



# Medicines & Healthcare products Regulatory Agency

## Minutes (Final)

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| <b>Title of meeting</b> | Corporate Executive Team formal monthly meeting |
| <b>Date</b>             | 11 August 2015                                  |
| <b>Time</b>             | 09.00 – 13.00                                   |
| <b>Venue</b>            | R-T-410, BPR                                    |
| <b>Chair</b>            | Ian Hudson                                      |
| <b>Attendees</b>        | CET   |
| <b>Apologies</b>        | John Quinn, Stephen Inglis                      |

CET attendees:

|                        |  |
|------------------------|--|
| Ian Hudson             | Chief Executive (Chair)  |
| Peter Commins          | Chief Operating Officer and Director of Finance  |
| Rachel Bosworth        | Director of Communications   |
| Phil Minor             | deputising for Director of the National Institute for Biological Standards and 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  |
| Andrea Johnson         | deputising for 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 John Quinn, Director of Information Management Division and Stephen Inglis, Director of NIBSC. 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 14 July Corporate Executive Team meeting (CET/15/179) including Table of Actions) and final minutes of the 19 June Corporate Executive Team (CET/15/180)

2.1 The draft minute of the 14 July CET meeting were agreed. The CET reviewed the table of actions

and an updated version was subsequently sent to CET. The final minutes of the 19 June CET meeting were noted.

### **3. Draft minutes of the Agency Board meeting of 20 July (CET/15/181) and final minutes of the Agency Board meeting of 22 June (CET/15/182)**

3.1 These were noted.

## **STRATEGY**

### **4. Vigilance Strategy (CET/15/183)**

4.1 June Raine and John Wilkinson introduced the Vigilance Strategy and asked [redacted] to outline the strategy in detail. The CET heard that the strategy aims to directly support the agency's primary objective, to enhance and safeguard the health of the public ensuring that medicines and medical devices work and are acceptably safe. It builds on the work already completed to put in place a single reporting tool for adverse drug reactions, device adverse incidents, counterfeit products and defective medicines. The CET heard that that the strategy takes into account the recent and ongoing changes to the UK healthcare system, including the replacement of NRLS, as well as the findings of the reports by Francis, Berwick, and Stephenson.

4.2 The CET agreed the overall strategic objectives for the strategy, namely to: move towards practice vigilance, to ensure a joined up approach across the agency improve MHRA's signal detection capability; improve signal and risk assessment including acquiring access to wider vigilance data pools such as CPRD; improve MHRA's ability to deliver and target safety and learning messages; improve benefit/risk assessment; and ensure effective capture of information from incident reports and also the wider scientific evidence base, including social media information and other technologies such as the YC App. The CET agreed that the strategy should cover only the elements currently included in the single reporting portal - therefore blood would be excluded. The CET agreed the proposal for an internal steering group to be established to further develop the strategy and oversee implementation. The CET asked the steering group to look at any vigilance best practices in Europe and beyond. It was also agreed that understanding UK health and social care environment, and the interfaces with the agency's vigilance activities, was also important. This would include links to the devolved administrations and the systems in place in those territories. The CET also suggested that part of the work to further develop the strategy should involve an analysis of the user journey, from the initial identification of reportable event, input to the agency and subsequent analysis, through to subsequent regulatory action and outward communication. In developing specific proposals for change the CET asked the steering group to be mindful of the need to avoid increasing the practical burdens on reporters. The CET agreed that any additional resource requirements should be the subject of individual business cases. Finally, the CET agreed that the paper should be presented to the Agency Board once modified to take account of the CET comments. A Board champion for the strategy would be proposed in due course, following discussion with the Chairman.

**Action:** VRMM to update the paper to reflect CET's comments before submitting to the September or October Agency Board.

### **5. Vaccine pharmacovigilance - key challenges for 2015/16 (CET/15/184)**

5.1 [redacted] presented a paper outlining the key vaccines pharmacovigilance challenges for the current year. The CET heard that two major new immunisation campaigns to protect against meningococcal group B and W are about to commence across the UK. In addition there is some public concern about a possible safety signal in relation to human papillomavirus (HPV) vaccine and MHRA is now leading on an EU referral of the issue. These issues present an opportunity for the agency to show leadership in evidence-based decision-making and the quality of UK expertise and data. In each case, the agency will seek to strengthen and make best use of internal networks, particularly joint working across the agency's three centres. The CET agreed that the VISION network will have an important role to play. The

CET noted that dedicated resource will be required over the next 12 months to actively gather robust data and fulfil our obligations in meeting these challenges. The CET suggested that a dedicated spokesperson should be identified to lead on communications for each vaccination programme.

