



Medicines & Healthcare products Regulatory Agency

Minutes (final)

CET/20/205

Title of meeting	Corporate Executive Team formal monthly meeting
Date	02 June 2020
Time	09.00 – 13.30, 14.30 – 16.30
Venue	Videoconference
Chair	June Raine
Attendees	CET
Apologies	Jon Fundrey

CET Attendees

June Raine	Interim Chief Executive Officer (Chair)
Christian Schneider	Director, National Institute for Biological Standards & Control
Vanessa Birchall-Scott	Director of Human Resources
Siu Ping Lam	Director of Licensing
Rachel Bosworth	Director of Communications
Janet Valentine	Director of the Clinical Practice Research Datalink
Boryana Stambolova	Deputising for the Chief Operating Officer
Graeme Tunbridge	Interim Director of Devices
Samantha Atkinson	Director of Inspection, Enforcement and Standards
Sarah Branch	Interim Director of Vigilance and Risk Management of Medicines
John Quinn	Director of Transformation
Jonathan Mogford	Director of Policy
Rachel Arrundale	deputising for Director of Policy, 09.00 – 10.00
Elizabeth O'Neill	Deputy Director, MHRA, Medicines & Pharmacy, Government Legal Department

Additional Attendees

Kirsty Wydenbach (Lic) for item 5: End to end vaccine offer
[REDACTED] for item 7: Impact of coronavirus on MHRA events programme
[REDACTED] for item 8: Managing public-facing meetings during the COVID-19 pandemic
[REDACTED] for item 10: Annual Information Assurance Report
Rachel Arrundale (Pol) for item 11: Proposal for further work on regulatory change
[REDACTED] for item 12: Transition Taskforce
[REDACTED] for item 13: Devices Transition paper
[REDACTED] for item 14: COI policy process for CHM EAGs and Ad Hoc Groups
[REDACTED] for item 15: 2020 Pay Award
[REDACTED] item 16: Mental Health Update
[REDACTED] Marie Donatantonio (NIBSC) for item 17: Health and Safety annual report
[REDACTED] for item 18: HR transformation
Keith McDonald, Dan O'Connor and Paula Walker for items 19 and 20: innovative licensing pathway / national MA applications after the transition period

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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5.1 [Redacted]

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[REDACTED]

[REDACTED]

[REDACTED]

6. Finance Report (CET/20/161)

6.1 Boryana Stambolova presented the April 2020 (P1) financial performance compared with the budget and the previous year. The CET noted that the Agency has started the financial year with an operating deficit of £0.4m; April revenue is £1.6m below budget and less than last year, however operating costs are also less than budget. Change costs are well below budget with an expenditure of £0.1m, however the CET noted that this does include a prior year cost correction. Compared to April 2019, the April 2020 operational deficit is level at £0.4m with lower costs compensating for the decrease in revenue. The latter is mainly due to lower regulatory income (licensing and inspections) combined with the now complete ceasing of EMA revenue. The CET noted that all three centres are behind budget in operational income. Operating costs were less than budget in all three centres; pay costs are also below budget.

6.2 With regards to change costs, the CET noted that the Change schedule has been updated to reflect the closure of the OT Programme and the evolving new structure of Change projects; one month in to the new financial year, spend has been low. All three Agency centres and the corporate divisions have lower than budgeted costs. In 20/21 the Corporate cost allocations model continues as agreed by CET in April 2019. The CET noted that at present spend continues on COVID-19 related projects. The CET considered that the impact of COVID-19 on normal business and additional costs needs to be the subject of reflection by the Performance Committee. It is important to note that a number of key members of staff have been working excess hours which should be taken into account in this analysis as this is unsustainable.

6.3 The CET noted that workforce planning is hugely important for the Agency to be able to address the current situation and upcoming changes. It was noted that some divisions have deferred certain work which was not directly fee-earning during COVID-19 so this should be taken into account. It was noted that with the closure of Operational Transformation and the new direction of the portfolio, the finance and project reporting will become properly aligned for future updates. The CET noted that it is important that business cases are approved in a timely manner so that projects are able to move into the delivery phase, and investment does not get deferred. The CET requested some work on how performance reporting to CET can be improved upon.

