



Medicines & Healthcare products Regulatory Agency

Minutes (final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	09 August 2016
Time	09.00 – 13.00
Venue	R-T-410, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Rachel Bosworth

CET Attendees

Ian Hudson	Chief Executive (Chair)
Vanessa Birchall-Scott	Director of Human Resources
John Quinn	Director of Information Management
Siu Ping Lam	Director of Licensing
Janet Valentine	Director of the Clinical Practice Research Datalink
John Wilkinson	Director of Devices
June Raine	Director of Vigilance and Risk Management of Medicines
Gerald Heddell	Director of Inspection, Enforcement and Standards
Jonathan Mogford	Director of Policy
Christian Schneider	Director of National Institute for Biological Standards & Control
Mark Wilson	DH Legal Services
Peter Commins	Chief Operating Officer and Finance Director
Richard Humphreys	Deputy Director - Finance
[Redacted]	deputising for Director of Communications Division

Additional attendees

Patience Wilson (Policy) for item 9: Business Continuity
[Names redacted under section 40 of the FOIA (personal data)]

1. Apologies and Announcements

1.1 Apologies were received from Rachel Bosworth; [name redacted under section 40 of the FOIA (personal data)] attended in her absence. Ian Hudson congratulated Mark Wilson on his new appointment to HMRC.

2. Draft minutes of the 12 July Corporate Executive Team meeting (CET/16/200) including table of actions and final minutes of the 14 June Corporate Executive Team meeting (CET/16/201)

2.1 The draft minutes of the 12 July meeting were agreed with minor updates. The CET reviewed, and provided updates on, the table of actions. The final minutes of the 14 June meeting were noted.

3. Draft minutes of the Agency Board of 15 July (CET/16/202) and final minutes of the 17 June Agency Board (CET/16/203)

3.1 The draft minutes of the 15 July Agency Board and the final minutes of the 17 June Agency Board meeting were noted.

STRATEGY

4. News, Digital and Content Strategy (CET/16/204a)

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

5. Operational Transformation Scoping Report (CET/16/205)

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

6. Post-EU referendum – update and discussion (CET/16/206)

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

GOVERNANCE AND DELIVERY

7. Finance and Procurement Report (CET/16/121)

7.1 Richard Humphreys presented the monthly Finance and Procurement report for the month of June. After the first quarter of the year, in-year performance shows the Regulator, Corporate, CPRD and NIBSC are all ahead of their budgeted surplus positions. Overall, after three months, the agency has a retained surplus of £2.7m, £1.4m above budget. The quarterly comparison of performance showed that Regulator income is up compared to the previous year, particularly in EMA and PLPI fees. Expenditure is up by £2.9m, there was also an increase in people costs of £1m due to a combination of factors including headcount and NI impacts. ICT expenditure is up which is a reflection of the Operational Transformation Programme expenditure at a higher level. The NIBSC income was down by £0.6m compared to the previous year due to reduction in flu standards and recognition of research grants. Staff expenditure increased by 8%. The CPRD operating surplus is £0.3m lower than the previous year; however the number of new customers and new licences has not yet been reflected in these figures. The super dividend was paid on 20 July.

8. Apprenticeship Scoping Report (CET/16/208)

8.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Apprenticeship Scoping Report to the CET. It is a Cabinet Office requirement for the Civil Service to deliver 3m apprenticeships by 2020; therefore MHRA needs to ensure 2.3% (28) of our workforce is made up of apprenticeships, year on year. The CET paper was written under the assumption that many of the apprenticeships can be sourced from current roles/staff, which can fit with apprenticeship criteria. In the first year, in addition to any new salary costs if there are new roles, the training cost for all apprentices will need to be funded by the Agency and have not been budgeted for. From April 2017 the Agency will pay a £250,000 apprenticeship levy and this will allow on average £8,000 to be drawn back per apprentice, but only if recruited on or after April 2017. This levy sum was already known and should be being budgeted for 2017/2018. Interim HR resource has been recruited to assist in the design and implementation of the apprenticeship scheme, however continuation of the Apprenticeship Project Coordinator for 1 further year to develop and manage the scheme was recommended. The first step in this project is having discussions with managers to identify skill gaps and identifying apprenticeship programmes which staff members can be placed on.

