Lateral Flow Devices, for use in asymptomatic individuals for the purpose of finding positive Covid-19 cases with the aim of preventing accidental onward transmission. The MHRA is represented on the Track and Trace Testing Initiatives Evaluation Board and the devices team continues to support Track and Trace in the development of their initiatives whilst retaining a separate dedicated workstream for proactive surveillance of their role.

8. We are increasingly seen as an authoritative source of information on Covid-19 tests and we are developing our devices safety pages to reinforce the importance of following the instructions for use on Lateral Flow tests and to answer questions on areas of concern identified by stakeholders have identified. We are continuing to support the NHSEI and the Devolved Administrations in their roll-out of lateral flow tests to find positive cases in health and social care workers.

Enabling Innovation

9. On 1st January following successful pilot work, we announced the launch of a new Innovative Licencing and Access Pathway which supports early access to innovative medicines via a single integrated platform for collaborative working between MHRA, partners including NICE and the Scottish Medicines Consortium, and the medicine developer. The pathway uses new tools, including a Target Development Profile, and embodies patient perspectives.

International work

10. The MHRA's International Office continues to coordinate our international effort working with regulators around the world on matters relating to Covid-19 vaccines and therapeutics. We are playing an active role in the International Coalition of Medicines Regulatory Authorities (ICMRA) where we co-chair the Covid-19 Working Group and lead two projects, one on vaccine vigilance readiness and another on the digital transformation of inspections.

11. We have organised two ad-hoc teleconferences with key global regulators, the first following the adverse reactions to the Pfizer/BioNTech vaccine in the UK and the second after our authorisation of the Oxford/AstraZeneca vaccine. We are planning to take part in several upcoming ICMRA workshops on vaccine vigilance.

12. Work is under way to strategize MHRA's ambition and plan for working with the ACCESS Consortium (Australia, Canada, Singapore, Switzerland and UK). In this month's Heads of Agency call, MHRA will suggest several areas for the Agency to

work closely with Access partners on, particularly in the areas of: exchanging information across drug lifecycles in areas where patients are under-represented, regular information sharing on post-market activity, alignment of IT systems and the harmonisation of clinical development requirements for authorisation.

13. Regarding bilateral relationships, in December we held a Heads of Agency meeting with Japan, which focussed on enhanced regulatory cooperation between regulators. We are now working on the development of a joint work plan to ensure engagement increases between regulators. We continue to work on securing our membership of key international regulatory organisations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Devices Regulators Forum (IMDRF).

Medicines and Medical Devices Bill

14. The Medicines and Medical Devices Bill, which will provide the powers necessary to update the regulations that govern medicines, clinical trials and medical devices, has continued its Parliamentary passage. On 12 January, Peers sat for the first day of Report Stage in the House of Lords. New Government amendments were tabled in advance of Report stage. These include powers to enable a statutory advisory committee for devices, the establishment of a Patient Safety Commissioner, and additional safeguards on powers to support the sharing of information internationally. The second day of Report Stage is scheduled for 14 January.

PATIENT SAFETY

Antiepileptics drugs and review of safety of use during pregnancy

15. The Commission on Human Medicines (CHM) considered the conclusions of a review of the available data relating to the safety of use of antiepileptic drugs during pregnancy including data on the risk of physical birth abnormalities, harmful effects on the growth of the unborn baby and adverse effects on the child's learning and thinking abilities. This review, which was initiated in the context of the known harms of valproate, considered the available data for all authorised antiepileptic drugs except those only authorised for status epilepticus, acute convulsions or refractory convulsive disorders.

16. The CHM fully supported the conclusions of this review, which included that lamotrigine and levetiracetam are safer to use during pregnancy than other epilepsy medicines, and also the plans for public communication on the conclusions of the review through the MHRA's Drug Safety Update (DSU) bulletin. The DSU article was published on 6 January and was accompanied by a Patient Safety Leaflet to support discussions between women and healthcare professionals. A Public Assessment Report has also been published. The communication materials have been developed with input from relevant stakeholders, including representatives from epilepsy charities and patient groups.

Isotretinoin public consultation

17. The public call for evidence on Isotretinoin, launched on 10 November, is ongoing, seeking views from patients and the public on the benefits and risks of isotretinoin and the measures to minimise risks. The responses will be carefully considered by the Isotretinoin Expert Group which will advise the CHM on the need for regulatory action.

Drug alerts and recalls

18. There were six drug alerts and recalls in December 2020. These included a class 2 medicines recall of Sodiofolin vials due to hairline damage to the shoulder of the vials; a class 2 medicines recall of Zerbaxa infusion as a precaution due to the presence of Ralstonia pickettii in recent batches; a company-led drug alert for Fresenius Kabi Ltd sodium chloride due to the presence of a Polish labelled ampoule within some cartons; a class 4 medicines defect issued due to discrepancy on product packaging for Co-Careldopa and another various produced by Mylan Generics UK due the Patient Information Leaflet (PIL) missing relevant important safety information; and a class 3 medicines recall was issued for Simvador as the simvastatin tablets were packaged with a version of the PIL which did not include the most up to date safety information.

DYNAMIC ORGANISATION

19. On a very positive note, the Agency is one of three applicants short listed for the Civil Service Science Awards for our innovative synthetic data work to support regulation of AI software algorithms.

Mental health and wellbeing

20. It is clear that whilst we have yet to finalise our People Survey related priorities for this coming year, wellbeing will continue to be a focus in 2021. We recognise that colleagues are not just experiencing significant changes and added pressures at present, both within and outside of work, but that some of these have now been in place for a significant period of time and this in itself escalates the likelihood and potential impact on the health and wellbeing of our staff.

21. We are continuing to signpost a wealth of support materials and tools, provide additional guidance and training for managers and signpost opportunities for interaction and support, such as our coaching offer, our employee assistance provider and a new service called Access to Work: Mental Health.

22. We are analysing the feedback from staff on the impact of Covid-19, which featured specifically within the latest People Survey and monitoring absences. Such feedback and data support us in focussing on priorities for action. This month we have launched a year-long calendar of activities on diversity and wellbeing, as well as a monthly newsletter with additional resources. We are on the verge of publicising a Wellbeing webinar, which has been in development and focusses specifically on identifying stress within ourselves and others and finding ways to alleviate this.

FINANCIAL SUSTAINABILITY

Agency Change programme

23. We continue to make progress on the Agency change programme and in particular the final elements of the proposed Future Operating Model. In addition, we are building both our capacity and capability in anticipation of next phases of more detailed design and moving into implementation. We are arranging to access additional Organisational Design expertise through Cabinet Office frameworks to support in-house capability in driving the next steps of change. Finally, we are progressing the required procurement

process to bring in the external support that we will need to help the Agency work through the next phases of work in order that we can move forward at pace.

June Raine
Interim CEO
January 2021

Medicines & Healthcare products Regulatory Agency

Board Meeting

19 January 2021

How will the EU Trade and Cooperation Agreement impact on the work of the Agency and the supply of medical products in the UK?

Issue: The need to understand the impact of the EU Trade and Cooperation Agreement on the work of the Agency and the supply of medical products in the UK.
Action required by the Board and by when (timings): The Board is asked to discuss and provide direction on the two sets of remaining challenges: 1. Resolving specific, outstanding issues resulting both from the negotiations, and from a series of EU Exit related milestones over the coming years. 2. Ensuring the sustainability of the new Agency operations under the wider Change Strategy
Implications for patients and the public: The Agency has successfully managed the final stages of Transition from the EU, with no regulatory interruption of supply of pharmaceuticals or devices to patients and ensuring industry are able to continue to conduct regulatory business with the MHRA.
Which of the theme (s) in the Corporate Plan 2019/2023 does the paper support? All **If relevant, which Business Plan strategic activity does it support?**
Author (s): Director of Policy and Transition Task Force
Board Sponsor: Dr Sam Atkinson, Chief Quality & Access Officer

How will the EU Trade and Cooperation Agreement impact on the work of the Agency and the supply of medical products in the UK?

