



Medicines & Healthcare products Regulatory Agency

Minutes (final)

CET/17/262

Title of meeting	Corporate Executive Team formal monthly meeting
Date	08 August 2017
Time	09.00 – 12.00
Venue	RT-410, BPR
Chair	Ian Hudson
Attendees	CET
Apologies	Paul Wright, Christian Schneider, Rachel Bosworth, Siu Ping Lam

CET Attendees

Ian Hudson	Chief Executive (Chair)
Jon Fundrey	Chief Operating Officer
Michael Armitage	DH Legal Services
[Name redacted under section 40 of the FOIA (personal data)]	deputising for Director of Communications
Liz Baker	deputising for Director of Licensing
Gerald Heddell	Director of Inspection, Enforcement and Standards
John Wilkinson	Director of Devices
[Name redacted under section 40 of the FOIA (personal data)]	deputising for Director of the National Institute for Biological Standards & Control
Janet Valentine	Director of the Clinical Practice Research Datalink
Samantha Atkinson	Director, Business Transformation
John Quinn	Director of Information Management
June Raine	Director of Vigilance and Risk Management of Medicines
Jonathan Mogford	Director of Policy
Vanessa Birchall-Scott	Director of Human Resources

Additional attendees

[Name redacted under section 40 of the FOIA (personal data)], staff observer
[Name redacted under section 40 of the FOIA (personal data)], staff observer
[Name redacted under section 40 of the FOIA (personal data)] for item 5: Genomics and Companion Diagnostics - update
[Name redacted under section 40 of the FOIA (personal data)] for item 6: Proposals for amendments to the MHRA Trading Fund Order
[Name redacted under section 40 of the FOIA (personal data)] and Patience Wilson (Policy) for item 8: Business plan report Q1 report
[Name redacted under section 40 of the FOIA (personal data)] for item 9: 'Shaping Our Future' learning programme paper
[Name redacted under section 40 of the FOIA (personal data)] for item 12: Workforce planning

[Names redacted under section 40 of the FOIA (personal data)] for item 13: Management Review of MHRA Quality Management Systems 2016-2017

Richard Humphreys (F&P) for items 15: Finance and procurement report, 16: New CET cover sheet, and 17: Review of Corporate Risk Register

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

1. Apologies and Announcements

1.1 Apologies were received from Paul Wright, Christian Schneider, Siu Ping Lam and Rachel Bosworth.

2. Draft minutes of the 11 July Corporate Executive Team meeting (CET/17/206) including table of actions and final minutes of the 06 June Corporate Executive Team meeting (CET/17/207)

2.1 The draft minutes of the 11 July meeting were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 06 June meeting were noted.

3. Final minutes of the 23 June Board meeting and draft note of the July Board/CET away day (CET/17/208)

3.1 The final minutes of the Board meeting of 23 June and the draft minutes of July Board/CET away day were noted.

STRATEGY

4. Brexit – update and discussion (CET/17/209)

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

5. Genomics and Companion Diagnostics - Update (CET/17/210)

5.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the work which has been ongoing on companion diagnostics. Previously at CET a 3-phase approach to develop a strategy for genomics and companion diagnostics was agreed; currently the project is in the second phase and has paused some elements of the work due to timings of the new device regulations. The NIBSC schedule for genomics reference materials is in place. It was noted that regulation of genomics is challenging and the Agency's approach needs to be proportionate whilst still protecting patients, given the importance of genomics tests. Our regulatory approach must also take into account NHS England's plans to rollout genomics service nationally. It was noted that the CMO's annual report focussed on genomics.

5.2 Licencing and Devices divisions have defined some policies around the regulation of diagnostic devices in clinical trials; more work is needed to be done on this. It was also noted that further work needed to be done to develop the infrastructure needed for assessing companion diagnostic performance studies. The CET noted that a great step forwards has been taken with the introduction of the In Vitro Diagnostics Regulations; it was noted that external experts such as Professor Munir Pirohamed could be consulted on what the regulatory strategy should look like. CET agreed that the Agency should develop an appropriate regulatory approach in this area, continuing to work with partners and experts. It was also noted that hospital exemptions were used for some diagnostics and the restructuring of the genomic services in the NHS may present an opportunity for the Agency

to work with stakeholders to ensure the appropriate standards are applied. The CET agreed the 3-year companion diagnostics timetable.

