



Medicines & Healthcare products Regulatory Agency

Minutes (final)

CET/20/153

Title of meeting	Corporate Executive Team formal monthly meeting
Date	07 April 2020
Time	09.00 – 13.00
Venue	Videoconference
Chair	June Raine
Attendees	CET
Apologies	Jon Fundrey

CET Attendees

June Raine	Interim Chief Executive Officer (Chair)
Boryana Stambolova	Deputising for the Chief Operating Officer
Rachel Bosworth	Director of Communications
Vanessa Birchall-Scott	Director of Human Resources
Samantha Atkinson	Director of Inspection, Enforcement and Standards
Janet Valentine	Director of the Clinical Practice Research Datalink
Siu Ping Lam	Director of Licensing
Sarah Branch	Interim Director of Vigilance and Risk Management of Medicines
Christian Schneider	Director, National Institute for Biological Standards & Control
Graeme Tunbridge	Interim Director of Devices
John Quinn	Director of Transformation
Jonathan Mogford	Director of Policy

Additional Attendees

██████████ for item 5: Transition Taskforce update
Keith McDonald (Licensing) for items 6: and National MA applications during the transition period, and 7: EAMS-COVID-19
Patience Wilson (Policy) for item 9: MHRA/NICE joint work ToR and initial priorities
██████████ for items 11: Regulatory Science update and 12: IMMDSR update
██████████ for item 13: AI
██████████ for item 14: Proposed changes to the oversight of blood safety and quality
██████████ for item 15: Breckenridge Lecture planning progress
██████████ for item 16: Patient and Public Engagement update
██████████ for item 18: Talent and Learning update
██████████ for item 19: People Survey
██████████ for all items.
██████████ staff observer, for all items except item 14: CET/20/110 Proposed changes to oversight of blood safety and quality

1. Apologies and Announcements

1.1 Apologies were received from Jon Fundrey and Elizabeth O'Neill.

2. Draft minutes of the 03 March CET meeting (CET/20/096) including table of actions and final minutes of the 04 February CET meeting (CET/20/097)

2.1 The draft minutes of the 03 March meeting were reviewed, with the CET adding some minor comments. The CET reviewed and provided updates on the table of actions. The final minutes of the 04 February CET meeting were noted.

STRATEGY

3. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4.1 [REDACTED]

[REDACTED]

[Redacted]

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[REDACTED]

[REDACTED]

8. MHRA / NICE joint work (CET/20/103)

8.1 Patience Wilson presented a paper on priorities for joint working between the National Institute of Health and Care Excellence (NICE) and the Agency, further to the paper discussed at the December 2019 CET meeting. The CET noted that a core group to steer joint working has been established, with the support of the Chief Executives of both organisations. Terms of reference, membership, and proposed priorities for the group’s work. The CET noted that in response to the current unprecedented challenge to public health from COVID-19, the proposition is that the first priority for joint working should be to develop integrated MHRA and NICE arrangements for the expedited clinical use of COVID-19 medicines.

8.2 The CET noted the update and commented that this is a vital area of work which the MHRA must take forward. CET commented that under the COVID-19 workstream MHRA should highlight repurposing of existing medicines as well as new medicines coming through the system. The CET endorsed the Terms of Reference, membership and priorities. This will be presented to the Board.

9. Operational Transformation – Portfolio Delivery (CET/20/104)

9.1 John Quinn presented an update on the Operational Transformation (OT) portfolio delivery. The CET noted that a 6-week impact assessment is underway against the new business strategy and business plan targets which includes an assessment of governance, project performance, and of a review of the technical architecture roadmap. The CET noted that the previously forecasted shortfall in benefits for the current financial year remains and will not be resolved without an update to the transformation programme business case; the OT portfolio status therefore remains at red. The CET noted that the focus for delivery remains on the three OT priority workstreams – Corporate, Customer, and Safety & Surveillance. It

was noted that a large amount of infrastructure work is underway; staff will be informed of any outages due to infrastructure updates.

9.2 The CET noted that a number of project managers are deployed across all areas; a number of these project managers have been redeployed temporarily to work on COVID-19 priorities. A workshop will be run with the CET to consider the future shape of OT, through discussion around priorities. The CET noted the impact statement and the benefits shortfall estimation; and noted that the team have been working exceptionally hard in difficult circumstances. CET agreed that it is vital to speed up delivery and prioritise the ongoing projects, and that this is likely to be a complicated piece of work. The CET agreed that the Agency should look to the change strategy with OT as an enabler. The CET also noted that it is important that CET makes decisions regarding which projects will be taken forward and funded; as there must be capacity available to execute these projects. The CET noted the update.

10. Regulatory Science Update (CET/20/105)

10.1 [REDACTED] presented an update on current activities relating to developing Regulatory Science, since the paper present dot the CET in January 2020. The CET noted that since the previous update, the EMA have published their Regulatory Science Strategy.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

10.2 [REDACTED]
[REDACTED]
[REDACTED] The aim is to develop a new set of Good Clinical Practice (GCP) guidelines for clinical trials. It was also noted that the business model for innovation regulatory science work will need to be carefully considered. The CET noted the update and agreed to the proposal to set up an advisory group to create a UK Regulatory Science Network and to help inform the development of regulatory science as part of the Agency's overarching Science Strategy. A further update will be presented to CET in August 2020.