1. Summary

The Agency has successfully managed the final stages of Transition from the EU, with no regulatory interruption of supply of pharmaceuticals or devices to patients and ensuring industry are able to continue to conduct regulatory business with the MHRA. This delivers on the objectives of the Transition Programme.

There are now two sets of challenges:

1. Resolving specific, outstanding issues resulting both from the negotiations, and from a series of EU Exit related milestones over the coming years. This work is underpinned by the need to explore what relationship the UK, as a "Third Country", can now be built with the EU.

2. Having successfully managed Transition under its existing structures and operations, and with significant work having been done to build the foundations of wider global joint working, the Change Strategy now needs to ensure the sustainability of the new Agency operations, particularly those relating to:

    - the support for innovation in pharmaceuticals (where the implications of industry being able to rely on EU scientific decisions for the purpose of GB market authorisation remain unclear)
    - The development of a Great Britain equivalent for the Falsified Medicines Directive (FMD) system
    - the future regulation of medical devices post 'standstill' arrangements
    - NIBSC batch release work (which is no longer mutually recognised between NIBSC and the EU).

The Agency Transition Task Force will remain in place for the first quarter of 2021 to trouble-shoot any problems that arise.

2. The outcome of the UK – EU negotiations

- Final agreement on the Comprehensive Trade Agreement (CTA) was reached on the 24 December 2020.

- Deal: The UK has now become a fully independent, "Third Country" to EU. The MHRA will remain the regulator for whole of UK, with powers to operate independently for Great Britain, but with EU regulation applying directly in Northern Ireland (NI) (and taking precedence over UK regulation where there is overlap).

- On the Mutual Recognition Agreement within the CTA: only mutual recognition of Good Manufacturing Practice (GMP) was agreed as the EU declined UK proposals for mutual recognition of batch testing by NIBSC, quality testing by companies located within Great Britain, and pharmacovigilance information sharing.

- With the known exception of COVID-19 vaccines, and to a lesser extent plasma pools, there will be little immediate change to levels of laboratory testing of biological medicines

at NIBSC. The public health rationale for testing COVID-19 vaccines and plasma pools in this scenario has been endorsed by the Commission on Human Medicines (CHM). Testing is already taking place for COVID-19 vaccines in a timely way and arrangements to ensure sufficient future testing capacity are in hand. A proposed Memorandum of Understanding to allow data sharing between NIBSC and the EU OCABR network has also been executed.

- Some exemptions have also been agreed for 12 months to the basic principle that EU rules apply entirely and directly in NI, specifically in relation to importation requirements and delaying certain requirements of pack serialisation under the Falsified Medicines Directive until end 2021. Following this period, full compliance with EU importation checks (including re-testing batches) and pack serialisation will be required.

- There have been separate agreements outside of the CTA to enable access to some EU databases, networks and systems which have ensured access needed for the purposes of conducting core regulatory processes for the purposes of NI, but not access to key repositories such as the data supporting marketing authorisations effective in NI, safety decisions and vigilance databases. As a result, the UK will now have very limited sight of EU decisions as they are being prepared.

- The EU CTA enables the continued exchange of essential confidential information and will also provide a framework for future regulatory cooperation.

3. Forward agenda

Having navigated the end of the transition period, focus now needs to turn to longer term activities required to facilitate the MHRA's standing as a sovereign regulator.

- **Medical Devices Regulation (MDR) in Northern Ireland from June 2021:** Under the terms of the Northern Ireland Protocol (NIP), from 1 January 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain (England, Wales and Scotland). The MDR will apply in Northern Ireland from 26 May 2021, in line with the EU's current implementation timeline.

- **UKCA marking manufacturers will need to undergo a new conformity assessment:** From 1 January 2021, a new UKCA product mark will be introduced in Great Britain, which will mirror the processes set out under current directives which have been transposed into UK law through UK Medical Devices Regulations (2002). Following the standstill period for medical devices it is anticipated that this will create significant demand for additional conformity assessments.

- **End of regulatory importation check exemptions and Falsified Medicines Directive exemptions in NI - December 2021:** The NIP came into effect from 1 January 2021 and has resulted in changes to regulations regarding medicines, specifically in relation to importation requirements and compliance with Falsified Medicines Directive. There will be a twelve-month phased in approach of these regulations, after which full compliance with EU importation checks (including re-testing batches) and pack serialisation will be required.

- **End of 'standstill' periods for pharmaceuticals and devices - 2022/3:** The UK Government has unilaterally extended 'standstill periods' to provide regulatory flexibility

for industry to ensure the ongoing supply of medicines and medical devices to the UK public. These flexibilities will come to an end in December 2022 & July 2023.

- **Northern Ireland Protocol (NIP) consent mechanism – 1 Jan 2025:** At the end of the transition period the provisions of the Northern Ireland Protocol have automatically come into effect. After four years [31 Dec 2024], the UK must provide Northern Ireland with the opportunity to decide whether or not those provisions remain in place.

- **Review of overall Trade and Cooperation Agreement – 1 Jan 2026:** The free trade agreement includes provisions which provides for a review of the agreement between the EU and the UK every five years.

As we look forward from the end of the Transition Period, the Agency remains focused on ensuring we are making both necessary and strategic changes which reflect our position as the stand-alone regulator for the UK. These are driven by both the known trigger points listed above from a regulatory perspective, but also driven by implementing robust strategies that ultimately puts the UK in the best position to have safe supply, as early as possible.

4. **Summary of the practical deliverables of Transition:**

The Transition Programme impacted every area of MHRA requiring co-ordination across all Divisions, NIBSC and with the Department of Health and Social Care. With 14 technical systems going live on 1 January 2021 this was largest single technical deployment the Agency has ever undertaken.

- Technical teams worked up to New Year's Eve and throughout New Year's Day to be ready to take over from the EU systems that were in use up until 11pm on the 31 December 2020.

- Guidance for Industry was also prepared in advance, to ensure webpages were refreshed with the new Guidance on 1 January 2021.

- The Agency began to receive its first submissions via the new systems at approximately 10am on 1 January.

By completing this activity the Agency was able to ensure it could continue to function effectively as the Regulator for the UK, including Northern Ireland under the Northern Ireland Protocol, and that there was no interruption to the supply of medicines or medical devices to patients.

5. **Assessment of impact on supply of medicines and medical devices**

A critical objective of the Transition Programme was to ensure that products will continue to flow to patients.

- The signals to date indicate that pharmaceuticals and devices continue to get to patients throughout the UK with no interruptions for regulatory reasons. We will continue to be vigilant and monitor the situation closely for any issues that might arise.

- We cannot rule out, however, that the end of the transition period will have an impact, including in supply into Northern Ireland, particularly if:

  - Companies decide to revaluate their UK product portfolios and supply chains

  - Companies (including wholesalers) decide that they don't want the unavoidable complexity, which involves more than regulation for which we are responsible, of trading across both UK and EU in NI context.

- There are a number of products currently with live applications in the mutual recognition/decentralised procedure, where the Marketing Authorisation Holder (MAH) is located in Great Britain. This is creating issues for individual companies, as it is not possible for a product to remain in the EU harmonisation procedure with the MAH located in Great Britain. We are working directly with the companies concerned.

6. **Assessment of impact on Agency work:**

- The Transition Task Force supported by the Transition Readiness Group (TRG) has worked to ensure the fundamentals of operational readiness were in place for day 1 across the business areas. The immediate activities have been successfully delivered across all agency divisions.

- 14 major Agency IT systems and process have now been switched over. Based on the initial volumes of activity since 1 Jan 2021, all systems are running as planned.

