



Medicines & Healthcare products
Regulatory Agency

Minutes

Title of meeting	Corporate Executive Team formal monthly meeting
Date	05 April 2016
Time	09.00 – 13.00
Venue	R-T-410, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	John Wilkinson

CET Attendees

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

Additional attendees

[Names redacted under section 40 of the FOIA (personal data)]
Richard Humphreys for item 14: Finance and Procurement Report

1. Apologies and Announcements

1.1 Apologies were received from John Wilkinson; [Name redacted under section 40 of the FOIA (personal data)] attended in his absence.

2. Draft minutes of the 10 March Corporate Executive Team meeting (CET/16/087) including table of actions and final minutes of the 2 February Corporate Executive Team (CET/16/088)

2.1 The draft minutes of the 10 March meeting were agreed. The CET reviewed, and provided updates on, the table of actions. The final minutes of the 2 February meeting were noted.

3. Draft minutes of the Agency Board of 14 March (CET/16/089) and final minutes of the 12 February Agency Board (CET/16/090)

3.1 The draft minutes of the 14 March Agency Board and the final minutes of the 12 February Agency Board meeting were noted.

STRATEGY

4. Vigilance Strategy (CET/16/091)

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

5. Enforcement Group Control Strategy (CET/16/092)

[Redacted under Section 31 of the FOIA (law enforcement)]

6. Strategy for Genomics and Companion Diagnostics (CET/16/114)

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

GOVERNANCE & DELIVERY

7. Innovation Office update (CET/16/093)

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented a review on the operation of the MHRA's Innovation Office since its introduction in March 2013. The Innovation Office is a virtual office that was introduced in 2013 to engage with developers of innovative medicines and medical devices and to provide regulatory advice. The Office currently answers approximately 12 queries a month; mostly by email; and mostly requested by SMEs and academics. The CET were asked for their comments on three recommendations: (1) that a more proactive approach be taken in future to inform stakeholders of the ways the MHRA supports innovation and can provide advice; (2) the MHRA continue to be a major contributor to the EU Innovation Network and contribute to the EMA's innovation task force advice meetings; and (3) that the MHRA internal procedures concerned with supporting innovation are refreshed.

7.2 The CET noted that the analysis of the Innovation Office showed just how valuable this resource is to stakeholders, such as charities who may lack regulatory knowledge. A question was raised on whether scientific advisory meetings and information provided by the Innovation Office translated in to rapporteurships down the line; and the CET noted that this certainly is a possibility therefore it is in the interest of the Agency to develop a business case to continue this work. There have also been a number of meetings with enquirers relating to the design of manufacturing facilities, which will encourage manufacturing within the UK. The CET encouraged the team to continue to solicit feedback from users. and in addition the CET supported the proposals that the Agency should begin to promote the Innovation Office more than has been done previously. Overall, the CET gave full support to the recommendations.

Action: Licencing to progress the business case separately for the proposed additional resource to support the Innovation Office's activities, to take forward these recommendations; and to consider undertaking a review of customer feedback.

8. French clinical trial – interim report (CET/16/094)

[Redacted under section 27 of the FOIA]

9. Customer Services Strategy Update (CET/16/095)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the customer service group's high-level discussions, and asked CET to comment on proposals of how Comms and IMD should continue to take this work forward. The report focussed on reviewing, at a high level, the services the Agency provides; customer insight; and the top 20 customers for each centre. Five important themes were identified: organisational culture, mission and values, commercial awareness, business

development, and management information. The proposals included the continuation of the customer service group meetings for another 4 months; to carry on investigation and analysis of customer insight and the top 20 customers, with a need to gather more information from some centres. Additional staff resource may also be pursued. Benchmarking visits to other high-performing customer focused organisations have been planned; proposed organisations include the hydrographical organisation and the John Lewis partnership. A customer and business development hub was proposed as a way to bring all three groups together for a central discussion; this idea will be explored further with the view to bringing this together by July 2016.

9.2 The CET thanked the group for their work and commented that it would be important to focus on the remit given to the group, namely customer focus, rather than expanding the remit into other areas such as business development. The group should look at a model of best practice for each centre, to be shared with each team, for them to take forward. The CET commented that benchmarking other organisations would be a good way to learn from those with good customer service; however it was noted that as the Agency has a highly specific technical function it is important to focus on organisations relevant to the work of the Agency.