Action: Set up an advisory group to create a UK Regulatory Science Network and to help inform the development of regulatory science as part of the Agency's overarching Science Strategy. Present a further update to CET in August 2020.

11. Independent Medicines and Medical Devices Safety (IMMDS) Review (CET/20/106)

11.1 [REDACTED] [REDACTED] presented an update on activities in response to the likely recommendations of the Independent Medicines and Medical Devices Safety (IMMDS) Review. The CET noted that the Report of the IMMDS Review publication has been postponed from 24th March 2020 due to COVID-19 and at present no publication date has been set. MHRA are continuing to take forward work and implement actions in response to the emerging issues from the Review, to improve safety and better support patients. The CET noted that a paper is being prepared for the May CHM meeting on a full range of options regarding valproate. Communications have been prepared for when the report is published. The CET commented that the Patient Group Consultative Forum (PGCF) should be consulted on the Agency's activities in response to the IMMDSR.

Action: Consult the PGCF on MHRA's activities in response to the IMMDSR.

12. Artificial Intelligence (AI) (CET/20/109)

12.1 [REDACTED]

12.2 [REDACTED]

The CET noted that an MHRA AI working group has been established to explore shared learning and synergies across the Agency’s AI initiatives. The CET commented that it is vital the Agency receives funding for these important pieces of work. The achievement in developing a synthetic dataset to regulate AI should be promoted as an important asset of the Agency; this should be used to facilitate this work and additionally to generate income.

[REDACTED]

[REDACTED]

[REDACTED]

GOVERNANCE AND DELIVERY

14. Breckenridge Lecture planning progress (CET/20/111)

14.1 [REDACTED] presented an update on progress with planning the Agency’s Annual Lecture. The CET noted that [REDACTED] office have formally indicated that he will be pleased to accept the invitation to give the agency’s Breckenridge Lecture (the 2020 annual lecture). A date of Thursday 8 October 2020 has been confirmed with [REDACTED] MHRA are keen for the event to go ahead but have not yet booked [REDACTED] due to pandemic crisis. A further stock take of the situation will be undertaken after Easter and discuss with [REDACTED] in late April. The CET noted the update and commented that during the panel discussion, more reflection on the work of the Agency should be included.

15. Patient and Public Engagement Strategy Update (CET/20/112)

15.1 ██████████ presented an update on the Patient and Public Engagement (PPE) strategy. CET noted that at present the government's focus is on COVID-19; MHRA are therefore in conversation with the DHSC Comms team about timings on publication of the report of the consultation findings given the current focus on COVID-19. MHRA continues to take forward as many of the actions identified in the consultation as possible. CET noted the update.

16. Talent and Learning Update (CET/20/114)

16.1 ██████████ presented an update on Talent and Learning. The CET noted the key activities and outcomes from 2019/20. The CET noted training for high potential G7 and SCS1 staff; which had positive evaluation feedback. An internal leadership development programme was launched for the top 120 G6 and G7 staff; in the form of workshops, coaching and lectures. Talent workshops were run for 72 staff between AO and EO, and 96 HEO and SEO staff. There was a 50% rise in applications for the future leaders scheme. MHRA continues to support postgraduate training; over 2000 days of technical training were recorded by staff. Monthly careers pathways slots were set up with an accredited coach; take up of these was successful.

16.2 On learning and development, training has become more and more targeted. The Transformation Academy was launched which is proving successful. This training includes management and leadership training and managing outcomes of change. The CET reviewed the plans and proposals for talent and learning during 2020/21. A significant expansion of the transformation academy is planned; and there is increased targeting of staff in change related roles. Increased professional support is planned from the central learning and development team; CET also noted a proposal for each division or centre to appoint an SMT member with lead responsibility for Learning and Development, who will liaise with training coordinators, which the CET agreed. An action was also taken to publicise this work on INsite.

Action: SMT members to be nominated from divisions; INsite update to be published.

17. People Survey (CET/20/115)

17.1 ██████████ presented an update on the 2019 People Survey. CET noted that divisions/centres have been working on their final action plans and the Agency-wide plan; CET reviewed the divisional plans and endorsed these. CET endorsed the Agency-wide action plan on Resilience and Wellbeing; HR will take this forward. The CET noted the free text comments – these have been analysed by theme and recommendations made to address these themes. The CET agreed that the current format of office working in 10SC will be reviewed once the COVID-19 crisis is over. The CET noted that a business case is being prepared for the 10th floor restack; this will be given more thought given the COVID-19 crisis.

INFORMATION

18. NIBSC monthly update for March and April (CET/20/116)

18.1 The CET noted the NIBSC monthly update for March and April 2020.

19. Final minutes of the January 2020 Regulatory Group meeting (CET/20/084)

19.1 The CET noted the final minutes of the February 2020 Regulatory Group meeting.

20. Updates from Cross-Agency teams

Governance Board
Portfolio Governance Board decisions
Risk and Audit Liaison Group

CET/20/118
CET/20/119
CET/20/123

21. Agreement of 05 May 2020 CET agenda (CET/20/125)

21.1 The CET reviewed and provided comments on the 05 May 2020 draft CET agenda.

22. AOB