- Having successfully delivered day 1 readiness for the Agency, there are three critical areas of work remaining to progress;

  (i) work to trouble-shoot any issues that arise in early post-Transition operations
  (ii) immediate challenges to the Agency's operations and
  (iii) longer-term sustainability

- To trouble-shoot practical issues which may arise as a result of the end of the Transition Period, the Transition Task Force will remain in place until at least April 2021 to progress any immediate issues.

- Having secured access to all essential data and information sharing in order to conduct regulatory activity in relation to Northern Ireland, we are now in the process of developing proposals for consideration by the European Medicines Agency to explore opportunities for more substantive information sharing agreements.

- The Agency has successfully managed Transition under its existing structures and operations; in parallel, significant work has been done to build the foundations of wider global joint working. The Terms of Reference for the Transition Programme were specifically set to avoid overlap with the wider Change Strategy. Transition from the EU brings with it major challenges and unknowns: we do not know, for example, to what extent the industry will make use of the option to rely on EU pharmaceutical decisions for the purposes of 'automatic recognition' into GB; we do not know how attracted the devices industry will be to the replacement of CE marks with UK conformity assessment marks.

- Our international joint working will be critical to the attractiveness of the UK for regulatory purposes - as will linkages with other part of the UK system and NHS demand/uptake of products [as has been demonstrated with recent work on COVID]. The Change Strategy now needs to ensure the sustainability of the new Agency operations, particularly those relating to the support for innovation and the regulation of devices.

Medicines & Healthcare products Regulatory Agency

Board Meeting

19th January 2021

What are the plans to introduce a new registration system to improve the oversight of medical devices in the UK?

Issue:

The Board requested a paper explaining how the Agency's plans to develop a register for all medical devices after 1 January 2021 fit with broader developments in the medical device data landscape, including registries to track long-term outcomes for devices and unique device identification.

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

To note the explanation provided about the current capabilities of the device registration system; the further development needed to create a comprehensive GB devices reference data system (Registration/UDI system); and the inter-relationship between this proposed system, the NHS Digital Medical Device Information System (MDIS) and work carried out under the NHSX Medical Device Safety Programme umbrella.

Implications for patients and the public:

The proposed Registration/UDI system – and the associated public-facing aspects of it – will be an important resource for patients and the public. Patients will be able to use the system to look for information about all devices used in the GB health system, using Unique Device Identifiers (UDIs) to identify them.

Which aspect(s) of the Business Plan does this paper address?

The creation of the Registration/UDI system aligns with a number of the Agency's priorities and strategic goals detailed in the 2020-2021 MHRA Business Plan.

Patient, public and health service - The Registration/UDI system will make device identification and safety information more accessible to patients, the public and the health services, through its availability online. (Strategic Goal 1)

Lifecycle and safety management to improve proportionate decision-making in the interests of patients - The Registration/UDI system will improve the range and quality of information on devices that the Agency holds and will enable "state-of the art" surveillance of medical devices. (Strategic Goal 3)

Data Analytics- The Registration/UDI system will be a “unique data asset” to the MHRA which will strengthen the Agency’s post-market and market surveillance activities. (Strategic Goal 4) **Governance and partnerships: reinforced governance, delivery capacity, and external partnership working-** The development of the device reference data system will enhance partnerships with NHS Digital, through the provision of essential reference data for the running of the Medical Device Information System, and with other organisations involved in the usage of medical devices and healthcare data. (Strategic Goal 5)
Author (s): Devices Division
Board Sponsor: John Quinn

Medical devices – registers, registries and Unique Device Identifiers

1. The aim of this paper is to provide an overview of the changes to the registration of medical devices with the Agency from 1 January 2021. It considers how the registration system (Registration/UDI system) can be built upon to create a comprehensive GB devices reference data system and how we envisage that this will be the main source of safety-related reference data for patients and the GB healthcare community including the NHS Digital Medical Device Information System (MDIS).

2. The paper also explains the inter-relationship between the MHRA's plans for product registration and plans to introduce comprehensive registries for implantable medical devices.

Background: the current situation, and changes as from 1 January 2021

3. The current MHRA medical devices registration system captures only Class I, In-Vitro Diagnostics (IVD) and custom-made devices, in accordance with the requirements of the existing EU directives on medical devices. It does not capture Class 2 or Class 3 devices.

4. From 1 January 2021, manufacturers of all classes of medical devices and IVDs will be required to register their devices with the MHRA in the Registration/UDI system. This new requirement will deliver a key source of information to support the MHRA's move to be a standalone regulator, no longer operating as part of the decentralised EU system of regulation. It will give the MHRA knowledge of all devices being sold into Great Britain for the first time, supporting our market surveillance activity and allowing the Agency to take rapid action where safety concerns are identified.

5. The January 2021 system will include significantly more data fields than the current registration system (for further detail see Appendix 1) but not all of the fields will be mandatory without underpinning legislation planned for 1 July 2023. In particular, the submission of Unique Device Identifiers (UDIs) will not be required, though manufacturers will be requested to submit them, if they are able to do so. Further information about UDIs is given in Appendix 2.

6. The Registration/UDI system itself also has limitations. It is a development of the system originally built as part of the European Systems Contingency (ESC) project based on the Appian platform, and it does not deliver the enhanced functionality – most notably the mandatory inclusion of UDIs – which would have been required had the MHRA needed to implement the Medical Devices Regulation 2017/745 (MDR). Other examples of the limited functionality are that only a small subset of information will be available to the public and the system will not support standardised methods for semi-automated data submission.

Future plans

7. In order to support the Agency's ambitious plans for the future of medical device regulation, further work will be required to develop a more comprehensive registration system that will also need to support, from July

2023, an enhanced role for the MHRA in pre-market assessment and approval of medical devices for the GB market.

8. The establishment of a more comprehensive system will allow the Agency to respond to the recommendation made *First Do No Harm (2020)*, which states that "*MHRA should keep a register of all devices approved for the UK market* and that *a public-facing Unique Device Identifier (UDI) database …. should be scoped".*

9. The Medicines and Medical Devices Act, anticipated in early 2021, will provide MHRA with powers to mandate a more comprehensive devices register and to disclose information held in the register to the public. Further discussions will be required on how the registration system can be developed or replaced, taking into account the broader decisions on IT development that the Agency will need to take over the coming weeks and months.

Purpose of the system

10. The Registration/UDI system will serve as a central source of information about all medical devices used in the GB healthcare system. A publicly accessible database (which will be part of the Registration/UDI system) will provide device identification and safety information for patients, healthcare providers and other key sectors of the GB healthcare community, as illustrated in Fig 1:

