Medicines & Healthcare products Regulatory Agency

Minutes (Final)

Title of meeting	Corporate Executive Team formal monthly meeting
Date	13 October 2015
Time	09.00 – 13.00
Venue	G3, BPR
Chair	Ian Hudson
Attendees	CET – see below
Apologies	Stephen Inglis

Ian Hudson	Chief Executive (Chair)
Peter Commins	Chief Operating Officer and Director of Finance
Rachel Bosworth	Director of Communications
Marie Donatantonio	deputising for 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 Wilkinson	Director of Devices
John Quinn	Director of Information Management division
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 of additional attendees for specific agenda items redacted]

1. Apologies and Announcements

1.1 Apologies were received from Stephen Inglis, Director of the National Institute for Biological Standards and Control. The Chief Executive welcomed [redacted] to the meeting as an observer. The aim is to give staff an understanding of how the agency's senior leadership team operates and how decisions are taken. A reminder was given that all meeting papers and discussions must be treated as confidential.

2. Draft minutes of the 15 September Corporate Executive Team (CET/15/224) Meeting, including Table of Actions, and final minutes of the 11 August Corporate Executive Team (CET/15/225)

2.1 The CET agreed the draft minutes of the 15 September CET meeting and noted the final minutes of the 11 August meeting.

3. Draft minutes of the Agency Board meeting of 18 September (CET/15/226) and final minutes of

the Agency Board meeting of 20 July (CET/15/227)

3.1 The CET noted the final minutes of the 20 July Board meeting and the draft minutes of the 18 September meeting.

STRATEGY

4. Corporate Plan refresh (CET/15/228)

4.1 [redacted] presented an update on the work to review the agency's corporate strategy and sought comments on, and agreement to, a paper to the 16 October Agency Board. The aim of the paper is to: remind the Board of the previous work on the agency's Corporate Plan 2013-2018; outline the recent CET work to review the strategy; and seek views from the Board on the initial thinking about priority areas.

4.2 The CET endorsed the aim of publishing an update to the existing Corporate Plan to coincide with the publication of the agency's Business Plan 2016/2017 on 1 April next year. Work would progress following the initial input from the Board on 16 October. This would include consultation with staff and with external stakeholders over the autumn, with a view to holding a substantive discussion about the priority areas and the feedback received at the joint CET/AB Awayday on 22 January.

4.3 The CET endorsed the nine key areas of strategic focus, which were developed following the earlier CET SWOT analysis and subsequent discussion. These cover: Supporting innovation; Leading patient safety and surveillance systems; Confidence in global supply chain to ensure safe supply of medicines/devices; People strategy; Customer service strategy; Digital strategy; Partnership in the health and care system; Optimising the USP of our three centres; and Business development. The CET agreed that the material provided on each of these topics needed to feature prominently in the Board paper. The CET asked for excellence in science to be reflected in the priority areas and for the unique contributions of NIBSC and CPRD to be given greater prominence. The CET supported the concepts represented in the flow diagram showing how the strategy fits together, with the 'business development' and 'three centre USP' aspects being seen as enablers of the other strategic areas.

4.4 The CET agreed that the proposed areas of focus, and the levels of ambition in each one, needed to be seen in the context of the constraints on the agency, including: the ability to recruit and retain high calibre staff; government-wide controls on spending in certain areas (e.g. IT, communications); the agency's Trading Fund status; and the rigid requirements of *Managing Public Money.* The CET agreed that it would be helpful to have a non-executive director work closely with the executive on the strategy as it develops. The Board paper would seek a nomination.

Action: Policy division to update the Board paper based on the comments from CET

5. UK Growth: the potential further contribution of our international strategy (CET/15/229)

5.1 Jonathan Mogford and [redacted] presented a discussion paper about the extent to which the agency could better generate income from certain international activities. This was in response to a discussion at the Annual Accountability Review meeting of 9 September. The CET heard that the agency has been asked to provide at least interim views to DH by 23 October.

5.2 The CET noted the preliminary thinking on some of the areas that will need to be considered in more detail, including: some of the challenges around developing a capacity building function for countries with little developed infrastructure; further commercialisation of established 'products', mainly in the CPRD and NIBSC areas; other commercial opportunities such as the development of British Pharmacopeia; and enhancing the agency's role in attracting inward investment by, for example, supporting innovation. It was acknowledged that the agency was already doing a lot in areas that would fall within this area and that this work might be pulled together as a first step

5.3 It was acknowledged that protecting public health remains the agency's highest priority and primary function. It was agreed, however, that there may be scope to deliver the agency's primary public health

responsibilities in ways that deliver secondary, income-related benefits. The CET considered whether there should be any distinction made between international and domestic income generation and agreed to explore further. It was acknowledged that some of the constraints identified in the context of the Corporate Plan review (listed above in item 4) would apply equally here. The CET agreed the proposal to set up a small task and finish group to progress this work and that it should be developed in the context of the business development strategic theme within the Corporate Plan review. In the short term the CET supported the proposal to provide a high-level overview of the areas being considered, pointing to a more robust and systematic analysis as part of the agency's review of the Corporate Plan.