6. Proposals for amendments to the MHRA Trading Fund Order (CET/17/231)

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

7. Operational Transformation (CET/17/234)

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

GOVERNANCE AND DELIVERY

8. Business plan report Q1 (CET/17/1211)

8.1 Patience Wilson and [name redacted under section 40 of the FOIA (personal data)] presented the business plan Q1 report to CET. There are 5 targets which currently are not on track; 2 of these are policy targets. One FOI missed the deadline; as the target is 100% the CET noted that this target has been missed for this year. 1 PQ was returned late; however it is possible that the target will be met by the end of the year. The CPRD target that 90% of research applications should receive feedback within a certain time period was discussed; it was noted that there are often difficulties in achieving this 90% target as external individuals play a part in contributing to the feedback. There were 6 targets at risk of delay which didn't deliver in Q1; these have been checked with the responsible divisions and should be delivered by the end of the year. The CET noted the report and provided updates on the targets and the Agency's performance in Q1.

9. 'Shaping Our Future' learning programme paper (CET/17/212)

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented the Shaping Our Future learning programme to the CET. Following on from previous CET papers relating to the Agency's Training Needs Analysis (TNA) and Employee Communications and Engagement Strategy by HR Learning and Talent Team (L&T) and Comms respectively; the need for a 'change readiness' learning programme was identified to give managers the skills to lead and manage through change, and to ensure that staff are supported. A phased approach of the change readiness learning programme was proposed to the CET, to reflect on and adapt learning outcomes. A pilot phase was proposed which will focus on people managers at G6 level or below, with 3 training courses ran (2 at BPR and 1 at NIBSC) before Christmas. It was noted that no additional funding is required as this will be funded from the training needs analysis funding.

9.2 Following the pilot, the L&T team will work in partnership with relevant parties to establish a programme of learning for non-managers and SLG members depending on the outcome of the pilot phase of the programme. The CET noted that it is important to ensure the maximum benefit can be taken from this learning programme. It was noted that this could also be included as part of the 5 days training staff should be undertaking each year. It was also noted that this is properly evaluated and a close in should be kept with Operational Transformation.

Action: Run the pilot courses for non-SCS managers, including a session to be held at NIBSC.

10. SCS annual pay guidance (CET/17/213)

10.1 Vanessa Birchall-Scott presented an update on the SCS annual pay guidance; the CET noted that the guidance has been received and this confirms the CET's original decision in principle of how to utilise the funding. The relevant communications and template letters will be sent out via directors.

11. Performance management flexibilities (CET/17/214)

11.1 Vanessa Birchall-Scott presented a report on performance management flexibilities. A Flexible Performance Management Framework (the Framework) has been agreed by Permanent Secretaries and this applied from April 2017. The Framework requires organisations to reflect several core elements in any new approach. There are 8 core elements of the framework which need to be fulfilled in the new approach. MHRA will be required to complete an attestation statement to indicate the Agency is complying with the core framework. A number of proposals were presented to CET for their comments.

11.2 With regards to proposals 1-4, concerning 1:1 meetings with staff; it was noted that guidance for managers to help prepare for 1:1 meetings is essential and it was noted that some divisions do already follow templates for 121s. It was noted that CET were in favour of simplifying the process and templates would be helpful with this, but there was no appetite to make templates mandatory. With regards to proposal 5-9 concerning SMT discussions, it was agreed that holding periodic SMT meetings which are not overly onerous, where staff performance development needs are discussed would be important.

11.3 With regards to proposals 10-13, concerning objectives, it was agreed that an annual review of objectives and personal development plans is essential and a 6-monthly review should also take place. All objectives should be SMART. Managers should also have objectives regarding management. With regards to proposals 14-18, concerning pay, it was agreed that the voucher scheme should continue. The CET agreed to retain the in-year bonus, and consider more flexibility with end of year bonuses; however it was noted that the end of year scoring system does not differentiate easily enough between staff. It was agreed that the CET's comments will be taken to the focus group, and a further report will be brought back to a future CET meeting for approval.

12. Workforce planning (CET/17/215)

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented a paper outlining the approach to workforce planning for the Agency. Discussions have taken place at SMT level across divisions/centres, which identified key workforce planning issues and commons themes. 2 areas highlighted were medical assessors and inspectors. Two pilot areas, Licencing and IE&S will be taken forward in terms of more detailed workforce planning; there will be focus on targeted recruitment in these areas. Secondment opportunities will be explored with other organisations, and it was proposed to build more formal relationships with academic institutes. Contract flexibility will be reviewed to identify where individuals can reduce hours. The apprentice inspector model will also be reviewed.

12.2 CET commented that the idea of joint appointments with other organisations could be very beneficial. A suggestion was also raised of employing individuals on a contractual basis to undertake project work. The CET gave a strong endorsement to progress the workforce planning work; individual teams will need to give consideration to how these jobs will evolve. It was agreed that an update will be given to CET in spring 2018.

13. Management review of MHRA quality management systems 2016-2017 (CET/17/233)

13.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on MHRA quality management systems. Most of the actions from the management review have been closed; work has been ongoing in to how the learning and development leads for the various quality standards can be met by the Taleo and Fusion systems. A meeting was held with HR colleagues to review these systems and it was noted that these systems do meet the ISO standards. CET noted that there are some areas of importance for the next year to focus on.