7. Impact of coronavirus on MHRA events programme (CET/20/164)

7.1 ██████████ presented an update on the impact of the coronavirus (COVID-19) pandemic on the agency events programme. The CET noted that the Agency organises a substantial event programme each year which has been impacted by the COVID-19 pandemic. The Agency's events programme will need to be redesigned and delivered through virtual events for at least the next 9-12 months. Virtually all conferences and exhibitions have either been cancelled or postponed. Events are moving online for the foreseeable future, both to maintain engagement but there is also an indication that there will be a shortage of venue capacity during Q4 of 2020 and Q1 of 2021.

7.2 The CET noted that face-to-face events will return but only once social distancing is lifted and people feel confident travelling to venues and gathering in large groups. Venue capacities will be significantly reduced to accommodate extra hygiene and people management measures. Industry insights suggest that the impact of COVID-19 on business events will be long lasting and will not return to any form of normality for at least 9-12 months. The CET noted the proposal that all events are delivered virtually for the next 9-12 months; following this, more virtual and hybrid events will be considered. The CET noted that any events the MHRA puts on as virtual events need to be undertaken in a careful manner to maintain professionalism.

7.3 The CET noted that while hosting virtual events, it will be possible to pre-record sessions for speakers ahead of time. The CET commented that a review of virtual events should be undertaken every 3 months to ensure that the Agency is delivering events in the appropriate way. With regards to finances, virtual meetings offer the opportunity of running events more than once, therefore generating greater return on investment. With the EU exit approaching there will be a opportunities for the Agency to run webinars and similar events to guide industry and other stakeholders.

Action: Undertake review of developments relating to MHRA events every 3 months.

8. Managing public-facing meetings during the COVID-19 pandemic (CET/20/165)

8.1 ██████████ presented a paper regarding public-facing meetings during the COVID-19 pandemic. The CET noted that public sessions of the Board have been on hold since the government's lockdown was introduced in March 2020; monthly Board meetings have successfully been taking place using telephone and video conferencing. It was noted that other public-facing and stakeholder meetings have been able to take place via Zoom, such as expert committee meetings, CHM, and the Valproate Stakeholder Network meeting. The CET noted that the next public Board meeting was scheduled for 23rd July 2020; a suggestion was made to the CET that this meeting be held via webinar, when members of the public and other stakeholders may submit their questions by email.

8.2 The CET noted the update and agreed that the next public Board meeting should be held by zoom webinar; however, care must be taken to ensure it runs smoothly on the day. It was noted that Microsoft Teams has the capability to run webinars, however if this is to become more commonplace in future then this will require resourcing.

9. Portfolio Delivery (CET/20/166)

9.1 John Quinn presented an update on the delivery of the 2020-21 Agency portfolio. The Portfolio is the list of prioritised projects and programmes that the Agency wishes to progress within the financial year. It can change as new priorities and strategies emerge. The CET reviewed the arrangements to transition from the pre-existing structures to support the Agency

Change strategy and direction. The CET noted that the portfolio is broken down into 4 categories: (i) Transition the Agency – essential changes to the Agency operations which are largely externally driven by January 2021; (ii) Change the Agency – the prioritised strategic change priorities that are largely internally driven; (iii) Agency Infrastructure – essential items that must be delivered to avoid critical service failures; and (iv) Divisional projects – priorities that will be managed by Divisions directly.

9.2 The CET noted that the scale of this Portfolio is significant; there are multiple dependencies between programmes of work, and delivery of this while most members of staff are working from home may be a complicating factor. The CET noted that progress will be reviewed each month through existing and future governance arrangements to support delivery. Senior Responsible Owners (SROs) should be appointed and held to account for delivering the benefits with which they are assigned. The CET noted the report and praised the progress made in the transformation of the Agency's Portfolio following the closure of Operational Transformation. Formal appointment letters will be issued to SROs. The CET agreed that when SROs have been appointed, this information will be communicated to all staff for awareness.

Action: Once SROs have been appointed this should be communicated to staff.