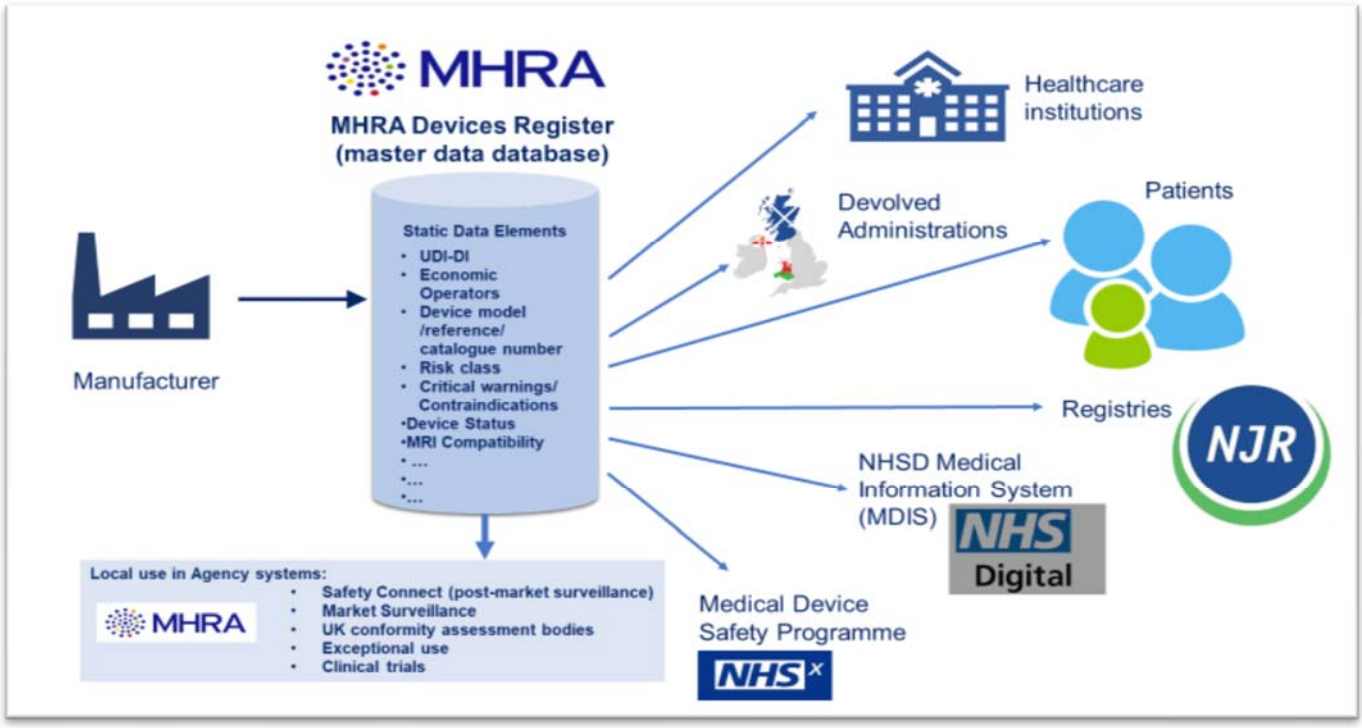

Fig 1. MHRA's device/UDI register provides important reference data for patients, MHRA and external systems and organisations.

Benefits

11. A single and definitive source of reference data about devices used in Great Britain (based on the MHRA Registration/UDI system) will be an invaluable resource to MHRA in its internal regulatory processes and will also benefit patients, health care providers, registries and the wider healthcare community:

12. ***Patients*** – The proposed system will allow patients immediate access to information about medical devices that may be involved in their care so that they can be reassured about safety. Patients will be able to use it to look for information about all devices used in the GB health system using Unique Device Identifiers (UDIs) as the key for identifying them. Patients receiving implants will be given an implant card (which includes UDI information) at the time of implantation. They will be able to interrogate the system for specific information about their device such as whether it contains latex or whether it is safe for them to have an MRI scan if they already have a particular implant; and whether a device is subject to a field safety corrective action.

13. ***MHRA*** – The Agency's information about devices used in the healthcare system is currently incomplete, and the available information is held in siloed systems which do not allow easy cross-referencing. The new Registration/UDI system will be a vital source of reference information for MHRA, and it will underpin future Devices Division and Agency information systems. The capture of comprehensive data on all devices entering the GB market will greatly improve the completeness and quality of the information that the Agency holds. The system will, for the first time, give MHRA a clear picture of all devices are used in the healthcare system. This will strengthen its ability to carry out market surveillance, by allowing the Agency unambiguously to identify devices and their safety characteristics from their UDIs.

14. The Registration/UDI system will be a significant enabler for the MHRA's market surveillance work. In the event of a device recall or safety action, the MHRA will be able to quickly confirm whether a device was legitimately on the GB market, and if necessary, take rapid action to safeguard public health.

15. ***NHS Digital Medical Device Information System (MDIS)*** – In July 2020 the Secretary of State for Health and Social Care directed NHS Digital (NHSD) to establish a comprehensive Medical Device Information System. The system will collect information about all implant procedures carried out in England including the UDIs of devices used (ideally by scanning device barcodes at the time of implantation). The MHRA will provide NHS Digital with reference data derived from the Registration/UDI system which will allow NHS Digital to 'decode' the UDIs recorded in the MDIS. This will facilitate data analysis relating to device safety/performance and will improve the ability of the health services to track-and-trace patients who have been implanted with devices which are subsequently subject to safety alerts or field safety corrective actions, including recall.

    NHSX Medical Device Safety Programme – NHSX is leading the Medical Device Safety Programme which focuses on leveraging data and information across the healthcare system to support patient safety and assurance, clinical improvement and aligned cross-system transformation. MHRA reference data from the Registration/UDI system will be a key component of this programme. Understanding the differences in what they collect/do, compared with the new MHRA system, will be an early next step.

16. ***Registries*** – There are several UK registries, mostly held by medical professional societies, which collect data on devices and procedures.

Currently not all these registries collect full details of implants used, and this limits their ability to provide information about the safety and performance of specific devices. Reference data from the Registration/UDI system will be supplied to registries, allowing them more easily to derive complete and accurate device information using UDI scanning or similar. This will facilitate registry data analysis and the identification of outlier devices (i.e. those models or brands which are performing less well than similar devices). For example, the MHRA has already provided reference data for implantable meshes (based on UDIs) to NHS Digital for the Pelvic Floor Registry pilots which started in August 2020.

17. ***Healthcare institutions*** – Reference data from the Registration/UDI system will support patient safety by enabling healthcare institutions to decode UDIs captured in their patient electronic record systems. This will facilitate patient recalls when safety issues associated with specific implantable devices are identified; and it will also help to determine whether it is safe for a patient to undergo MRI imaging if they have previously received an implant.

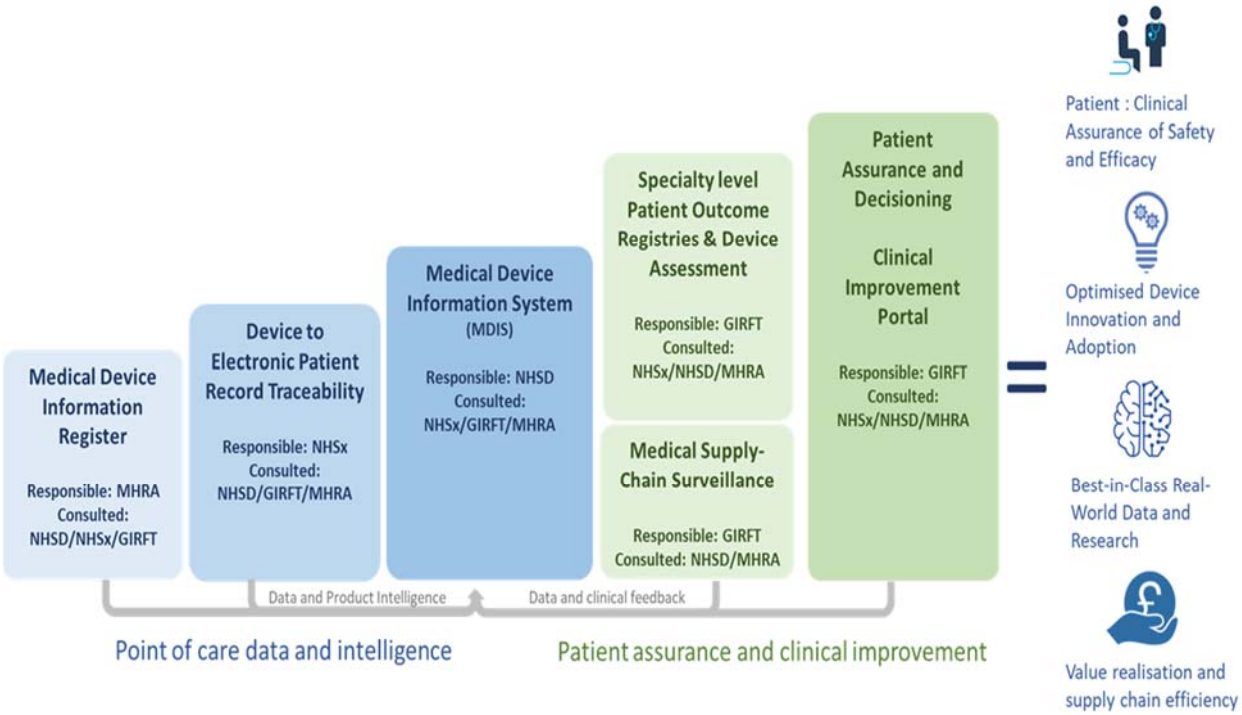

Fig 2. How new and existing systems relate and build new capabilities.

