



# Medicines & Healthcare products Regulatory Agency

## Minutes (FINAL)

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	08 December 2015
<b>Time</b>	08.30 – 13.00
<b>Venue</b>	G1, BPR
<b>Chair</b>	Ian Hudson
<b>Attendees</b>	CET
<b>Apologies</b>	John Quinn

Ian Hudson	Chief Executive (Chair)
Peter Commins	Chief Operating Officer and Director of Finance
Rachel Bosworth	Director of Communications
Stephen Inglis	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
[Redacted under section 40 of the FOIA (personal data)]	
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*

Richard Humphreys, Finance and Procurement, for Item 5: Annual Strategic Finance Update; Item 17: Finance and Procurement Report; and Item 18: Corporate Risk Register  
 Patience Wilson for Item 8: Conflicts of interest (COI) – processes for handling COI/governance arrangements

[Names redacted under section 40 of the FOIA (personal data)]

### **1. Apologies and Announcements**

1.1 Apologies were received from John Quinn. The Chief Executive welcomed [Redacted under section 40 of the FOIA (personal data)] 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 4 November Corporate Executive Team meeting (CET/15/275) including table of actions and final minutes of the 13 October Corporate Executive Team (CET/15/276)**

2.1 The CET agreed the draft minutes of the 4 November CET meeting and noted the final minutes of the 13 October meeting.

### **3. Draft minutes of the Agency Board meeting of 20 November (CET/15/277) and final minutes of the Agency Board meeting of 16 October (CET/15/278)**

3.1 The CET noted the draft minutes of the 20 November Board meeting and the final minutes of the 16 October meeting.

## **STRATEGY**

### **4. Corporate Plan review and Business Plan 2016/2017 (CET/15/279)**

4.1 Jonathan Mogford presented an update on the work to refresh the agency's corporate strategy. The CET agreed that the existing Corporate Plan 2013-2018 remains sound and that there are no entirely new areas of activity that need to be brought into focus. The CET agreed the proposal to develop an addendum to the existing Corporate Plan, to be published alongside the Business Plan 2016-2017. The addendum will (i) summarise the achievements so far; (ii) define clear objectives and workplans for the remainder of the Corporate Plan period as well as mechanisms to measure success; and (iii) signal the longer term areas of strategic focus, to be developed for the next Corporate Plan period (2018-2023). The CET agreed the proposed high-level objectives for the review process, subject to ensuring that Devices interests are covered adequately throughout and to the addition of an objective in engaging staff in the refresh process.

4.2 The CET noted and agreed the substantive presentation of material on the achievements so far and short and long-term goals – all within each of the 5 Corporate Plan themes and in the two additional cross-cutting themes (developing the agency's business and the agency's USP). Some initial views were provided on this material and directors were asked to forward all specific comments in writing to Policy division by Tuesday 15 December. The CET also agreed the proposed emerging elements to be handled in the Business Plan 2016/2017. Finally, the skeleton programme for the 15 January Board/CET Awayday was agreed and this will be presented to the Board on 9 December for agreement. CET also agreed the need to involve staff in the refresh process and it was proposed to hold some facilitated focus groups with staff in January in addition to the December team brief. Trade associations would also be consulted.

**Action:** directors to forward any specific comments on the work to refresh the Corporate Plan and develop the Business Plan 2016/2017 to Policy division by 15 December. Policy to work with Communication on ensuring appropriate staff engagement in the refresh

### **5. Annual strategic finance update (CET/15/280)**

5.1 Peter Commins presented the strategic finance update, in advance of the 15 January 2016 Board/CET Awayday. Following CET, the paper will be presented to the Board for discussion. The CET agreed that the strategic finance update must be seen in parallel to the work to review the agency's corporate strategy. The CET heard that the current update examines the strategic financial trends that will affect the agency as it enters the next five year financial objective period from 2018. It was noted that the annual budget setting process is underway and will separately address short term activity and manpower changes.

5.2 It was noted that the agency is on course to exceed its current required rate of return by approximately £60m (130%) by 2018, at which point the clock will be reset and performance from that point onwards will be measured. The CET noted that with two years to go there is no threat to the agency in meeting its legal duty. The CET agreed the need to reinvigorate the agency's interrelated plans on IT/digital, people/workforce, financial and indeed other areas to ensure that the agency enters the next 5 year period (2018-2023) in an equally strong position and so is able to deliver the strategic priorities set out in the corporate plan refresh and beyond.