Action: The customer service group should continue to meet for the next 4 months to develop plans in line with the remit of the group. A further report should be brought back to the CET at the 12 July meeting

10. Managers' conference and Senior Leadership Group planning (CET/16/096)

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper on proposals for the future Senior Leadership Group meeting in June 2016; an evaluation of the recent managers' conference in February 2016; an update on the progress of the development of the new strategic narrative; and initial proposals for the next managers' conference in September 2016.

10.2 The frequency and duration of the SLG meetings was discussed, with a proposal for more frequent but shorter meetings; feedback from previous SLG meetings via survey monkey demonstrated that 80% were happy with the length and format of the current meetings. Therefore CET agreed that the current timetable of biannual 4-hour sessions will continue. In the past, external speakers such as David Behan from the CQC have spoken at the SLG meetings; speakers such as Dame Sally Davies or Duncan Selbie were suggested for the CET's consideration, however the CET agreed that it would be preferable to maintain internal leadership of the meetings at present. It was noted that breakout sessions are key to engage the SLG members. It was also noted that future sessions could focus on topics such as leadership and cultural change.

10.3 The CET discussed the managers' conference which took place on 25 February 2016. Overall satisfaction was high, and similar to previous conferences, although not as high as the September session David MacLeod session which achieved exceptional results. There was only 53% attendance of all Agency managers, and 19% of those who registered did not attend; however the CET noted that this may be due to commitments such as European meetings. A list of managers who did not attend will be circulated to CET.

10.4 Proposals for the upcoming managers' conference in September 2016 were discussed; feedback from previous meetings indicated that there was high support for external speakers. Four suggestions for future conference topics were posed: Inclusive leadership; Organisational transformation – where will we be in 10 years; Effective leadership in times of change; and Learning from other organisations. There was support for option 2, a session on organisational transformation led by Gerry McGovern.

Action: Comms to work on a more detailed programme for the SLG and the managers' conference and bring a report back to CET in June. Comms will circulate a list of managers who did not attend the recent managers' conference to CET.

11. Annual Report 2015/2016 (CET/16/097)

11.1 [Name redacted under section 40 of the FOIA (personal data)] presented a report of the early draft of the Annual Report and Accounts to the CET. A previous paper had been presented to CET in December

2015 describing extra information the National Audit Office require to be included in the Annual Report. There is now a requirement that the Governance report includes a biography for the Chief Executive and the Chief Information Officer as they are considered for reporting purposes to be part of The Board; however biographies for other members of CET are not able to be included in this section. CET members agreed that a sentence should be added stating that biographies of the other 10 members of the CET can be found on the Agency's website.

11.2 The CET discussed the content of the annual report, and suggested that including high level narratives of the Agency's achievements would be a good way of presenting important information in an easy to find format. The CET noted that as the annual report took a large amount of effort to put together, the format should be tailored to maximise the value of the report. It may be useful to review the format of annual reports from other European Agencies.

11.3 The CET discussed the best way to share the draft annual report to the Agency Board; a general paper focussing on the content to be included will be drafted.

Action: Comms will consider new ways of formatting the annual report; and will put together a high level document of achievements. A table of contents and description of what will be contained in each section of the annual report will be put together for the Agency Board.

12. Proposal to replace SOP working group with new Policy and Procedures Working Group (CET/16/098)

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper which sets out a clear and simplified oversight and assurance mechanism for policy and procedure documents. It was proposed to set up a new Policy and Procedure Working Group to approve SOPs and policies, to meet every 2 months. The CET discussed the new proposed terminology: Policy documents which contain a set of guiding principles; and Procedures which are simple instruments to implement the policies. CET agreed that they are happy with the proposed terminology however as the term SOP is so well established it may be difficult to change this to Procedure; and noted that a Standard Operating Procedure is technically a Procedure anyway.

12.2 The CET considered the proposal to set up a new Policy and Procedure Working Group to replace the current SOP working group; and agreed this should go ahead, and that the group should be accountable to the CET. The CET commented that it would be important to identify and define exactly where particular Policies or Procedures should be signed off; and which need to be brought before the CET for approval. A mapping exercise of all current policies and SOPs should be undertaken to identify areas where there is unnecessary duplication, or if there are any gaps where procedures should be implemented. These changes should be communicated appropriately to staff once implemented.