18. ***Devolved Administrations*** – Scotland and Wales are currently developing programmes to use Unique Device Identification to improve patient safety, by recording the UDIs for devices used in the treatment of patients. Reference data from the Registration/UDI system will allow them to derive complete and accurate information about the devices from the UDIs captured.

Conclusion

19. This paper has set out the situation that will be in place on 1 January 2021 regarding registration of devices in Great Britain. It has described how development of the Registration/UDI system will make it fully capable of collecting comprehensive reference data for all medical devices placed on the GB market. Reference data from the Registration/UDI system will make device identification and safety information accessible to patients, the public, and the healthcare community; it will strengthen the MHRA's ability to carry out regulatory oversight and market surveillance of medical devices in the interests of patients safety; and it will enhance the capabilities of the NHS Digital Medical Device Information System and the NHS X Medical Device Safety Programme.

Appendix 1 - Information to be captured in the devices reference data system from January 2021

The system will capture identification and safety information about all medical devices used in the healthcare system including:

- Information which allows all devices to be unambiguously identified i.e. the Unique Device Identifier (UDI-DI), device model details and catalogue/reference number
- Manufacturer details (address/contact details)
- Sterilisation information (supplied sterile/needs sterilisation prior to use/method of sterilisation)
- Medical Device Nomenclature codes/terms – important for safety analysis
- Medical device usage information (single use/reusable)
- critical warnings and contraindications
- MRI safety information
- Key regulatory information -medical device type, risk class
- Device status – whether the device is / has been subject to a Field Safety Corrective Action (FSCA).

This approach aligns closely with similar systems already in place the US (the Global Unique Device Identification Database - GUDID) and planned in Europe (the European UDI/Registration database - Eudamed).

The MHRA system will not contain any information about patients, procedures or how devices have been used. For implantable devices this will be captured in the NHS Digital Medical Device Information System which will use reference data from the MHRA registration/UDI system to 'decode' the UDIs recorded.

Appendix 2 - Unique Device Identification (UDI)

Definition of Unique Device Identification
UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the *unambiguous identification* of a specific medical device on the market.
UDI consist so two components

(i) **Device identifiers** - The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

(ii) **Production identifiers** - The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date.

Note: The MHRA Registration /UDI will collect UDI-DI only as reference data. The NHS Digital Medical Device Information System will collect both UDI-DI and UDI-PI and will use MHRA reference data to 'decode' the UDI-DI element.

Key elements of a UDI system

i. The manufacturer allocates UDI-DI and UDI-PI to all products.
ii. The manufacturer places UDI-DI and UDI-PI on product labels/packaging in both machine readable (barcode etc) and human readable formats.
iii. (MHRA) establishes an electronic system for Unique Device Identification ('UDI database') and manufacturers submit required information to it (this is the MHRA Registration/UDI database).
iv. economic operators, health institutions and healthcare professionals store UDI information (information collated in the NHS Digital Medical Device Information System).

Benefits of UDI
Using a Unique Device Identification (UDI) system based on international guidance should significantly enhance the post-market safety of medical devices by:

- improving incident reporting
- better targeting of recalls
- better monitoring by competent authorities (MHRA)
- reducing medical errors
- fighting against counterfeit devices
- improving purchase-policy and stock-management by hospitals

Medicines & Healthcare products Regulatory Agency

Board Meeting

19th January 2021

WHAT ARE THE SHORT, MEDIUM AND LONG-TERM DELIVERABLES ON THE AGENCY RECOMMENDATIONS FROM THE CUMBERLEGE REVIEW?

Issue: To provide an overview of the short, medium and long-term deliverables on the Agency 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 consider and endorse the short, medium and long-term deliverables on the Agency recommendations from the IMMDS Review.
Implications for patients and the public: The Agency is taking forward a number of deliverables and actions to address the issues that have been highlighted in the Review to improve patient safety and how the Agency listens and responds to concerns.
Which aspect(s) of the Business Plan does this paper address? All, particularly Patients, Public and Health Service
Author (s): IMMDS Review co-ordination group
Board 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 provides a further update on what the MHRA is doing to address the recommendations of the Cumberlege Review, and outlines the short, medium and long-term deliverables.

Background, response to the report and working with others in the healthcare system

3. Recommendation 6 of the IMMDRS 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.*
4. A Written Ministerial Statement providing a progress update to Parliament in response to the Report was published on 11 January.
5. 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.

Overview of deliverables for MHRA in relation to the Review

6. The priority MHRA areas of work fall into the following themes:
    - developing our patient and public engagement and involvement
    - developing a more responsive safety and reporting system
    - improve evidence for patient safety

7. There are a number of deliverables for the Agency in relation to the recommendations from the Cumberlege Review, which are short, medium and long-term, and an overview of these are provided.

Short term deliverables

<u>Patient and public engagement and involvement: publication and delivery of strategy and pilot strengthened engagement</u>

8. The Agency will publish a Public Engagement and Involvement (PPEI) Strategy, which builds on a consultation asking patients how we can best engage and involve them in our work. The Agency's Patient Group Consultative Forum (PGCF) has been engaged through the development of the PPEI Strategy and will continue to be engaged in delivering the Strategy.

9. A current example of the new priority for the MHRA relates to ongoing concerns about the safety of isotretinoin (a treatment for severe acne), we are piloting strengthened PPEI in a review of suspected psychiatric and sexual side effects. On 10 November the Agency launched a 12 week call for information to support the review. Patients and their families, healthcare professionals, researchers and other organisations have been invited to contribute to the review through the call for information and by submitting Yellow Card reports. The call for information has been promoted through direct emails, an article in Drug Safety Update and on social media.

10. All of the responses to the call for information will be considered by the Isotretinoin Expert Working Group and there will be an opportunity for patients and other stakeholders to present their views to the Group. The dates for the next meetings of the Isotretinoin Expert Working Group have not yet been finalised but are anticipated to be in April or May. The Agency has committed to providing patients and stakeholder who may attend the Expert Working Group Meeting with a preparatory meeting to ensure they are supported and familiar with the process.

Antiepileptic drugs (AEDs) review and impact on switching from valproate

11. In order to help support informed decision making when initiating and reviewing anti-epileptic treatment options for girls and women, and when switching from valproate, the Commission on Human Medicines (CHM) has reviewed the safety of use of other antiepileptic drugs (AEDs) during pregnancy. The review has concluded that lamotrigine and levetiracetam are safer to use and that some other AEDs may also be associated with harms to the child, although not to such a severe extent as valproate.

12. The CHM advice has been communicated through our Drug Safety Update bulletin and a public assessment report and will also be accompanied by a Patient Safety Leaflet that provides the information in a more patient friendly manner. The communication materials, which aim to support discussions between women and healthcare professionals and aid joint decision making, have been developed with input from relevant stakeholders including representatives from epilepsy charities and relevant patient groups. NICE will include this information in their existing epilepsies guidance. The impact of the review and updated guidance will be carefully monitored together with the effectiveness of communication as it is likely that repeated messaging will be required.

Strengthening leadership accountability and board assurance

13. The Agency is strengthening leadership and board assurance, with the recruitment of a new Chief Safety Officer and the establishment of a new Patient Safety and Engagement Committee. The Patient Safety and Engagement Committee is a new assurance committee of the Board which will include two lay members.

14. The new Chief Safety Officer will lead the implementation of the recommendations from the Cumberlege Review and will be overseeing the development of a revitalised approach to vigilance of both medicines and medical devices.