8.2 The CET thanked [name redacted under section 40 of the FOIA (personal data)] for the paper, and commented that the next step will be for her to work with divisions to identify current roles/staff whose positions can contribute to the quota. Training programmes which take place in CPRD for individuals from other organisations were suggested as a possibility to fill apprenticeship spaces; however it was confirmed that all apprentices will need to be employed by the Agency for a minimum of 30 hours per week. NIBSC maternity cover posts were also confirmed as of questionable suitability to be considered as

apprenticeships, as apprenticeships need to be at least 12 months long; and staff members on maternity leave have the right to return to work when they wish. IMD outsources a lot of work; there is the opportunity to insource this work and for this to potentially save the Agency money. There is a model called FDM which recruits IT graduates and loans them out as consultants to companies for 2 years, with the opportunity for recruitment at the end of the 2 year period; John Quinn will also discuss this model with HR. The CET noted that there are medical assessor and pharmaceutical assessor competence development frameworks, which would not be able to be rebranded as apprenticeships; however there could be scope to work to create standards for these types of roles, which could be included in this scheme in the longer term.

8.3 It was noted that clarity was still being sought over whether the Agency will only need to have a total of 28 apprentices at any one time – or 28 new recruits per year. The CET noted that it may be worth working with a skills agency to develop this as a core concept of the Agency, rather than adjusting current training programmes to make this fit. It is possible to have apprentices at many levels – such as degree level, coordinator level and management level. It may be possible to attach a relevant qualification or professional registration to particular roles which will qualify them for apprenticeship. This work should be linked with the career pathways work which is currently ongoing.

Action: HR and IMD to discuss FDM model of employing apprentices; HR to work with divisions to consider what will be possible and practical. A business case to be put forward for extending the Apprenticeship lead role. An update will be brought to CET in November.

9. Business Continuity (CET/16/209)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on business continuity, to ask for sign off with the caveat that only the tier 1 activities were listed within the annexe. Tier 1 activities are activities which need to be completed within 24 hours of an incident. The CET noted the update and approved the Business Impact Analysis. The CET were asked to comment on nomination of a chair for physical incident management teams; the current plan notes that the chair should be someone related to the incident; however best practice guidelines state that incident management chairs should be somebody with no relation to the incident but with the chairperson skills to manage the incident. The CET agreed that the incident management chair should be sourced from Group Manager level; however had a preference for somebody who had knowledge of the incident area. The CET were asked to send nominations for incident management chairpersons. It was decided that if the Agency needed a staff member to perform a gatekeeper function if required for future incidents, this responsibility would fall to the Chief Operating Officer.

Action: CET members to nominate incident management chairpersons.

10. Quarterly Report – progress against business targets and activities (CET/16/210)

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented the quarterly report on progress against business targets and activities. The CET noted that the majority of targets have been met in Q1; 5 targets have not been met; the CET noted the reasons for the missed targets. There were 5 activities due in Q1 which were at risk of delay; of which the CET discussed and the reasons for delay. Activity 5Fi should be updated to remove individuals' names.

Action: Update activity 5Fi

11. Management Review of MHRA Quality Management Systems (CET/16/211)

11.1 [Name redacted under section 40 of the FOIA (personal data)] presented the management review of MHRA quality management systems. This paper was drawn together with the quality leads from each division. The CET were asked to provide comment on and endorse 5 key points:

- a. NIBSC should be included in the ISO 9001 Scope with BSI so one Certifying Body covers the whole Agency. The CET endorsed this.

- b. Consider if quality objectives (similar to the Health and Safety Objectives) should be developed to ensure buy-in for the QMS at all levels; the CET agreed that some managers objectives could be updated to include smart objectives to address this.
- c. The NIBSC complaints procedure currently is not linked to the agency complaints procedure. Need to make sure regular reporting is aligned; the CET endorsed this link.
- d. Agree that resources within the Divisions that support the embedded QMS should continue to be reviewed to determine the resource requirements for the new devolved system; the CET were content.
- e. Agree a review as to how the new HR Training Module could be used to all record the Agency's training needs including the QMS requirements. The CET endorsed this.
- f. The CET agreed that a paper should be developed to outline how the Agency can transition to ISO 9007:2015 and present a proposal to CET in February 2017.