5.3 As part of the plan to ensure that the agency is best placed to deliver an ambitious corporate strategy, the CET agreed the recommendation to develop a proposal to commission external support to help develop an 'operational transformation' strategy and investment plan. The CET agreed that a strategy

developed internally may not be sufficiently ambitious and that on this occasion the agency would benefit from an external perspective. The CET was clear that ownership of the direction of the strategy and investment plan would remain with the agency and would be subject to CET agreement and oversight as well as Board agreement. The purpose of the external element would be to stimulate new thinking and challenge any longstanding assumptions about the level of change possible. It was agreed to engage the agency's Senior Leadership Group in the next phase with a view to producing a firm proposal for consideration in the New Year. The CET agreed that very careful consideration would need to be given to the selection of the external element.

5.4 Finally, as part of the strategic finance update, the CET also noted the agency's income portfolio and growth path since 2006 as well as the individual strategic finance plans for the three centres, including the latest regulator income assumptions and the NIBSC Investment Plan. The accommodation update was also noted.

**Action:** Finance and Procurement to develop the more detailed proposal for engaging external support and to work with Communications division on involving the SLG on the next phase

## **6. Developing and implementing a communications plan for supporting innovation (CET/15/281)**

6.1 [Redacted under section 40 of the FOIA (personal data)] presented an update on the development of a communications plan on supporting innovation, aimed at industry, academia and healthcare professionals. The CET heard that there is considerable appetite among stakeholders and customers for information, advice and guidance on the measures in place in the agency to support innovation. A great deal of work has already been done and there have already been some significant successes. For example, the joint work with the Medicines Manufacture Industry Partnership to publish a series of case studies has proved to be very effective at showcasing the agency's contribution to innovation. To date seven case studies have been published and several more are planned. The CET also noted the success of the MHRA Innovation Symposium on 30 November.

6.2 The CET agreed the initial areas of focus for the innovation communications plan: (i) Early Access to Medicines Scheme; (ii) MHRA Innovation Office; and (iii) Scientific advice meetings. Key messages will be developed to convey the agency's USP in these areas and they will be promoted across the agency's communications channels. The CET agreed the proposals for generating key messages and the channels and mechanisms for communication. Specific internal communications will also feature so that staff are made aware of the excellent work being done. The timescales for delivery were agreed and it was noted that the contribution of CPRD and NIBSC to supporting innovation will be reviewed and incorporated in the plan from April 2016.

## **7. Customer services strategy workshops and high level strategy (CET/15/282)**

7.1 [Redacted under section 40 of the FOIA (personal data)] and [redacted] provided an update on further developing the agency's approach to customer services and sought comments from CET in a number of areas. The CET agreed that good progress had been made in developing a more customer-focussed approach to delivering products and services. The agreement to a Customer Services Strategy 2015-2018 launched a customer insight programme (see item 11 below) and established working group to review customer service standards across the agency. The current corporate strategy review has identified customer services as a central focus.

7.2 The CET supported the analysis provided in the paper of where we are now, having developed marketing plans for priority areas of the agency, and continuing to develop the customer insight work as well as rolling out a Digital Strategy. In developing a level of ambition for where the agency should position itself, as well as to gather specific views and begin to prioritise actions, Communications division ran a series of staff customer services workshops for staff. The CET watched a short video of feedback and was encouraged by the enthusiasm shown by staff – over 180 staff attended the workshops at BPR and NIBSC in November. The CET noted the range of comments received and the themes that had begun to emerge and supported the need for a more detailed analysis of this material. The analysis would incorporate the other inputs, for example the People Survey comments and the work to review the Corporate Plan and

implement a Digital Strategy. The CET agreed that placing the customer at the heart of the agency's activities was as much a cultural transformation as an operational change. The CET agreed to the setting up of a time-limited cross-agency Working Group, chaired jointly by Rachel Bosworth and John Quinn, to explore the issues further. A more detailed analysis with options for taking forward this work would be made to CET in the coming months.