15. The purpose of the Patient Safety and Engagement Committee is to provide independent consideration of patient safety and patient engagement, such that these are paramount in regulatory decision-making at the MHRA, and to advise the Board accordingly. The Committee's specific duties and responsibilities are to:

    a) Monitor and advise the Board on aspects of patient safety in the Agency's procedures for its initial assessments of medicines, medical devices and blood products, the continued surveillance of their use, and its processes for dealing with information derived from surveillance such that patient safety is the primary priority and there is a culture of continuous, iterative improvement.

    b) To consider, and advise the Board on all aspects of the ways in which the Agency engages with patients and with the public, such that patient views are consistently considered in regulatory decision-making; the Agency is responsive to the needs of patients and their concepts of risks and benefits, in its consideration of patient safety; and processes are in place to encourage and acquire information from patients, and to inform them, at all stages of the Agency's regulation of medicines, medical devices and blood products.

The Committee will comprise a minimum of three Non-Executive Directors of the MHRA, one of whom will be appointed as Chair of the Committee and three Executive Directors (ie Chief Scientific Officer, Chief Safety Officer and Chief Quality & Access Officer). Two lay members will also be appointed on the Committee in line with the recruitment principles of the Agency's Expert Committees.

Medium term deliverables

Responsive ADR system which enables greater interaction with reporters

16. The Agency's SafetyConnect programme of work, to introduce 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, is continuing. 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. We are also continuing to engage with the public directly in gaining user feedback and perceptions on the SafetyConnect programme of work through user needs sessions and the feedback gathered through these sessions is being used to help ensure requirements of the new system are met.

17. Work on overhauling the Yellow Card reporting platform has already begun. New technologies have been introduced for the reporting of adverse events for products used to treat Coronavirus as well as vaccines and our COVID-19 vaccine active surveillance system has been developed in addition to the implementation of new analytical methodologies and enhanced use of the Clinical Practice Research Datalink (CPRD).

18. In December we deployed a new Artificial Intelligence (AI) tool to support our processing of suspected adverse reactions received through the Coronavirus Yellow Card reporting site and Yellow Card App. The AI tool uses natural language processing so that the free text information provided by patients and healthcare professionals in their Yellow Card reports can be automatically coded and processed more efficiently. This reduction in manual effort will help support the availability of these reports for rapid review and analysis. Later deployments will follow in January and February to update the AI models that have been trained on MHRA data.

19. A common improved technology platform for incident management and signal detection for medicines and devices is nearing the end of a tender exercise using the OJEU (Official Journal of the European Union) process. Five bids are being evaluated and we expected to contract with the successful bidder in March following a period of negotiation.

Better evidence – registries and new data linkages

20. In 2018, the NHS 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 program 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 continuing to be held by NHSX with the main stakeholders, including MHRA. The introduction of mandatory registration for all medical devices coming onto the GB market from 1 January is a key first step towards building a key underpinning dataset to support the Agency's safety and surveillance work.

21. Work is progressing on developing an antiepileptics registry. NHSD have led development of the core registry for valproate, linking together and analysing England-wide data sets to establish the full cohort of women currently or recently prescribed valproate and to identify all pregnancies exposed. A report from this first stage of the registry will be available shortly.

22. Within the MHRA's work to strengthen the evidence base, the safety of medicines in pregnancy is of utmost importance. In the UK, three-quarters of a million babies are born each year, and more than half of expectant mothers will need to take medicines when pregnant. We must ensure that women have high-quality, accessible information to be able to make informed decisions about their healthcare.

23. A CHM 'Expert Working Group on Optimising Data on Medicines used during Pregnancy' has delivered a report on how to make best use of real-world data on medicines exposure during pregnancy and breastfeeding 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 comprised key data holders and included 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 a patient representative. The Group has developed a set of recommendations with the goal of improving data collection, quality and access via enhanced capture of information and linkage of databases. The report and recommendations of the Group were launched in January, coinciding with the Minister's update.

24. We have established The *Safer Medicines in Pregnancy and Breastfeeding Consortium* which brings together 16 leading organisations under a common pledge to meet the information needs of women and healthcare professionals, through accessible, clear and consistent advice. Its strategy was also launched at the same time as the Minister's statement. The group is now delivering a long-term programme of work to improve information provision on medicines for women who are thinking about becoming pregnant, are pregnant, or are breastfeeding.

25. A programme of work is underway to review and update the risk minimisation approach for key teratogens. A review of teratogenic products and current restrictions on use is currently ongoing. Once this review is completed, early patient and stakeholder consultation will be sought on levels of teratogenic risk and to develop guidance on appropriate risk minimisation for these taking into consideration clinical use and need for treatment. Input will also be sought from patients and stakeholders, plus expert advice on communicating these including development of new risk minimisation materials, if needed.

26. To support better evidence generation to enable safer use of medicines in pregnancy and breast-feeding, MHRA is working with EMA and FDA to develop a co-ordinated strategy for the regulatory requirements and guidance to industry on the evidence to be collected throughout a product's lifecycle. An initial workshop was held at MHRA in January 2020 and a report of the meeting has been submitted to *Clinical Pharmacology and Therapeutics* for publication. A full report of the meeting will be published on the Agencies' websites to coincide with publication. Awareness of the strategy amongst MHRA staff will be raised via training. MHRA is also working with other stakeholders in a number of initiatives to improve the evidence base.

<u>Patients feel listened to and their views acted on</u>

27. The Agency will carry out a further survey to measure whether there is an improvement in the way that patients feel listened to and whether their views have been acted on.

Long term deliverables

Revision of legal frameworks with particular focus on medical devices

28. 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 expected to progress swiftly through January. House of Lords Report stage commenced on 12 January, where debate will focus on amendments tabled by Peers, this includes Redress, and Government amendments. Government amendments include powers to establish a statutory advisory committee for devices and to deliver on a central recommendation of the Report to establish an independent Patient Safety Commissioner. If the Bill progresses through the remaining stages at minimal intervals, Royal Assent could be reached by early February. We will then have the powers necessary to move forward actions requiring legislative change. For example, the Bill enables increased transparency about the data we hold on medical devices and a new devices enforcement framework.
29. UK will unilaterally accept CE marked medical devices until 30 June 2023. Now that we have left the Transition Period with the EU, we now have the opportunity to develop a more transparent, robust, world-leading regulatory regime for medical devices that prioritises patient safety, while ensuring the UK remains an attractive place to market devices. This will be enabled through the powers created through the Medicines and Medical Devices Bill.
30. As part of the development of this new regime for medical devices and IVDs, we are taking into consideration international standards and global harmonisation. We have begun our engagement with stakeholders within the life sciences and healthcare sectors on this proposed regime. As part of these discussions, we are identifying and prioritising elements of international practice that promote public health and patient safety. This will be followed by a formal public consultation later in 2021, with the aim of delivering an attractive world-class regulatory system.

Patients actively involved in regulatory decision-making processes

31. We are considering and developing ways to improve and ensure that patients are actively involved in the regulatory decision-making processes. Some of the current examples can be seen below:

    - A Patient Engagement tool is being developed as part of Innovative Licensing & Access Pathway
    - Standard wording on patient engagement added to staff objectives and work templates to ensure assessment staff consider patient perspective in their work and decision-making
    - Exploring scope for patient representatives (as distinct from lay members) to be recruited to all Commission on Human Medicines (CHM) expert committees
    - The Clinical Trials Unit is now actively looking for evidence of Sponsors' patient engagement during the development and implementation of clinical trials whilst assessing their suitability for regulatory approval. Companies are therefore encouraged to undertake a more explicit consideration of patient outcomes and engagement to help maximise the clinical benefit of trial outcomes that are meaningful to patients

- Safety & Surveillance team in the Devices Division are developing and implementing new approaches to ensure patient involvement in their decision-making process. Developments include:

    - Devices Patient Panel
    - Person specification for the patient reps on Expert Advisory Groups (EAGs), ensure that we are including patients when we set up new EAGs
    - Signal Risk Messaging (SRM) meeting to include patients. Pilot planned from April to ensure patients are involved in all aspects of our post-market decision making
    - Shared Decision Making – decision aids for high risk devices
    - Research into patient and public perceptions of risk
    - Longer term divisional plans include exploring options for patient involvement in pre-market e.g. clinical investigations, exceptional use authorisations

Actions for the Board

32. The Board is asked to consider and endorse the Agency's short, medium and long-term deliverables in response to the Review recommendations.