Action: Divisions to identify representatives for the new group, the new P & P group to pull together a map across the Agency of current policies and procedures; and identify where and by whom different types of policies should be approved; and whether there are any gaps that require filling.

13. CPRD Quarterly Report (CET/16/099)

13.1 Janet Valentine presented the CPRD Quarterly Report, covering: staff restructure; data acquisition; data linkage; information governance; internal audit of CPRD's KPIs; partnerships; business development; observational research; and clinical trials an intervention studies. The CET heard that considerable positive progress had been made in all areas. This was particularly impressive in the light of the considerable work and focus to support the staff restructure and the CET offered their congratulations to Janet on these achievements.

14. Finance and Procurement Report (CET/16/100)

14.1 Richard Humphreys presented the monthly Finance and Procurement report for the month of February and the first 11 months of the 2015/2016 financial year. The CET noted the agency's total operating surplus for the year to 29 February of £16.9m against a budgeted surplus of £15.8m. The operating surplus comprised £9.0m, £5.5m and £2.4m for the regulator, NIBSC and CPRD respectively. Following payment of dividends the overall retained surplus is £10.4m against a budget of £8.9m. The cash position at 28 February stood at £212.5m and trade receivables were at £30.1m. The forecast surplus at year end after dividend of £8.8m against a budgeted surplus of £9.0m was also noted. The CET noted the detailed income and expenditure accounts including the continuation of the significant expenditure variance on staff costs, which are now £3.9m (6%) below budget.

14.2 The CET noted the statement of financial position including the debtors' analysis, deferred revenue and cash positions and the Income Risk Assessment. It was noted that the reduction between January and February 2016 in assets under construction reflects the treatment of the BI asset following the review of the life of the original phase 1 asset. CET were informed that the £10m DH dividend is expected to be paid at the end of April; this will be highlighted to the Agency Board in the report.

15. Digital, Information Management, Technology – Quarterly Update (CET/16/102)

15.1 John Quinn presented a quarterly update to the CET on progress on delivery of technology, information management, and the digital business plans. The CET noted that the infrastructure transition was the largest focus of work from the previous year, with the transition from single supplier down to multiple suppliers. A CET planning day was held which considered the long term future of the agency's three themes of supply chain, surveillance, and innovation; and then considered what this meant for the Agency's future IT systems. CET noted the collation of the outputs from this planning day. IMD has proposed to produce a Digital Strategy paper for the May 2016 CET; and provide this summary to the Agency Board. The CET endorsed the recommendations from this item. CET also noted that it will be helpful when the new strategy starts to become more concrete in nature.

Action: IMD to produce a Digital Strategy paper for the May 2016 CET.

16. BPR relocation – verbal update and Q&A (CET/16/103)

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

Action: update to be brought to May 2016 CET meeting.

INFORMATION

17. NIBSC SMT update (CET/16/104)

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

18. Draft minutes of the 23 March Regulatory Group meeting (CET/16/105) and final minutes of 23 February Regulatory Group (CET/16/106)

18.1 The final minutes of the 23 February meeting was noted and the draft March RG minutes were sent to CET for information after the meeting.

19. Updates from Cross-Agency teams

19.1 These updates were noted by the CET.

Information Management Governance Board (Feb. 2016 final)	CET/16/107	Peter Commins
Information Management Governance Board (March. 2016 draft)	CET/16/108	Peter Commins
Finance Sub Committee meeting (Feb 2015 final)	CET/16/109	Peter Commins

SOP Working Group (next meeting April 2015)
Health and Safety Strategy Group (March 2016 draft)
Audit and Risk Assurance Committee (March 2016 draft)
(deferred to May 2016 CET)
Risk Management & Audit Liaison Group (Feb 2016 draft)
Equality and Diversity Group (next meeting 21 April)

Gerald Heddell
CET/16/110 Christian Schneider
CET/16/111 Peter Commins

CET/16/112 Peter Commins
Vanessa Birchall-Scott

20. Agreement of 4 May CET agenda (CET/16/113)

20.1 The CET agreed the agenda for the 4 May March meeting.

21. AOB

None.