**Action:** Communications division and IMD to establish time limited cross agency group to explore these issues further, with a view to a more detailed analysis for CET in the coming months

## **GOVERNANCE & DELIVERY**

### **8. Conflicts of interest (COI) – processes for handling COI/governance arrangements (CET/15/283)**

8.1 Patience Wilson outlined the existing policy for handling conflicts of interest (COI) between the different centres in the agency. This was agreed and put in place in April 2013, following the merger with NIBSC and launch of CPRD the previous year. Under the policy it was envisaged that the majority of potential COI would be handled at an operational level and mechanisms were developed to avoid – or where necessary handle - potential COI. An escalation process was put in place to manage those exceptional cases where NIBSC or CPRD considered that there might be justification in undertaking activities that fall outside agreed parameters. The process involves consideration of the case by a CET subgroup with the possibility of further escalation to a Board subgroup. Where exceptional cases are agreed, an arrangement is in place whereby the agency can ask another EU regulator (either Germany or Ireland) to provide any necessary independent oversight of the activity that gave rise to the perceived COI.

8.2 The CET agreed that the policy should be updated to reflect the experience gained over recent years. It will be expanded to cover financial COI. The role of the Chief Executive was highlighted, in receiving advice from the CET subgroup, and in deciding on whether to escalate to the Board. It was agreed that the policy would be updated and submitted to CET for approval in early 2016.

**Action:** Policy to update the COI policy and submit to CET for approval

### **9. Update on the falsified medicines & medical devices campaign (CET/15/284)**

9.1 [Redacted under section 40 of the FOIA (personal data)] presented an overview of the falsified medicines and devices communications campaign phases and activities over the next 2-3 years, beginning in January 2016 with the promotion of the Falsified Medicines Directive logo. Agreement was sought from CET to the detailed approach. The CET had in September 2015 supported the concept of a major public facing campaign and in November the Board also supported the proposal. It was noted that comprehensive desk research has highlighted the medicines and devices on which to focus: slimming pills; erectile dysfunction; condoms; self-test kits; cognitive enhancers; and dental equipment (hand pieces). Engagement with the medicines and devices trade associations has already begun and this includes discussions about the possibility of joint-funding towards aspects of the overall campaign. Discussions are also taking place with other stakeholders, including other government departments, to ensure alignment with other associated communications campaigns.

9.2 The CET noted and agreed the campaign objectives, key messages, and the phases of the campaign. Following the initial focus on the FMD logo, as outlined above, phase 2 will test our key messages and channels on 18-30 year olds, including extensive work on social media. Phase 3 will focus on Operation Pangea with Phase 4 targeting slimming pills. The remaining areas of focus and repeat/reinforcement of previous phases will be delivered throughout 2017 and 2018.

9.3 The CET supported the proposed approach and agreed the estimated costs. The CET noted the potential to learn from other regulators, both within the UK in other areas, and in an EU and international context. Seeking additional sources of funding through partnership working was also supported. It was noted that the Professional Assurance Communications Control process will apply and that approval for the

overall cost, which is in the region of £731,000 - £909,000, will need to be approved by DH, DH minister and Cabinet Office. A further update will be provided to CET in April 2016.

**Action:** Communications to progress the Cabinet Office exemption

## **10. Annual report structure and timetable (CET/15/285)**

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented an overview of plans to produce the Annual Report and Accounts 2015/2016. This included the proposal to follow the same format as last year of producing a narrative based on the corporate plan themes. This approach was agreed by CET. It was noted that some changes to the format and content had been introduced centrally and these would be incorporated as the requirements become clearer. The CET also agreed the proposed production timetable. Contributions to the Annual Report will be sought from divisions and centres in the New Year.

## **11. Customer insight research into Licensing: follow up report (CET/15/286)**

11.1 Siu Ping Lam and [Name redacted under section 40 of the FOIA (personal data)] presented a progress report on work to address areas for improvement identified in the customer insight research into Licensing. The CET noted that the customer insight research had confirmed that the agency has a strong reputation, particularly in terms of its licensing and scientific advice functions. Some areas for improvement were identified (including cost, some areas around customer services and communications with assessors) and these have been explored more fully. A number of recommendations were provided in the report with designated leads and timelines for completion and these were all agreed by the CET.

## **12. Health and Safety 6-monthly Report (CET/15/287)**

12.1 [Name redacted under section 40 of the FOIA (personal data)] presented an interim Health and Safety Report covering the period April to November 2015. The CET noted the key elements of the report including: the performance against KPIs; the results of NIBSC and MHRA internal and external audits; the improvements to risk management; health and safety training delivered to appropriate staff; incident and accident reporting; and H&S communications.