10. Annual Information Assurance Report (CET/20/167)

10.1 [REDACTED] presented the annual Information Assurance Report. The CET reviewed the report, which provides a summary of the Agency position in relation to information assurance, compliance with information legislation, and the Agency response to Cyber Security threats. The CET noted that over several years the Agency has been addressing issues relating to information management which had accumulated, creating risk from information loss and theft; non-compliance with information legislation; risk of uninformed decision making; increased costs of finding and storing information; and cost and complexity of implementing new services, systems and processes due to high levels of complexity. Much of this has now been addressed. However, the CET noted that there is more to do, and some significant opportunities will arise in order to maximise the information assets we hold, create new knowledge, and automate our information lifecycle.

10.2 The CET noted the progress which has been made in this area and reviewed the clear plan for the future, and how the risks are being managed at a level the Agency is able to invest in. As the Agency develops the Digital Workplace as we retire aging systems, review our data holdings and archive and delete information that is no longer required, the Agency's capability for information management will be significantly improved. The CET endorsed the update and noted this will be presented at ARAC. The proactive approach to talking about issues related to information management was commended.

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[REDACTED]

[REDACTED]

11.2 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12.4 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

GOVERNANCE AND DELIVERY

14. COI policy process for CHM EAGs and Ad Hoc Groups (CET/20/168)

14.1 [REDACTED] presented an update on the development of a Conflict of Interest (COI) policy process for the Commission on Human Medicines (CHM) Expert Advisory Groups (EAGs) and ad-hoc groups. The CET had considered a paper on this topic previously and considered the progress on the recommended actions. It was noted that a new Breach of Trust procedure has been implemented; the current Declaration of Interests has been updated to include a confidentiality undertaking. An additional process is being drafted to identified companies involved, which will allow a Register of Interests to be utilised proactively prior to meetings. A recommendation was made previously to explore the feasibility of a central electronic Agency database of expert members to include interests; this project is currently on pause, however discussions are ongoing with TD on when this project can be taken forward.

14.2 The CET noted that the website information for CHM appointments has been updated with recruitment advertisements. A review has been undertaken of the Conflicts of Interest policy for members of CHM and EAGs, in which alternative policies from a range of Agencies were reviewed (including from the FDA, NICE, EMA and Food Standards Agency). An analysis of the types of interests causing concern was undertaken by conducting a trawl of past issues. A consultation paper has been developed and a workshop with external stakeholders has

been proposed. The CET noted that as expected, the experts with the most experience tended to have the most conflicts of interest; this is acknowledged to be an issue for regulators internationally.

14.3 The CET noted the update and agreed that this is key to maintaining public confidence. A key goal is to apply a consistent approach to all committees. It was noted that a senior lawyer from DH Legal Services will be assigned to work on this new COI policy. The CET agreed that the timetable for consultation will be agreed [REDACTED]

Action: Develop updated COI policy with legal input; agree timetable for consultation.

15. 2020 Pay Award (CET/20/180)

15.1 [REDACTED] presented final options for the implementation of the 2020/21 pay award. The CET was previously consulted in May 2020 on a range of possibilities for the pay award. The Civil Service pay guidance for 2020/21 was issued on 19th May 2020. With the context of this guidance, the CET reviewed the pay award options. The CET noted that the guidance indicates the pay award should be between 1.5-2.5%. MHRA had budgeted for a 2% pay award, it was noted that anything above 2% will require a business case to be submitted to SOS for agreement. Other Agencies were consulted and it was noted that the majority are opting for a pay award of 2.5%.

15.2 The CET commented that the way the budgets are currently issued, this increase in the pay award from 2% to 2.5% will have bigger implications for some divisions compared with others. The CET commented that workforce planning is an important activity which needs to be progressed. The CET agreed to progress with the 2.5% pay award; a submission will be drafted with PHE and DHSC for submission to SOS.

16. Mental Health Update (CET/20/169)

16.1 [REDACTED] presented a paper on staff mental health-related absence and support mechanisms. The CET previously commissioned a report to investigate the rise in and high level of mental health related absence following the Q1 HR report. The CET noted that since the previous report was presented at CET, there has been a major change in working practices due to COVID-19. It was noted that a reduction of sickness absence rates has been observed, however there may be an impact on mental health which has not been identified yet. Pulse surveys have been issued to gain an understanding of this. Since the lockdown INsite has been used as a vehicle to deliver some of the support mechanisms for staff.