January 2021

Medicines & Healthcare products Regulatory Agency

Board Meeting

19 January 2021

What are the final proposed Terms of Reference for the three new Board Assurance Committees?

Issue:

There is a need for the Board to approve the final proposed Terms of Reference of the new Board Assurance Committees after the Board agreed to their establishment in October 2020 and agreed their membership in November 2020. The Board also considered the draft Terms of Reference for these committees at a Board Seminar in December 2020.

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

The Board is asked to approve the final proposed Terms of Reference for the:

- Audit and Risk Assurance Committee
- Patient Safety and Engagement Committee
- Organisational Development and Remuneration Committee

Implications for patients and the public:

The Patient Safety and Engagement Committee will provide assurance to the Board that the Agency has the necessary systems, controls and governance to enable patient engagement and patient involvement in the discharge of its statutory responsibilities on patient safety.

The Audit and Risk Assurance Committee will provide assurance to the Board that the Agency has the necessary systems, controls and governance to manage risk and discharge its financial responsibilities in line with public sector requirements.

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?

Authors and Board Sponsors:

Michael Whitehouse, Mercy Jeyasingham and Anne-Toni Rodgers

Medicines and Healthcare products Regulatory Agency

Audit and Risk Assurance Committee

Terms of Reference

1. The purpose of the Audit and Risk Committee is to provide an independent and objective view of governance and internal control at the Medicines and Healthcare products Regulatory Agency (MHRA) and to advise the Board accordingly.

2. The Committee's duties are 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;

   - 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;

   - Highlighting to the Board and Executive any issues arising from assurance work which have the potential to improve the Agency's performance and delivery of its objectives.

3. To meet these responsibilities the Committee will:

   - review the Corporate Risk Register and the management actions to mitigate the risks each quarter;

   - review quarterly financial reports and the management actions to ensure the financial sustainability of the Agency;

   - review the raising and investigation of concerns (whistle blowing);

   - seek assurance on the adequacy of the Agency's arrangements to prevent fraud;

   - approve the internal and external audit work plans and review performance against those plans;

   - consider the appointment and dismissal of the internal auditor within the authority delegated to the MHRA; and

   - periodically review its own effectiveness and report the results to the Board.

4. The Committee will recommend to the Board approval of MHRA's annual report and accounts.

5. The Committee will formally report annually to the Board on the outcome of its work on the effectiveness of the MHRA's governance and internal controls.

6. In order to meet its duties and responsibilities, the Committee is authorised by the Board to:

    - seek any information it requires from any employee; and
    - obtain outside legal or other professional advice if required.

Membership

7. The Committee will comprise a minimum of three Non-Executive Directors of the MHRA, one of whom will be appointed as Chair of the Committee.

8. In addition, three Executive Committee members of the MHRA will be standing invitees who attend the Committee's meetings:

    - the Chief Executive Officer;
    - the Chief Operating Officer; and
    - the Chief Technology Officer.

9. The independence of the Committee will be further maintained by the Non-Executive Chair having casting vote where consensus cannot be reached. Before a decision to move to a vote is made, the Chair will in all cases consider whether continuing the discussion at a subsequent meeting is likely to lead to a consensus.

10. Committee members shall comply with the Committee's Terms of Reference, which set out the scope of the Committee's work and its authority.

11. Other directors and staff shall be invited at the discretion of the Committee when matters relating to their area of responsibility are being discussed.

Quorum

12. The quorum is set at two Non-Executive Members. No business shall be transacted unless the meeting is quorate with the attendance of at least two Executive Committee standing invitees. If the Chair cannot attend, he/she will delegate the casting vote to a Non-Executive Member in the event that a consensus cannot be reached.

Arrangements for meetings

13. All members must make a declaration of any potential conflicts of interests that may require their withdrawal in advance of each meeting.

14. The Committee shall meet a minimum of five times a year. Four meetings in January / February, May, June and November will cover standing items. The meeting in June will focus primarily on reviewing the annual report and financial statements. A fifth meeting will address current issues of more immediate strategic relevance or priority to the Agency's business requiring additional assurance.

15. The Committee shall meet in private session with the internal and external auditors respectively, to consider matters of internal control or any other matter within its Terms of Reference.

16. No other business shall be discussed at the meeting except at the discretion of the Chair.

Minutes

17. The minutes of the Committee shall be formally recorded and submitted to the next meeting for approval. Once approved, the minutes shall be submitted to the Board.

18. Additionally, immediately after each Committee meeting, the Chair shall produce a short summary of proceedings for the next meeting of the Board. The Chair of the Committee shall draw to the attention of the Board any issues that require disclosure to the full Board, or that require executive action.

19. Minutes will be published on the MHRA website subject to the redaction of any confidential or otherwise exempt material

Other matters

20. The Corporate Governance team will provide support to the meetings.

21. The internal and external auditors shall have direct access to the Chair.

22. These Terms of Reference will be reviewed annually. The next review date is February 2022.

(December 2020 v0.2)

Medicines and Healthcare products Regulatory Agency

Patient Safety and Engagement Committee

Terms of Reference

Terms of Reference (ToR)

1. The purpose of the Patient Safety and Engagement Committee is to provide independent consideration of patient safety and patient engagement, such that these are paramount in regulatory decision-making (including decisions about safety signals, from surveillance) at the Medicines and Healthcare products Regulatory Agency (MHRA), and to advise the Board accordingly.

2. The Committee's duties and responsibilities are to:

   a) Monitor and advise the Board on aspects of patient safety in the Agency's procedures for its initial assessments of medicines, medical devices and blood products, the continued surveillance of their use, and its processes for dealing with information derived from surveillance such that:
      i. Patient safety is the primary priority.
      ii. There is a culture of continuous, iterative improvement.

   b) To consider, and advise the Board on all aspects of the ways in which the Agency engages with patients and with the public, such that:
      i. Patient views are consistently considered in regulatory decision-making
      ii. The Agency is responsive to the needs of patients and their concepts of risks and benefits, in its consideration of patient safety.
      iii. Processes are in place to encourage and acquire information from patients, and to inform them, at all stages of the Agency's regulation of medicines, medical devices and blood products.

   c) Make recommendations to the Audit and Risk Assurance Committee concerning the internal audit programme, to the extent that it applies to matters within this ToR.

   d) Periodically review its own effectiveness and report the results to the Board.

3. To meet these responsibilities the Committee will:

   - Scrutinise the processes, systems and structures within the Agency to ensure that patient safety is paramount in regulation;

   - Scrutinise the processes, systems and structures within the Agency to ensure that patient and public engagement is utilised throughout regulation – including the initial assessment of medicines, medical devices and blood products, surveillance of their use, and decisions made as a result of possible safety signals.

- Consider ways in which engagement with patients and the public can be maximised; and their concepts of risk and benefit can be incorporated into regulatory decision-making.

- Provide challenge to the Executive on aspects of the regulatory systems that could be modified to improve patient safety and patient engagement.

- Provide 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, in the interests of patient safety.

- Review the Risk Register regarding patient safety, patient and public engagement, and report concerns to ARAC.

4. The Committee will formally report annually to the Board on the assurance it can provide on the effectiveness of patient safety as well as patient and public engagement.