**Action:** VRMM to identify a nominated spokesperson for each immunisation campaign

## GOVERNANCE & DELIVERY

### 6. NIBSC Quarterly Report (CET/15/185)

6.1 Phil Minor presented the NIBSC Quarterly Report, which the CET noted. The CET heard that all of the NIBSC objectives, targets and key performance indicators are on track, besides two. These are on the launch of the new CT-LIMS system for batch release control, and the work to enable NIBSC to securely access regulatory information to support control testing activities. For both of these IMD were asked to provide an update on progress to CET.

**Action:** IMD to provide an update to CET on the progress of CT-LIMS and enabling secure exchange of regulatory information with NIBSC

### 7. Monitoring report on business plan targets and activities for Quarter 1 (CET/15/186)

7.1 [redacted] presented the Q1 monitoring report for the agency's 2015-2016 Business Plan targets, activities and metrics. In summary, the agency is on track to meet all but two of its performance targets. The two that are not currently on track are: PM7(b) increasing population cover of primary care data within CPRD to 20% by year-end; and PM8(b) answering at least 80% of PQs within a set deadline. [Section 35 redaction: formulation of government policy]

7.2 The CET noted progress against the strategic activities and the actions in place to mitigate the risk of delay for some activities. The CET also noted the metrics that were provided.

### 8. Investors In People (CET/15/187)

8.1 [redacted] presented a summary of the renewal process for Investors in People (IIP) reaccreditation and asked for comments from CET on the scope of the agency's IIP ambitions. The CET heard that the agency achieved Bronze accreditation at the last renewal stage. This predates the launch of CPRD and merger with NIBSC and so only applies to the regulatory and corporate divisions. The CET heard about the potential benefits of achieving reaccreditation and the opportunity to stretch and go for the silver accreditation, although it was recognised that the agency had not fully realised the benefits of the existing Bronze accreditation. It was thought that in recent years the IIP standard had lost some of its profile. It was noted that in some parts of the agency an IIP action plan is still in place, linked to the staff survey action plan and other improvement tools. The CET thought that on balance the agency should seek reaccreditation against bronze for the regulatory and corporate parts of the Agency, commencing with an informal review by the IIP inspectors to inform the final decision. The inclusion of NIBSC would require further discussion. CET also asked HR to investigate whether other government departments are still pursuing IIP accreditation or whether there were other more effective organisational development standards that might be an alternative. HR also agreed to look into the governance of IIP and whether it remains in public sector ownership. The CET agreed that the option of a 3 month extension to the December deadline for reaccreditation should be pursued. The scale of the agency's ambitions would be considered again following the health check, although the initial feeling was that aiming to move from 'bronze' to 'silver' accreditation may be premature and it was not clear whether there would be any value in doing so at this stage. It was agreed that CPRD would be considered for inclusion at a later point (not to be included in the proposed reaccreditation) on the basis that its focus at present was on developing the business and the team.

**Action:** HR to investigate whether other government departments were still using IIP and also to look into the governance of IIP (public sector or otherwise)

## 9. Talent Management (CET/15/188)

9.1 Vanessa Birchall-Scott and [redacted] presented an update on the agency's Talent Management Strategy. The CET noted the update and in particular the roll out of the initial phase of the 5 year strategy, involving the identification of SCS2 staff and their direct reports at SCS1 level for the Civil Service and DH talent management programmes. It was noted that HR will be exploring specific development support for staff that did not wish to be nominated for these programmes or who were unsuccessful. The CET noted that the next phase involves rolling out the agency's talent management programme, including training on conducting career conversations and on using the 9 box grid, to all SCS1 staff and also piloting the approach in both Policy and IE&S for staff at all grades in those two divisions. This will commence in October 2015. The CET asked HR to provide a map of all of the career progression programmes available to staff. The CET also agreed to review progress with the programmes, including discussion on how they fits into the overall L&D offering in early 2016, as well as to hold a discussion in early 2016 about future leadership talent and succession planning. It was agreed that the agency Talent Management approach needed to be the focus and CS/DH programmes were one of many tools to be utilised.

**Action:** HR to provide a map of all of the career progression programmes available to staff, to return to CET with an update on the scheme and how it fits into the overall programme of L&D, and to organise a CET discussion on talent and succession planning in early 2016.

## 10. Equality and Diversity – agency responsibilities, current position and plans (CET/15/189)

10.1 Vanessa Birchall-Scott presented a paper describing the agency's equality and diversity responsibilities and outlined a number of proposed next steps. The CET noted the legal requirements set out in the Equalities Act 2010, including the general duty, which applies to all organisations, and the specific duty, which applies only to public sector organisations. The CET noted that the general duty includes a requirement to collect information and data on equality and to assess the impact of key policies on staff holding one or more of the eight 'protected characteristics' set out in the Equalities Act. The specific duty adds further obligations, including the requirement to publish equality information, prepare and publish equality objectives, and monitor compliance. The CET noted that the focus to date on staff and on buildings (disability access in particular) made sense and that this should continue alongside a focus on those areas of business that also required consideration.