12.2 The CET reviewed the amber and red status KPIs and further information on the specific reason that each one was not currently on track. The single Red status KPI - relating to total number of 'near miss' reports within the Accidents/Incidents Group - was discussed by CET. Although assessed as Red by virtue of showing a negative trend (in this case an increasing number of reports), the CET thought this may be symptomatic of an increase in profile across the agency of staff H&S responsibilities and better information on how to report events and near misses. With this in mind the CET supported the proposal to review the KPIs to that the final list adequately represents the actual H&S risks present across the agency and the trends that would cause real concern.

## **13. Managing Change – People and Posts (CET/15/288)**

13.1 Vanessa Birchall-Scott outlined the exit routes currently available to staff. This was in response to a CET discussion in April 2015. The CET noted the very helpful document and asked for a further section to be added setting out 'probation' processes and the options available to recruiting managers when a probation period ends.

## **14. Equality and Diversity objectives and pledge (CET/15/289)**

14.1 Vanessa Birchall-Scott presented an update on the work to develop and publish three equality and diversity objectives. This need has arisen as part of the Equalities Act 2010, which requires all public bodies to publish at least one specific and measurable equality objective. For the agency, three objectives have been developed, which correspond to the three equality areas that were agreed by CET in September 2015 (Business/services; Employer; and Estate/site owner). The CET agreed the objectives in principle subject to some minor alteration and clarification (to be confirmed in writing). The associated means of measuring the success of each objective were also agreed.

14.2 In addition, the agency is required by the Civil Service Talent Action Plan to produce a senior leadership team pledge on diversity. The CET agreed that for the agency a single pledge should be agreed and the proposed wording was endorsed subject to a small change. The updated objectives and pledge would be updated and sent to CET for information. They would then be made available to staff via a dedicated Equality and Diversity INsite page.

**Action:** HR to update the equality and diversity objectives and pledge and send to CET for agreement in a written procedure

## **15. Employee Benefits (CET/15/290)**

15.1 Vanessa Birchall-Scott presented an update on the development of an improved employee benefits package, including the launch of the new Civil Service Benefits Portal. The CET noted the results of the research into the range of benefits currently on offer, which took place in July and August 2015, as well as the results of the employee benefits staff survey, which ran in October/November. The INsite survey indicated that for the majority of respondents (426 staff members completed the survey) the ability to work flexibly, annual leave provision, and the Civil Service Pension schemes are the benefits they value most. A number of suggestions for additional benefits were suggested by staff and these were all noted by CET. The CET agreed the analysis of those additional benefits that might feasibly be implemented in 2016; those that will form part of the Civil Service Benefits Portal offer from April 2016; and those that are not considered to be feasible at this time.

15.2 The CET suggested that further work should be carried out to classify the benefits into those that apply to different profiles of staff (e.g. CS terms/Agenda for Change; SCS/integrated paybands; BPR/South Mimms). In addition, in the communications to staff, the benefits should be placed in the wider context of the less tangible benefits of working in the agency (e.g. the rewarding nature of working to protect public health).

**Action:** HR to classify the benefits into those that apply to different profiles of staff (e.g. CS terms/Agenda for Change; SCS/integrated paybands; BPR/South Mimms) and to work on internal communications

## **16. Performance/Talent planning for 2016, including implementation of 360 feedback process for SCS staff (CET/15/291)**

16.1 Vanessa Birchall-Scott presented an update on talent/planning for 2016 including implementation of 360 degree feedback process for SCS staff. The CET noted that all Civil Service organisations are required to implement 360 degree feedback processes as part of the performance management cycle by March 2016. At the March 2015 CET meeting it was agreed to implement 360 degree feedback for the SLG and a small number of specific g6/7 posts (67 posts in total). The CET heard that it had been seen as broadly positive. The main concern was the opportunity cost of providing feedback, particularly where an individual was asked to provide feedback to several colleagues.

16.2 The revised approach takes the total number of staff required to seek 360 degree feedback to 121 (including a small number of g6/7 posts as last year).

16.3 The CET noted the lack of discretion in whether, and how, to implement the requirement. However it was suggested that conducting a feedback exercise every 2 years (staggered to even out the workload year on year), rather than annually, might achieve the same benefits with lower 'overheads'. It was agreed to determine whether other similar bodies (e.g. HTA, PHE) share the agency's concerns with a view to seeking changes centrally for the following year. Evidence will be collected in the coming year (e.g. case studies, quantification of opportunity cost, if possible) to support discussions.