Action: a paper should be developed to outline how the Agency can transition to ISO 9007:2015 and present a proposal to CET in February 2017.

12. Quarterly special bonus update (CET/16/212)

12.1 Vanessa Birchall-Scott presented the quarterly special bonus update. The CET noted that the Agency is within the 15% of staff and the 0.25% of pay bill limit for the whole year, and that this will continue to be monitored. The equality statistics are currently being reviewed by the Equality and Diversity subgroup; and an in-depth trend analysis will be undertaken to review the statistics. The CET noted that the statistics from some divisions are slightly delayed, as the bonus figures are pulled from the payroll, rather than the month when staff are nominated for a special bonus.

13. Equality and Diversity update (CET/16/213)

13.1 Vanessa Birchall-Scott presented an update on Equality and Diversity – responsibilities, the current position of the Agency and proposed plans. The new Equality and Diversity group was set up in October 2015; which meets quarterly. The group has implemented a number of initiatives and these include; an agency pledge and objectives, an Equality and Diversity page on INsite and the establishment of an equality and diversity staff data sub group, who carried out a review of the data available in 2015 and will do the same for the 2016 data provided to CET. A range of further initiatives are planned including Equality and Diversity training. The group is also exploring the possibility of agency protected characteristic groups. The CET noted the update.

14. CPRD quarterly update (CET/16/216)

14.1 Janet Valentine presented the CPRD quarterly update to the CET, covering: staff restructure; data acquisition; vision; EMIS; SystmOne; data linkage; GP practice recruitment; the Caldicott 3 National Data Guardian Review; Care.data; transparency of uses and users of CPRD data; ISO9001 review; the DECIDE study; clinical referral services; and observational research. The CET heard that considerable positive progress had been made in all areas, in particular the staff restructuring and the GP practice recruitment, and the CET offered their congratulations to Janet on these achievements. The CET noted the issues with TPP, and congratulated the Janet and her team on the successes with EMIS. The CET noted the good outcomes of the Caldicott report, and agreed that CPRD should lead a consultation on the behalf of the MHRA, with PEAG and CHM involvement.

Action: CPRD lead a consultation on the Caldicott Review.

15. NIBSC quarterly report (CET/16/223)

15.1 Christian Schneider presented the NIBSC quarterly report. The CET noted the Report and in particular the performance against the objectives in the Agency's business plan as well as the performance measures that are monitored by the NIBSC SMT. The three NIBSC boards – on standards, control and research – all reported to NIBSC SMT and are all on track. The CET noted the first standard to support gene therapy has been approved; along with standards for zika diagnostics, and new standards to support development of

biosimilar products for solid tumour therapy (targeting ErbB/Her family receptor proteins). Standards sales showed strong flu sales. The Control Programme Board reported good progress in the first quarter with 100% achievement of the KPI for turnaround time of batch release. CTLIMS has been successfully launched with help from the IMD project manager. The Research Programme Board launched the PhD students annual programme, open to international students. The NIBSC Regulatory Sciences Symposium was held; the number of scientific publications from NIBSC is at 31 from this quarter. The CET noted the future challenges for polio vaccine once the virus has been eradicated. All activities bar one are on track for the NIBSC comms and engagement strategy. The main priorities for the next period were also noted by the CET.

16. Agreement of team briefing notes (CET/16/214)

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

INFORMATION

17. NIBSC SMT update (CET/16/215)

17.1 The CET noted the notes from the July NIBSC SMT meeting.

18. Draft minutes of the 19 July Regulatory Group meeting (CET/16/217) and final minutes of 23 June Regulatory Group (CET/16/218)

18.1 The final minutes of the 23 June meeting and the draft minutes of the 19 July meeting were noted.

19. Updates from Cross-Agency teams

19.1 These updates were noted by the CET.

Information Management Governance Board (July 2016 final)
Finance Sub Committee meeting (June 2016 final)
Policy and Procedures Committee (July 2016 draft)

CET/16/219 Peter Commins
CET/16/220 Peter Commins
CET/16/221 Gerald Heddell

20. Agreement of 31 August CET agenda (CET/16/222)

20.1 The CET agreed the agenda for the 31 August meeting.

21. AOB

None.