



# Medicines & Healthcare products Regulatory Agency

## Minutes (draft)

CET/17/151

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	11 April 2017
<b>Time</b>	09.00 – 13.00
<b>Venue</b>	G1, BPR
<b>Chair</b>	Ian Hudson
<b>Attendees</b>	CET
<b>Apologies</b>	Vanessa Birchall-Scott, Paul Wright, June Raine

### CET Attendees

Ian Hudson	Chief Executive (Chair)
Jon Fundrey	Chief Operating Officer
[Name redacted under section 40 of the FOIA (personal data)]	deputising for Director of Human Resources
Sarah Branch	deputising for Director of Vigilance and Risk Management of Medicines
Melissa Coutinho	DH Legal Services
John Quinn	Director of Information Management
Janet Valentine	Director of the Clinical Practice Research Datalink
Christian Schneider	Director of the National Institute for Biological Standards & Control
Rachel Bosworth	Director of Communications
John Wilkinson	Director of Devices
Jonathan Mogford	Director of Policy
Siu Ping Lam	Director of Licensing
Gerald Heddell	Director of Inspection, Enforcement and Standards

### Additional attendees

[Names redacted under section 40 of the FOIA (personal data)] for item 5: Moving towards greater transparency on using animals in research

[Name redacted under section 40 of the FOIA (personal data)] for item 6: Employee Communications & Engagement Strategy

[Name redacted under section 40 of the FOIA (personal data)] for items 6: Employee Communications & Engagement Strategy and 16: Next series of managers' events

[Name redacted under section 40 of the FOIA (personal data)] for item 7: Patient and Public Engagement Strategy 2017-2020

Samantha Atkinson (IE&S) for items 8: BP Digital Project – Outcome of the Feasibility Study; 9: Future lab provision for the BP/MHRA and 10: MHRA hosting OMCL Meeting

[Name redacted under section 40 of the FOIA (personal data)] for item 11: MHRA Quality Management Systems

[Name redacted under section 40 of the FOIA (personal data)] for item 12: CHMP consultation on first in human trials

Richard Humphreys (F&P) for item 20: Finance and Procurement Report

[Name redacted under section 40 of the FOIA (personal data)] and Patience Wilson (Policy) for item 14: DH Triennial Review

[Name redacted under section 40 of the FOIA (personal data)] for all items

## **1. Apologies and Announcements**

1.1 Apologies were received from June Raine, Vanessa Birchall-Scott and Paul Wright.

## **2. Draft minutes of the 03 March Corporate Executive Team meeting (CET/17/092) including table of actions and final minutes of the 01 February Corporate Executive Team meeting (CET/17/093)**

2.1 The draft minutes of the 03 March meeting were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 01 February meeting were noted.

## **3. Final minutes of the 17 February Board meeting and draft minutes of the 17 March Board meeting (CET/17/094)**

3.1 The final minutes of the Board meeting of 17 February and the draft minutes of the 17 March 2017 Board meeting were noted.

## **STRATEGY**

### **4. Brexit – update and discussion (verbal) (CET/17/095)**

4.1 [Redacted under section 35 of the FOIA (Formulation of government policy)]

### **5. Moving towards greater transparency on using animals in research (CET/17/097)**

5.1 [Redacted under section 35 of the FOIA (Formulation of government policy)]

### **6. Employee Communications & Engagement Strategy (CET/17/098)**

6.1 [Names redacted under section 40 of the FOIA (personal data)] presented the employee communications and engagement strategy. There are three challenges facing the Agency over the next two years; Brexit, digital transformation and the accommodation move. It is important the Agency understands the dependencies between these three challenges and adapt approaches to employee communication and engagement accordingly. Critically, the Agency must recognise and appreciate the impact on our employees. The aim of the new employee communications and engagement strategy is to: Create a positive climate for business change across the Agency so staff can confidently make the changes to their ways of working while continuing to deliver services effectively.