10.2 The CET noted the initial assessment of the agency's compliance with the equality requirements. Although there is a great deal of good practice across the agency, the CET agreed that there was a need to sharpen the agency's performance in some areas. The CET agreed the proposal to identify equal opportunity officers and asked Vanessa Birchall-Scott to lead with [redacted] and a nomination from Policy division to act as champions for specific areas of equality (employment, estate and business respectively). The CET also supported the reconvening of the Equality and Diversity Group. The CET reviewed and agreed the proposed ToR for the group, subject to the addition of a duty to report to CET if there are concerns about compliance with equalities requirements as required. Vanessa Birchall-Scott agreed to seek nominations from divisions. The remaining recommendations were agreed, including the development of equal opportunity objectives for the organisation. These would be agreed by CET at a later date.

**Action:** HR to: confirm the equal opportunities champions; seek nominations for the E&D Group; propose organisational objectives on equal opportunities; and prepare a report for the October AB

## 11. Quarterly report on division and centre bonus allocation (CET/15/190)

11.1 Vanessa Birchall-Scott reported on the quarterly monitoring report on the special bonuses awarded across the agency from 1 January 2015 to 31 March 2015. This was noted by CET. The CET agreed that it was difficult to draw meaningful conclusions from the statistics in many places – particularly those that profile the types of staff that are receiving bonuses. The CET therefore supported the proposal for HR to

seek statistical expertise from Licensing division so that the next report can identify any outlier trends. It was noted that similar support with analysis was required with the earlier staff diversity information.

**Action:** Licensing to provide analytical support to HR

## 12. Performance Management – Annual Objectives (CET/15/191)

12.1 Vanessa Birchall-Scott presented a sample of staff annual objectives across all grades and divisions. The aim was to provide assurance to CET about the robustness of objectives and comparability and consistency within grades. The CET noted the report and agreed that there was a wide variation in the quality and consistency of objectives, even within divisions at the same grade. The CET agreed that any good practices within divisions should be shared more widely. The CET also supported the suggestion that divisions may benefit from a peer review of a sample of objectives at the beginning of each year. In this respect divisions were invited to 'buddy up' with another division with a view to comparing objectives. CET asked HR to continue to work on this, and think further about how best to ensure a more robust and consistent approach.

**Action:** HR to continue to work on this, and think further about how best to ensure a more robust and consistent approach

## 13. Finance and Procurement Report (CET/15/192)

13.1 [redacted] presented the monthly Finance and Procurement report for the month of June and for the first quarter of 2015/2016. The CET noted the agency's total operating surplus for the year to 30 June of £7.9m against a budgeted surplus of £3.5m. The operating surplus comprised £4.4m, £2.7m and £0.8m for the regulator, NIBSC and CPRD respectively. A major component of the agency's performance was MHRA (Regulator) income, particularly from DCP RMS, which is £2.0m above budget, and NIBSC income, which is £1.1m above budget. The CET also noted that income from CPRD clinical trials had been generated for the first time in Q1 and stood at £0.07m at 31 June 2015.

14.2 The CET noted the Statement of Financial Position (SFP) and the analysis and illustration of debtors, receipts and payments on account.

## INFORMATION

### 14. NIBSC SMT Report (CET/15/193)

14.1 This was noted by the CET

### 15. CPRD SMT Report (CET/15/194)

15.1 This was noted by the CET

### 16. Draft minutes of the 28 July Regulatory Group meeting (CET/15/195) and Final minutes of 30 June Regulatory Group (CET/15/196)

16.1 These were noted.

### 17. Updates from Cross-Agency teams

|  |                           |
|--|---------------------------|
| Information Management Governance Board (next meeting 2 September) | Peter Commins             |
| Finance Sub Committee meeting (18 June final)                      | CET/15/197 Peter Commins  |
| SOP Working Group (6 July, draft)                                  | CET/15/198 Gerald Heddell |
| Health and Safety (next meeting 3 September)                       | Stephen Inglis            |
| Audit and Risk Assurance Committee (11 June draft)                 | CET/15/199 Peter Commins  |

**18. Agreement of 15 September CET agenda (CET/15/200)**

18.1 This was agreed, subject to the deferral of the CPRD quarterly report to the October meeting.

**19. AOB**

19.1 The CET agreed the Agency Board forward programme of business and provided some minor comments.