   Additionally, immediately after each Committee meeting, the Chair shall produce a short summary of proceedings for the next meeting of the Board. The Chair of the Committee shall draw to the attention of the Board any issues that require disclosure to the full Board, or that require executive action.

5. In order to meet its duties and responsibilities the Committee is authorised by the Board to:
   . seek any information it requires from any MHRA employee.

   . obtain outside legal or other professional advice if required.

Membership

6. The Committee will comprise a minimum of three Non-Executive Directors of the MHRA, one of whom will be appointed as Chair of the Committee. Three Executive Directors will also be members of this committee and are expected to attend all committee meetings:
   - Chief Scientific Officer
   - Chief Safety Officer
   - Chief Quality and Access Officer

7. The Committee will operate in accordance with the unitary status of the Agency Board by taking a collaborative approach, utilising constructive challenge, to fulfil the purpose and responsibilities set out above.

8. The independence of the Committee will be further maintained by the Non- Executive Chair having a casting vote where consensus cannot be reached, and a vote is required. Before a decision to move to a vote is made, the Chair will in all cases consider whether continuing the discussion at a subsequent meeting is likely to lead to a consensus.

9. The Committee will appoint specialist independent representatives (lay members) who will hold non-voting positions on the Committee, to supplement its range of skills and experience. Two lay members will be appointed in line with the recruitment principles of the Agency's Expert Committees.

10. Committee members shall comply with the Committee's Terms of Reference, which set out the scope of the Committee's work and its authority.

11. Other directors and staff shall be invited at the discretion of the Committee when matters relating to their areas of responsibility are being discussed.

Quorum

12. The quorum of the committee will be four members, including at least two Non-Executive members and at least two Executive members.

13. Deputies will only be permitted in exceptional circumstances, with prior, written agreement from the Chair. When appointed, deputies will have the same Committee rights and responsibilities as non-deputies.

14. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any decisions made will be non-binding and will require subsequent ratification from a quorate meeting.

    A decision put to a vote at a quorate Committee meeting will be determined by a simple majority of voting members and deputies present. In the case of an equal vote, the Chair of the Committee at that meeting will cast a second, deciding vote.

Arrangements for meetings

Frequency of Meetings

15. The Committee will normally meet every two months and otherwise as the Chair of the Committee deems necessary.

Secretariat

16. The Committee Secretariat will be responsible for:
    - Preparing the agenda in consultation with the Chair;
    - Commissioning Committee papers;
    - Circulating Committee papers to members and invitees, normally five working days before each meeting;
    - Documenting the outcome of all votes taken in the Committee meeting minutes;
    - Producing and circulating draft minutes of the Committee meetings to members, normally ten working days after each meeting; And
    - Maintaining an action log.

Minutes

17. Minutes of the committee will be provided to the Agency Board for information, consideration and, where relevant, action. The minutes of committee will be made available on the Agency's web page on GOV.UK.

Review of these Terms of Reference

18. The Committee will review its ToR at least annually. Amendments to the Terms of Reference will be subject to review and approval by the Board.

Medicines and Healthcare products Regulatory Agency

Organisational Development and Remuneration Committee

Terms of Reference

1. Purpose

1.1. The purpose of the Organisational Development and Remuneration Committee is to provide independent and objective advice to the Agency Board and the Chief Executive on their responsibilities relating to workforce planning, development and rewards at the Medicines and Healthcare products Regulatory Agency (MHRA).

2. Responsibilities

2.1. **The Committee's duties and responsibilities are to:**

- Scrutinise the processes, systems and structures in place within the Agency to attract, retain, and develop staff capabilities & talent in a changing environment.
- Provide challenge to the Executive on the development and implementation of the People Strategy.
- Provide assurance to the Board that the Agency has appropriate culture and procedures in place for managing and developing its workforce capabilities and delivering change.
- Provide a formal and transparent process for determining Executive remuneration.

2.2. **The role of the Committee Chair is to:**

- ensure a high standard of discussion;
- facilitate collective working;
- facilitate Committee meetings and uphold other agreed ways of working;
- agree a Forward Look of meeting agendas and clear papers, with Secretariat support;
- ensure line of sight between the Committee and Agency Board; and
- ensure that a Committee effectiveness evaluation is carried out annually, and that results are acted upon.

2.3. **The role of the Non-Executive members of the committee:**

- use their experience and skills from outside the Agency to provide constructive, effective and objective challenge to officials;
- provide an independent perspective and assurance;
- give support, advice and challenge on the progress and implications of policy proposals and Agency operational issues.

2.4. **The role of Executive Team members is to**:

- represent the Agency;
- input into collective decision-making on matters under the remit of the Committee;
- provide in-depth knowledge and expertise of the Agency in order to raise issues for discussion at the appropriate time;
- ensure line of sight between the Committee and the Executive

3. Composition

3.1. The Committee will be comprised of the following:

- NED (Chair)
- NED Member
- NED Member
- Chief Executive Officer
- Chief Operating Officer
- Director of Human Resources

4. Membership

4.1. All meetings will be chaired by the NED Chair. In the absence of the Chair, one of the two other NED members will chair the meeting by agreement with the Chair.
4.2. Any changes to the membership of the Committee must be approved by the Chair of the Board and subsequently ratified by the Board.

5. Quorum

5.1. Quorum will consist of four members with at least two Executive members and at least two NED members present.
5.2. If a meeting is not quorate it may still proceed, with agreement from a majority of Committee members (including those not in attendance). In such circumstances, any decisions made will be non-binding and will require subsequent ratification from a quorate meeting.
5.3. A decision put to a vote at a quorate Committee meeting will be determined by a simple majority of voting members. In the case of an equal vote, the Chair of the Committee at that meeting will cast a second, deciding vote.

6. Sub Committees

6.1. The related executive committee of the Agency is the People and Culture committee. This committee will draw upon their work as a source of assurance for the matters within its scope (see Section 1 above).
6.2. The Committee may, subject to the approval of the Board, establish sub committees to carry out specific aspects of Committee business, on its behalf.

7. Frequency of Meetings

7.1. The Committee will meet quarterly taking account of the Agency's cycle for talent management and remuneration processes. Additional meetings may be called, or meetings postponed if circumstances warrant.

8. Attendance

8.1. Other individuals may be invited to attend for all or part of any meeting for a specific agenda item.
8.2. Such members of staff and other persons as the Chair may require depending on the business of the meeting.

9. Secretariat

9.1. The Committee Secretariat will be responsible for:

- Preparing the agenda in consultation with the Chair;
- Commissioning Committee papers;
- Circulating Committee papers to members and invitees, normally at least five working days before each meeting;
- Documenting the outcome of all votes taken in the Committee meeting minutes;
- Producing and circulating draft minutes of the Committee meetings to members, normally ten working days after each meeting; And
- Maintaining an action log.

10. Delegated Authority

10.1. The Board authorises the Committee to investigate or have investigated any activity in-line with its responsibilities, as set out in the Terms of Reference. In doing so, the Committee can rightfully inspect any documents, ensuring that data, confidentiality and security are maintained and all relevant policies adhered to. It may seek relevant information from any employee other committee, subcommittee or Group set up by the Board to assist it in the delivery of its functions.

11. Reporting to the Board

11.1 The Committee will formally report annually to the Board on the outcome of its work.

11.2 Once approved, the minutes of the Committee shall be submitted to the Board.

11.3 Additionally, immediately after each Committee meeting, the Chair shall produce a short summary of proceedings for the next meeting of the Board. The Chair of the Committee shall draw to the attention of the Board any issues that require disclosure to the full Board, or that require executive action

12. Review of these Terms of Reference

12.1. The Committee will review its Terms of Reference at least annually. Amendments to the terms of reference will be subject to review and approval by the Agency Board.

12.2. The Committee effectiveness evaluation process is based on guidance for Departmental Boards contained in Chapter 3 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609668/PU2076_corporate_governance_guidance.pdf