6.2 It is proposed to achieve this aim through three high-level objectives:

- a) Contribute to employees feeling better informed about the business changes and ensure they are engaged in preparing for our future.
- b) Improve employee engagement / voice by creating a climate of listening and feedback; and improve the effectiveness of internal communications channels.

- c) Help staff be clear that their day-to-day dealings with customers influences what they think about us and that this impacts on our reputation and future commercial viability.

The internal communications and engagement will be evaluated using the Civil Service people survey and other measures. Work will be undertaken with HR to set up new manager induction training slots; and reviewing managers' behaviour. The Agency has a well-established framework of staff engagement events such as the SLG meetings; work will be done to assess if additional events are needed. An internal comms survey was previously undertaken, which found that staff do not want any new channels of communication but want to improve on what is already in place. Office365 will help with this.

6.3 The CET noted that better coordination of communications between Brexit, digital transformation and the move will help staff see the links between these changes. The CET speculated that managers may underestimate the time needed to drive messages home to staff; reiteration of information should be undertaken. It was noted that different staff have different communication styles therefore utilisation of many forms of communication is advised. A quarterly pulse survey has been trialled in Comms division which asks 3 questions with a free text comments box, to give a finger on the pulse of the general thoughts of staff; however it was noted that the Agency should be conscious of survey fatigue; and surveys are no substitute for management holding discussions and 121s separately. The CET noted that there may be some scope for topic based pulse surveys. HR guidance on regular 121s should be followed.

## **7. Patient and Public Engagement Strategy 2017-2020 (CET/17/099)**

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented the refreshed Patient and Public Engagement (PPE) strategy. Significant progress has been made with patient and public engagement within the Agency over the last 5 years. This refreshed strategy is in response to a number of external factors that, collectively, have increased both Government and public expectation for patient involvement throughout the development and delivery of medicine, particularly in relation to innovative treatments and products. These include most recently the recommendations of the Accelerated Access Review. Six actions were proposed for an updated strategic approach to help MHRA to further increase engagement with patients and the public:

- i) Update the Agency engagement policy to ensure that it recognises the value and formalises the role of patient and public involvement in regulatory decision-making and policy development.
- ii) Strengthen the role of the Patient Group Consultative Forum.
- iii) Increase the role of patients in the licensing process building on work done to date.
- iv) Develop support materials to facilitate patient involvement with the Agency.
- v) Develop an evaluation process to assess the impact of greater patient engagement.
- vi) Expand our collaboration with domestic, EU and international peer organisations and the Devolved Administrations to support future development.

7.2 The CET thanked [Name redacted under section 40 of the FOIA (personal data)] for this work and suggested that there could be scope for a trial in some areas; to give consideration to what will actually be involved and how engagement will fit in with the process given that, for example the EAMS process is only 45 days therefore representing a real operational challenge. It was noted that a new lay member needs to be recruited to CHM, who will act as the PPE EAG chair. It was noted that NIHR have an extensive patient and public involvement enterprise; this could be tapped into to create a remote grouping to discuss the Agency's needs. It was noted that there is a new strategic forum to involve networks of patients; however with the caveat that a lot of the same individuals turn up to many forums. Getting involvement in strategic considerations is easier than day to day

operational issues; PPE involvement in this work should be made on a case by case basis. Considerations between patient and lay members should be considered as they bring different perspectives.

## **GOVERNANCE AND DELIVERY**

### **8. BP Digital Project – Outcome of the Feasibility Study (CET/17/100)**

8.1 Sam Atkinson presented the outcome of the feasibility study of the BP digital project. Following a business review of the BP business, a paper was brought to CET in March which proposed a feasibility study into bringing elements of the BP production in house; to give more control over the strategic future of the BP and more opportunities to innovate at pace; allowing sales to expand in to new global markets and maximise improvements in public health. The strategy also allows for a smaller, less tailored contract that increases opportunities for competition during any procurement. Further, there are risks associated with retaining the existing model long term, as it leaves the agency overly dependent on a single supplier.