13.2 The first area of importance is relating to document control. There are some concerns regarding change control and version management at BPR; CET noted that once SharePoint has been introduced, this will be utilised in future to manage document control. CET agreed that better document control should be investigated at both the NIBSC and BPR sites. An area identified for improvement of record keeping was cross-divisional working. This was identified at the BEMA audit as evidence of effectiveness was difficult to identify. Key systems need to be reviewed, including crisis management; it was agreed that crisis management policies should be reviewed. CET endorsed the proposals in the paper.

14. Finance and Procurement Report (CET/17/217)

14.1 Richard Humphreys presented the finance and procurement report for the first quarter of the 2017/18 financial year. The CET noted that there have been some technical issues with the new reporting system but these are being improved. After allowing for Dividends and Financing, after the first quarter of the year the Agency has a retained deficit of £1.6m which is £0.7m better than budget. The Agency is budgeted, after the costs of Operational and Digital transformation are considered, to deliver a retained deficit in 2017/18 of £13.2m and is currently on track to deliver this budget. The CET noted the report.

14.2 The CET were also presented with the procurement waiver report; this is presented on a quarterly basis to ARAC. The CET noted the action required by ARAC in the procurement waiver report and noted that management of information of contracts should be captured fully in this paper.

15. New CET cover sheet (CET/17/232)

15.1 Richard Humphreys presented a new draft of the CET cover sheet, with an updated procurement section to understand where future procurement issues may come up. The CET agreed the new template.

16. Review of Corporate Risk Register (CET/17/218)

16.1 Richard Humphreys presented the Corporate Risk Register (CRR). It was noted that there are a number of new risks which have been added to the CRR; including the risk of a cyber attack on NIBSC and the Brexit impact on the IT portfolio. The CET noted the risks and provided updates.

17. NIBSC Q1 report to CET (CET/17/230)

17.1 [Name redacted under section 40 of the FOIA (personal data)] presented the NIBSC Q1 report to the CET. The Standards Programme Board reported that sixteen proposals for new or replacement standards have been submitted to WHO for the ECBS meeting; the majority of these are new standards which reflects the innovation work ongoing at NIBSC. The CET noted that the future pipeline of standards is very encouraging. The Control Programme Board reported achievement for each of the KPIs in turnaround times for batch

release testing. A benefits realisation analysis of CT-LIMs data management software was carried out and reported to the Information Management Governance Board (IMGB).

17.2 The Research Programme Board (RPB) reported that 33 publications have been published between January and June 2017 with NIBSC scientists as author or co-author. Work is taking place to also look at making a comprehensive record of NIBSC staff contributing to non-authored documents so that this effort can be reported on where appropriate. The RPB also reported on progress being made in the application for Regulatory Science Research Unit (RSRU) funding from the Department of Health; this will be submitted next month.

17.3 In Virology, good work has continued in the influenza area. In the poliovirus area, vaccine strains found in sewage samples from London provide evidence for the development of a sensitive surveillance system that would detect circulating wild and vaccine-derived poliovirus strains in the environment. A grant has been awarded from PATH/Gates for research into the safety of Sabin-IPV vaccines and polio vaccine. Work on developing standards for biosimilars is moving forward.

17.4 In the area of Next Generation Sequencing, there are plans to further apply this specialist cross divisional sequencing resource to cutting edge research projects across the Institute. At the end of Q1, the new Head of Advanced Therapies took up post and will start to take forward two objectives that had been delayed. The CET noted the update and the achievements made in the first quarter.

18. Agreement of team briefing notes (CET/17/219)

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

INFORMATION

19. CPRD SMT Partners meeting of 20 July 2017 – draft minutes (CET/17/220)

19.1 The CPRD SMT partners meeting minutes were noted.

20. NIBSC SMT briefing (CET/17/229)

20.1 The NIBSC SMT briefing for CET was noted.

21. Draft minutes of the 24 July Regulatory Group meeting & final minutes of the 20 June Regulatory Group meeting (CET/17/221)

21.1 The draft minutes of the 24 July Regulatory Group meeting and the final minutes of the 20 June Regulatory Group were noted.

22. Updates from Cross-Agency teams

19.1 These updates were noted by the CET:

Information Management Governance Board (IMGB)
Finance Sub Committee meeting
Audit and Risk Assurance Committee

CET/17/222
CET/17/223
CET/17/224

23. Agreement of 08 August 2017 CET agenda (CET/17/228)

22.1 The CET agreed reviewed and commented on the draft agenda for the 4th September CET meeting. It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

24. AOB

None.