16.2 The CET noted that there have been some changes in impact assessments related to diversity and inclusion impact assessments; this also caters for mental health issues. With regards to Occupational Health, a deep dive is being undertaken to understand the proportion of consultations relating to psychological stress, and whether it is home- or work-related stressors that staff are dealing with while working at home during the pandemic. There is further work to do to understand how staff are feeling about returning to office spaces, including commuting using public transport.

16.3 The CET thanked [REDACTED] for the update and commented that there may be a need for training for managers in this area. The CET commented that while staff are working at home during the lockdown, there may be a number of staff working excessive hours which will have an impact on staff wellbeing. CET noted the benefits of proper breaks and avoiding holding meetings over lunch times. A further update will be given in 2-3 months' time.

Action: Provide a further update and analysis of mental health in September / October 2020.

17. Health and Safety Annual Report (CET/20/170)

17.1 Marie Donatantonio and [REDACTED] presented the Health and Safety (H&S) Annual Report for the Agency for 2019/20. This outlined progress made against planned objectives, Key Performance Indicators (KPIs) and other relevant activities for the past financial year. The plan also highlighted future priorities for H&S management across the Agency, including key risk areas and identifying significant resource requirements. The CET noted that good progress had been achieved against planned objectives, although some delays have been experienced, many due to pressure on current resources from reactive work.

17.2 As part of the report, Ms Donatantonio reported that the Certification to Occupational Health and Safety Assessment Series (OHSAS) 18801 for the 10 South Colonnade site has been maintained, while the planned migration to the new International standard ISO45001 is 50% complete. The CET noted that the Overseas Policy and procedure are embedded, with data on the number of trips and destination risk level provided to managers. Moreover, a travel safety app has now been agreed and will be procured shortly. Once this app has been implemented, an internal crisis management process will be agreed. The CET noted that a UK working policy and procedure is being developed to replace the current Offsite Working Policy. The CET also noted work on Fire Safety Risk assessments, accident and incident analysis, and Health and Safety Executive Intervention Plan, and more recently work on Coronavirus-related activities.

17.3 The CET commended the progress that had been achieved and made a number of specific comments:

- Benchmarking – The CET asked that the Agency benchmark NIBSC's and the Agency's experiences with similar organisations, such as Public Health England. There is currently joint working with other organisations but it was agreed more benchmarking would still be valuable.
- Homeworking during the pandemic – The CET commented on the health and safety challenges faced by staff who are working from home on a prolonged basis and were advised that Health and Safety Executive is undertaking work in this area. The CET asked that greater publicity, e.g. messaging and advice on Insite, be given so that staff can record accidents and near misses at home, as they would if they were office-based. The CET advised that baseline data should be collected on rates of Repetitive Strain Injury (RSI). The CET advised that for staff to work effectively and safely from home on a prolonged basis they need the right equipment.
- Other work locations – The CET asked that future health and safety reports take into account other work locations, such as the Agency's office in York, and when staff are travelling and working elsewhere in the UK.
- Overseas travel – The CET noted that staff who were due to speak at conferences in the Lebanon and Nigeria were asked to withdraw their travel by the Agency H&S sponsor due to safety concerns; the conferences were subsequently cancelled by the organisers due to the risk being recognised. The CET advised that, in future, consideration be given to staff joining overseas conferences and meetings remotely.

[REDACTED]
[REDACTED] It was noted that an increasing number of staff have now attended Hostile Environment Awareness Training (HEAT) training.

- Formal report back by CET directors each year – The CET asked if something similar to the annual return by CET directors to the Senior Information Responsible Officer

could be applied to an annual health and safety return. Ms Donatantonio reported that this is currently under consideration.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

19.2 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

INFORMATION

20. NIBSC monthly update for CET (CET/20/172)

20.1 The CET noted the NIBSC monthly update.

21. Final minutes of April 2020 Regulatory Group meeting (CET/20/173)

21.1 The CET noted the final minutes of the April 2020 Regulatory Group meeting.

22. Updates from Cross-Agency teams

Governance Board	CET/20/174
Performance Committee Meeting	CET/20/175

19. Agreement of 07 July 2020 CET agenda (CET/20/179)

19.1 The CET reviewed and provided comments on the 07 July 2020 draft CET agenda.

20. AOB

20.1 No items of AOB were raised.