8.2 [Redacted under section 43 of the FOIA (Commercial interests)]

**Action:** Bring update to CET in 1 months' time on feasibility of this project, including justification for the fixed term position.

### **9. Future lab provision for the BP/MHRA (CET/17/101)**

9.1 [Redacted under section 43 of the FOIA (Commercial interests)]

### **10. MHRA hosting OMCL meeting (CET/17/102)**

10.1 Sam Atkinson presented a paper outlining a proposal to host the Official Medicines Control Laboratories (OMCL) Annual General Meeting in 2019/2020. The OMCL Network holds an annual meeting each year, hosted by different member states, where work programmes, rules, technical protocols and other matters are adopted. MHRA attends every year, sending delegates from the BP and Laboratory Services Group and from NIBSC. To date, the UK has never hosted this meeting. The CET noted that with the cheaper options, European Directorate for the Quality of Medicines (EDQM) contribution and judicious contingency usage, it should cost around £95k to host the meeting in London. The CET agreed to host the OMCL meeting. It was also noted that there is potential to explore holding other activities at the same time, while the OMCL stakeholders are all visiting London. OLS could be approached to support this activity.

### **11. MHRA Quality Management Systems (CET/17/096)**

11.1 Penny Carter and [Name redacted under section 40 of the FOIA (personal data)] presented an update on the management review of MHRA quality management systems. In September 2015, the ISO9001 standard was revised; with a much greater emphasis on leadership, a need to cover the understanding of the context in the system; and undertake a new risk-based system. A gap analysis was performed which identified a number of areas where the Agency would not meet the requirements of the new standard, in areas such as risk management and security. The CET noted that the Agency already has systems in place in these areas which are audited by PWC; it was agreed that no auditing should be undertaken twice. It was suggested that the Agency should engage with the ISO9001 auditors when required, and this was agreed at ARAC. The CET agreed to sign up to the ISO9001 2015 standard; and to take this management review to ARAC.

## **12. CHMP consultation on first in human trials (CET/17/103)**

12.1 [Redacted under section 35 of the FOIA (Formulation of government policy)]

## **13. DH Triennial Review (CET/17/106)**

13.1 Patience Wilson and [Name redacted under section 40 of the FOIA (personal data)] presented an update on the implementation of the Triennial Review recommendations. The CET were presented with a tracker of implementation of the recommendations, which was reviewed by the CET. Of the 21 original recommendations for the Agency, 12 have been completed, and significant progress has been made on the other nine. For CHM, only one of the original six recommendations is outstanding. For BPC, only one of the original 11 recommendations is outstanding. The CET gave updates to the tracker and agreed to send any additional comments back to Policy colleagues by Thursday 13<sup>th</sup> April.

## **14. Annual Report and Accounts 2016/17 (CET/17/107)**

14.1 Rachel Bosworth presented an early draft of the annual report and accounts 2016/17, for comments from the CET. The CET noted that more public health information could be included in the report. The CET agreed to send any additional comments back to Comms division.

## **15. Next series of managers' events (CET/17/108)**

15.1 [Names redacted under section 40 of the FOIA (personal data)] presented an update on the plans for the next series of managers' events. The CET were presented with a draft agenda and comments on the next SLG meeting of 14<sup>th</sup> June; CET agreed with the agenda for this meeting and discussed the frequency of the SLG meetings and proposed the meetings could be held 4x a year lasting 1.5 hours; with video link for members of staff unable to travel to BPR that often; CET agreed with the proposed change. It was noted the proposed themes for the managers' conference are all behavioural and it would be good to broaden the scope; it may be a good idea to have more case studies and pop ups at these meetings as these have proven popular with staff. It was agreed to approach a neuroscience speaker and bring this proposal back to CET in the near future.