Action: Policy division to prepare the interim response to the DH outlining the agency's thinking and the plans to develop further thoughts in the context of the Corporate Plan review

6. Next Generation Sequencing plan of action (CET/15/230)

6.1 [redacted] and [redacted] updated the CET on the landscape around Next Generation Sequencing and genomics in the UK. This follows an open day that the agency hosted on earlier this year, which brought together experts in this area to identify the challenges and opportunities in the field.

6.2 The CET supported the ambition stated in the paper, which is for the agency to become world leaders in the regulation of NGS and genomics. It was agreed, however, that even keeping pace with scientific developments would require a clear strategy, involving external partners as necessary, and a sustained investment in capability and capacity. The CET noted that four main workstreams have been identified, although others may emerge as the agency's knowledge and expertise in NGS/genomics develops. They are: Companion Diagnostics; Software (including bioinformatics); Best Practice guidance (including the role of reference materials); and Patient and Public Engagement.

6.3 The CET asked for a clearer definition of the overall strategy, recognising that due to the specialist nature of NGS and genomics it may not possible to develop a full strategy without an initial investment in relevant expertise and some iterative work. The CET asked for a full workplan to be developed for the January CET meeting. This would identify the priority areas, taking into account the workstreams ad deliverables identified already, and would discuss the expertise and resources needed to flesh out the preliminary thinking into a full strategy. Investment in additional expertise and capacity would be subject to the established business case process.

Action: Devices to develop clearer definition of the overall strategy and submit a workplan to the January CET

GOVERNANCE & DELIVERY

7. CPRD Quarterly Report & metrics (CET/15/231)

7.1 Janet Valentine presented the CPRD quarterly report and provided an update on CPRD population coverage and the progress towards receiving streamlined daily data extracts from all three GP system software supplies (Vision, IMIS and TTP/SystmOne). The CET noted the work in progress to incentivise GP practices to join CPRD and provide data through a software provider. It was noted that a member of staff from the Royal College of General Practitioners had commenced a 6-month secondment to CPRD to lead on this work. The CET also noted updates on: engagement with HSCIC and developing a more structured relationship; increasing data linkages; developing observational research activities; and progress in clinical trials and interventional studies.

7.2 The CET asked for an update on the process for identifying and managing actual and perceived conflicts of interest between the agency's regulatory activities (particularly Clinical Trial Authorisation assessments and Good Clinical Practice inspections, including financial considerations) and CPRD activities with regard to clinical trial design and providing data for interventional studies.

7.3 The CET noted the presentation of comprehensive management information on CPRD activities. The CET agreed that the metrics would vastly improve the ability of the agency to set targets, track growth

and identify trends and outlier events. It was agreed to use the metrics as the basis for a programme of work to improve understanding within DH of the role of CPRD. The CET noted that proposals for a longer term CPRD strategy, with revised growth targets, would be presented to the November CET for agreement.

Action: CPRD and Policy division to report on the procedures in place to manage actual and perceived conflicts of interest between the Regulatory and CPRD centres

8. Corporate Risk Register (CET/15/232)

8.1 [redacted] presented the CRR for approval. This was last reviewed by CET on 19 June and by the Audit and Risk Assurance Committee on 22 June. Following the current review by CET, the CRR would be submitted to the 16 October ARAC for review. The CET agreed the CRR, including the proposed changes, subject to the following:

- Proposed new risks 1 to 5 on implementing the e-cigarette provisions of the Tobacco Products Directive to be merged into a single risk, focusing on the reputational and financial/resourcing aspects. The elements covered in draft risks 3 and 5 would not be covered. Policy division agreed to suggest a form of wording
- Risk 21 on the CPRD/HSCIC relationship would be retained as status Green until the next review, at which time the CET will consider whether to remove it from the CRR
- Risk 34 on HR Data Quality and Security was approved for removal from the CRR

Action: (i) Policy division to provide a form of wording for the TPD e-cigarettes risk; (ii) F&P to update the CRR before submission to ARAC

9. Review of Agency's External Fraud Register (CET/15/233)

9.1 [redacted] presented the agency's External Fraud Risk Register, which was last reviewed by CET on 3 March and by ARAC on 23 March. Following the current review by CET it will be submitted to the 16 October ARAC for review.