16.4 The CET agreed the recommended timetable for implementation with the process being commenced in January so that feedback can be available in mid February for discussion in the appraisals process. Training for managers on the process will be made available and well-publicised.

**Action:** HR to roll out the 360 degree feedback process to all SCS staff in January; (ii) HR to speak to other similar bodies about concerns; (iii) HR consider further the best way to collect evidence about the opportunity costs versus the benefits

## **17. Finance and Procurement Report (CET/15/292)**

17.1 [Name redacted under section 40 of the FOIA (personal data)] presented the monthly Finance and Procurement report for the month of October and for the first seven months of the 2015/2016 financial year. The CET noted the agency's total operating surplus for the year to 31 October of £15.5m against a budgeted surplus of £7.6m. The operating surplus comprised £8.3m, £4.5m and £2.7m for the regulator, NIBSC and CPRD respectively. The cash position at 31 October stood at £217.9m and trade receivables were at £22.6m. The CET noted the significant expenditure variance on staff costs, which are now £2.8m (6%) below budget. The CET noted the Income Risk Assessment, the information on deferred revenue and the statement of financial position. The CET noted the 2015/2016 Forecast Summary, which indicates a maximum favourable and unfavourable in-year retained surplus forecast of £24.6m and £17.7m respectively (2.4% range).

17.2 [Redacted under section 43 of the FOIA]

## **18. Corporate Risk Register (CET/15/293)**

18.1 Richard Humphreys presented the agency's Corporate Risk Register (CRR), which was last seen by CET on 13 October and by the Audit and Risk Assurance Committee (ARAC) on 16 October. ARAC will review the CRR again on 14 January.

18.2 The CET agreed the new or revised text proposed in risks 1, 2, 3, 10, 12, 14, 15, 22(b), 26a, 28, 29 and 30. The addition of the below new risks at Amber status was agreed:

*New Risk 11: Government Digital Service (GDS) do not accept IMD's technical designs and proposed delivery methodologies. The risk is that approval of Business Cases is slowed down or not agreed, and that IMD are directed to use technologies and approaches it does not support, putting at risk the delivery of benefits, and increasing timescales and costs*

*New Risk 24: Accelerated Access Review (AAR): Risk of review which does not adequately take MHRA views into account or cuts - inappropriately - across existing policy and systems.*

18.3 The CET asked for the proposed new Risk 25 to be limited to the risks to income derived from new fee types (in this case for devices and e-cigarettes). The existing fees legislation will remain extant until the new fees legislation comes into force. Finally, the CET agreed to the removal of Risk 32 and to the removal of Risk 27 (but only if the risks of maintaining a paper mountain are reflected elsewhere).

**Action:** F&P to update the CRR to reflect CET's comments and submit to ARAC for discussion on 14 January

## **19. Triennial Review Update (CET/15/294)**

19.1 Jonathan Mogford asked the CET to agree a progress report on the implementation of the recommendations made by the Triennial reviews into the agency, the Commission on Human Medicines and the British Pharmacopeia. These were agreed by CET. They were subsequently submitted to the Board for agreement. A progress report for the agency-wide review will be sent to Cabinet Office in January 2016, which is 6 months after publication of the recommendations. Progress reports were sent for the CHM and BPC reports (which were published earlier) in September.

## **INFORMATION**

## **20. NIBSC SMT update (CET/15/295)**

20.1 The CET noted the update from the NIBSC SMT.

#### **21. CPRD SMT minutes (CET/15/296)**

21.1 The CET noted the minutes of the 21 September SMT meeting.

#### **22. Draft minutes of the 24 November Regulatory Group meeting (CET/15/297) and final minutes of the 29 October Regulatory Group (CET/15/298)**

22.1 The CET noted the draft minutes of the 24 November RG meeting and the final note of the 29 September meeting.

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

23.1 These were all noted by the CET.

Information Management Governance Board (CET/15/299)

Information Management Governance Board (CET/15/300)

Finance Sub Committee meeting (CET/15/301)

SOP Working Group (CET/15/302)

Health and Safety Working Group (next meeting 3 December)

Audit and Risk Assurance Committee (CET/15/303)

Risk Management & Audit Liaison Group (CET/15/304)

#### **24. Agreement of 5 January CET agenda (CET/15/305)**

23.1 The CET reviewed and agreed the agenda for the 5 January meeting subject to some minor alterations.

#### **25. AOB**

None.