**Action:** approach speaker for managers' conference and bring back the details to an upcoming CET meeting.

## **16. MPS/R&D approval (CET/17/109)**

16.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper relating to Market Pay Supplement (MPS) and Recruitment and Development supplement (R&D) for delegated grades. Following the Department of Health (DH) decision to allow the Agency to make the final decisions in respect of R&D and MPS cases (with DH governance limited to monthly reporting and occasional follow up) the intention is to formally establish an Agency Individual Cases Pay Committee (ICPC) – so called in order not to confuse it with the CET Delegated grade and SCS Pay Committees which form part of the internal, annual performance management governance arrangements. The CET reviewed the Terms of Reference as presented in the paper, and the establishment of the ICPC. The CET noted that under the existing assessor and inspector competence framework, a pay offer calculator exists; this should be integrated in to this paper. It was noted that the MPS/ supplements will come out of this 1% pot which finances end of year bonuses for staff.

## **17. Verbal update on the move (CET/17/110)**

17.1 Jon Fundrey gave a verbal update on the accommodation move to Canary Wharf. It was noted that we are awaiting a response on our request for extra space; there are sensitivities around this issue. An IT project manager is starting shortly for the move; a project manager from BNP Paribas has met the relocation programme board and will begin soon. The CET noted that the issue of additional accommodation is becoming critical.

## **18. Report on CET papers – update (CET/17/111)**

18.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update following the report on CET papers heard at the December CET meeting. A paper was brought to the CET in December which reviewed the papers brought to the CET, and CET were presented with a number of recommendations to improve the management of papers to CET. An action was taken to review the Terms of Reference (ToR) and draw together some practical guidance to consider prior to submitting a paper to the CET. The CET were presented with the Terms of Reference for information. A number of points of guidance were drawn up to consider prior to submitting a paper to CET, and when writing CET papers and guidance for presentation at CET meetings.

18.2 The CET gave a small update to be made to the ToR. The CET agreed that powerpoint slides should only be used if they are very limited; and should be circulated ahead of time. The CET agreed to publish the guidance and remit of CET, also alongside the remits for the Regulatory Group and IMGB, for staff information.

## **19. Finance and Procurement Report (CET/17/112)**

19.1 Richard Humphreys presented the finance and procurement report for the first 11 months of the financial year. After allowing for Dividends and Financing, after eleven months of the year the Agency has a retained surplus of £5.7m which is £5.3m above budget. The Agency is forecast to deliver a retained surplus in 2016/17 of £8.6m which is £2.1m above budget; but is subject to change. The CET noted the update.

## **20. Agreement of team briefing notes**

20.1 The items appropriate for circulating to staff as team briefing were agreed by the CET.

## **INFORMATION**

### **21. CPRD Executive Minutes (CET/17/114)**

20.1 The CPRD Executive Minutes were noted.

### **22. NIBSC monthly briefing for CET (CET/17/115)**

21.1 The NIBSC monthly briefing report was noted.

### **23. Draft minutes of the 21 March Regulatory Group meeting & final minutes of the 21 February Regulatory Group meeting (CET/17/081)**

22.1 The draft minutes of the 21 March Regulatory Group meeting and the final minutes of the 21 February Regulatory Group were noted.

## **24. Updates from Cross-Agency teams**

23.1 These updates were noted by the CET:

Information Management Governance Board (IMGB)	CET/17/117
Finance Sub Committee meeting	CET/17/118
Policy and Procedures Committee	CET/17/119
Audit and Risk Assurance Committee	CET/17/086
Health and Safety Strategy Group	CET/17/120
Audit and Risk Assurance Committee	CET/17/121
Risk and Audit Liaison Group	CET/17/122
Equality & Diversity Group	CET/17/123

## **25. Agreement of 9 May 2017 CET agenda (CET/17/124)**

24.1 The CET agreed reviewed and commented on the draft agenda for the 9 May CET meeting. It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

## **26. AOB**

None.