9.2 The CET agreed the risk register, including the risk ratings, subject to one minor observation: the NIBSC risk 2, on the production and selling of counterfeit biological reference materials, would apply equally to chemical reference materials. Finance and Procurement agreed to reflect on how best to include this element of the risk.

Action: F&P to include the risks relating to the production of counterfeit chemical reference materials

10. Finance and Procurement Report (CET/15/234)

10.1 [redacted] presented the monthly Finance and Procurement report for the month of August and for the five months of financial year 2015/2016. The CET noted the agency's total operating surplus for the year to 31 August of £11.2m against a budgeted surplus of £5.4m. The operating surplus comprised £6.5m, £3.4m and £1.3m for the regulator, NIBSC and CPRD respectively. The cash position at 31 July stood at £209.5m and trade receivables were at £35.0m. The CET noted the significant expenditure variance on staff costs, which are £2.1m (7%) below budget. The CET noted the Income Risk Assessment.

10.2 Finally, the CET offered congratulations to the Finance and Procurement team for the achievement of being shortlisted for a Civil Service Award in the 'financial management' category.

11. Health and Safety – approval of policies (CET/15/235)

a. Lone Working (CET/15/235A)

b. Employee Health Assessment (CET/15/235B)

11.1 Marie Donatantonio introduced this item and asked [redacted] to present the detailed policies for agreement. Firstly, [redacted] presented the Lone Working policy. This was agreed by the CET subject to

the addition of the policy regarding lone home working in BPR and a definition and guidance around of 'out of hours' BPR working. The policy would be updated to include this definition and policy and would be agreed by correspondence.

11.2 [redacted] and [redacted] presented the Employee Health Assessment policy for agreement. The CET noted the need to associate a Job Hazard Profile with every new vacancy and the requirement for job candidates, upon receipt of an offer of employment, to complete a 'pre-employment Work Health Assessment'. These would be used by Occupational Health, together with the job description, to undertake a worker health assessment for all proposed new staff (and indeed staff on transfer within the agency to new positions) in order to provide information on any workplace adjustments that are needed to safeguard the wellbeing of the individual. Information on any workplace adjustments would be passed to HR to implement, with input from the recruiting manager. In terms of monitoring, the CET noted the aggregated data that could be made available to monitor the performance of OH (e.g. in terms of the time taken to produce a Work Health Assessment outcome form for each candidate/vacancy). Qualitative performance data could also be provided.

11.3 The CET heard that the it would acceptable for the agency to produce a single, generic Job Hazard Profile for all standard administrative positons in BPR, with further generic profiles being made available for other groups of staff (e.g. inspectors, staff working in facilities and estates). These could be held by OH. For each vacancy, the recruiting manager would simply confirm that the generic profile was appropriate.

11.4 The CET asked for a further paper outlining how the process would work from end to end, integrating with HR processes, to ensure that it is as streamlined as possible, to avoid any further delays to new staff starting. Although not strictly part of the policy, this would include the operational interface between the delivery by OH of the Work Health Assessment Outcome form and the implementation of any reasonable adjustments or other recommended actions.

Action: (i) H&S team to update the Lone Working policy to include the policy regarding lone home working in BPR and a definition and guidance around of 'out of hours' BPR working and send to CET for agreement; and (ii) H&S team to work with HR to produce the paper outlining the end to end process (including operational interface into HR) to ensure it is as streamlined as possible

12. Stakeholder perceptions audit (CET/15/236)

12.1 [redacted] outlined plans to undertake a perceptions audit of the agency's key external stakeholders. This is due to commence in November 2015 and a report on findings will be presented to CET in January 2016. The CET supported the plans for the audit. The CET heard that approximately 20 in-depth face to face interviews with key stakeholders will be undertaken by a research company that has been commissioned to carry out this work. Interviewees will be drawn from the wide range of sectors that interact with the agency including, for example, royal colleges, colleagues from the NHS and health and social care system, industry trade associations, academics, and other EU and international regulatory colleagues. The final 20 bodies will be drawn from a long list, with the remainder invited to contribute to the research via a survey.

12.2 The CET supported the overall approach and in particular the need for discussions with stakeholders to be kept confidential, to protect the anonymity of participants and to encourage honest input. Given the broad range of stakeholders the CET felt some focus might be necessary to ensure a value output. It was agreed to circulate the list of stakeholders included in the interviews together with a summary of the nature of the questions and issues being explored (the 'Topic Guide') such that the CET could be satisfied that the depth of the questions should ensure sufficiently meaningful responses.

Action: Communications division to circulate the list of 20 stakeholders proposed to involved in the interviews for CET endorsement as well as the Topic Guide

13. SLG Dec. 2015 and managers' conference Feb. 2016 (CET/15/237)

13.1 [redacted] and [redacted] presented feedback on the 8 June SLG and 11 September Managers' Conference. Feedback on both events was very positive, although for both there were lessons to take forward into the next meetings. In particular, for the SLG, feedback suggests that the agency needs to do more to follow through on discussions, by keeping SLG members up to date with the topics discussed and the commitments made.

13.2 The CET agreed the propose approach and the draft agenda for the 1 December SLG. Likewise, the approach for the next MC – which will now take place on 25 February – was agreed. Further thought will be given to a potential speaker for the MC and the CET will consider a range of options at its December meeting.

Action: Communications division to produce options for the 25 February Managers' Conference speaker for CET to consider in December

14. Review of Team Briefing (CET/15/238)

14.1 [redacted] presented the results of a full review of the current Team Briefing process and asked the CET to agree a proposal for a future approach. The CET heard the positive feedback from staff about Team Briefing, showing that a majority of staff that responded felt better informed as the result of attending a briefing session. A slight majority also thought that it had improved two way communication in the agency. The CET noted the analysis of the different models of Team Briefing, including the approaches in place in other organisations.

14.2 The CET agreed the proposed approach, which builds on the current model but considers new delivery methods (e.g. slides) and different approaches to selecting topics. It was agreed that the most successful briefings involve a two way discussion. Where possible, the topics must be selected on the basis that the agency wants to receive input and feedback from staff. The CET also supported the proposal to ensure that Team Briefing remains topical by linking it to the issues discussed by CET at its monthly meeting. The proposals for enhanced feedback options, including the possibility of anonymous feedback provided online, was also supported. Whilst it was recognised that the topics selected might not always be of direct interest to all parts of the agency, the CET remained of the view that it should be delivered by managers to all staff.

15. Professional Assurance Communication Controls (CET/15/248)

15.1 [redacted] presented a report highlighting the Cabinet Office changes to the existing communications and marketing exemptions process and the steps taken in the agency to ensure compliance. A review of the use of the process in the last three years, and the issues and themes that have emerged, was also presented.

15.2 The CET heard that strengthening the process is intended to signal that the Government is serious about reducing inefficiency and ensuring that investment in communications and marketing takes place only when there is clear evidence that it will be effective.

15.3 The CET noted the main changes, including a new request form for applications over £100,000 (the agency retains delegated authority to approve request below net £100,000 spend), which now includes a requirement to provide data on the expected 'return on marketing investment' (ROMI). There is also a new application form for requests under £100,000. Important changes to the process for approval have also been made. The CET heard that ministerial approval is now required for applications over £100,000 and this would need to be obtained from DH in advance of submission to the Cabinet Office.

15.4 The CET noted the changes and agreed that certain aspects present challenges to the agency. The CET noted that support would be provided to divisions on the new aspects, including on providing information and data to support the new ROMI requirement. Examples of good practice in the development of marketing exemptions, for various scenarios, would be developed.

15.5 The CET reviewed the metrics on the exemptions sought and achieved (including values) and concluded that in general terms the quality of exemption application has improved over the three years since the process was introduced. Staff have developed experience in the process and the reservoir of data that can be drawn into applications has increased over time. The CET asked that work continues to ensure this necessary process is taken forward in as proportionate and helpful way as possible, with model answers available to staff.

Action: Communications division to work with divisions to implement the new form and requirements, and produce best practice examples of successful applications

INFORMATION

16. NIBSC SMT (CET/15/239)

16.1 The CET noted the summary of the NIBSC SMT.

17. CPRD SMT minutes (next meeting 28 October)

18. Draft minutes of the 30 September Regulatory Group meeting (CET/15/240) and final minutes of 1 September Regulatory Group (CET/15/241)

18.1 These were noted.

19. Updates from Cross-Agency teams

Information Management Governance Board (2 Sept final)	CET/15/242	Peter Commins
Finance Sub Committee meeting (20 Aug final)	CET/15/243	Peter Commins
SOP Working Group (7 Sept draft)	CET/15/244	Gerald Heddell
Health and Safety Working Group (3 Sept draft)	CET/15/245	Stephen Inglis
Audit and Risk Assurance Committee (next meeting 16 Oct)		Peter Commins
Risk Management & Audit Liaison Group (9 Sept draft)	CET/15/246	Peter Commins

20. Agreement of 4 November CET agenda (CET/15/247)

20.1 The agenda was agreed.

21. AOB