



# Medicines & Healthcare products Regulatory Agency

## Minutes (final)

CET/17/180

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	09 May 2017
<b>Time</b>	09.00 – 12.00
<b>Venue</b>	G1, BPR
<b>Chair</b>	Ian Hudson
<b>Attendees</b>	CET
<b>Apologies</b>	John Wilkinson

### CET Attendees

Ian Hudson	Chief Executive (Chair)
Jon Fundrey	Chief Operating Officer
Vanessa Birchall-Scott	Director of Human Resources
June Raine	Director of Vigilance and Risk Management of Medicines
Anne Paskin	DH Legal Services
John Quinn	Director of Information Management
Janet Valentine	Director of the Clinical Practice Research Datalink
Christian Schneider	Director of the National Institute for Biological Standards & Control
Rachel Bosworth	Director of Communications
[Name redacted under section 40 of the FOIA (personal data)]	deputising for Director of Devices
Jonathan Mogford	Director of Policy
Siu Ping Lam	Director of Licensing
Gerald Heddell	Director of Inspection, Enforcement and Standards

### Additional attendees

Andy Gregory (Policy) for items 4: Brexit – oral update and discussion and 5: Brexit – IMD Brexit European Systems Analysis  
Richard Humphreys (F&P) for items 4: Brexit – oral update and discussion 5: Brexit – IMD Brexit European Systems Analysis and 13: Finance and Procurement Report  
Ian Feavers and [name redacted under section 40 of the FOIA (personal data)] for item 6: NIBSC Biotech Extension  
[Name redacted under section 40 of the FOIA (personal data)] for item 9: Whistleblowing policy and procedure  
Patience Wilson (Policy) for items 9: Whistleblowing policy and procedure and 12: End of year monitoring report for the Agency's 2016-17 Business Plan targets, activities and metrics  
[Names redacted under section 40 of the FOIA (personal data)] for item 12: End of year monitoring report for the Agency's 2016-17 Business Plan targets, activities and metrics  
[Name redacted under section 40 of the FOIA (personal data)] for all items

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

1.1 Apologies were received from John Wilkinson and Paul Wright.

**2. Draft minutes of the 11 April Corporate Executive Team meeting (CET/17/125) including table of actions and final minutes of the 03 March Corporate Executive Team meeting (CET/17/126)**

2.1 The draft minutes of the 11 April meeting were agreed. The CET reviewed and provided updates on the table of actions. The final minutes of the 03 March meeting were noted.

**3. Final minutes of the 17 March Board meeting and draft minutes of the 24 April Board meeting (CET/17/127)**

3.1 The final minutes of the Board meeting of 17 March and the draft minutes of the 24 April 2017 Board meeting were noted.

## **STRATEGY**

**4. Brexit – update and discussion (verbal) (CET/17/128)**

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

**5. Brexit – IMD Brexit European Systems Analysis (CET/17/149)**

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

## **GOVERNANCE & DELIVERY**

**6. NIBSC Biotech Extension (CET/17/130)**

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

**7. Horizon Scanning (CET/17/131)**

7.1 Christian Schneider presented an update on the horizon scanning work. A post has been created to work with teams on horizon scanning across the Agency; this post will be able to network with the UK and European and worldwide infrastructures. Interviews will be held in May for this post. The horizon scanning group meets 3-4 times a year; this will be chaired by the new colleague in future. [Redacted under section 43 of the FOIA (Commercial interests)]. The horizon scanning summary was sent to OLS for information.

7.2 The CET thanked Dr Schneider for the update, and noted that the horizon scanning group would consider who is best in the Agency to take forward the four areas of interest. It was noted that there are opportunities for the UK in relation to the future of clinical trials for medical devices which the horizon scanning group should look at. The CET agreed that the next step should be to hold a seminar available to present the findings more widely; and to agree the relevant teams in the Agency to take forward the areas of particular interest.

**8. Academic Relationships (CET/17/147)**

8.1 Christian Schneider presented an update on the progress in building and maintaining academic relationships across the Agency. Academic relationships are an agreed and important strategic component of the Agency's current and future work. Academic links have

to be maintained after their formal establishment, and the number of activities, also including new partners, has increased or may soon expect to increase with new senior staff arriving. Four main areas have been identified in which to establish academic links which are strategically important to the Agency and to the UK's life science sector. The areas identified are regenerative medicine, clinical trial design, supporting emergency response to disease, and use of real world data. The CET heard updates on progress in the four main areas. It was proposed that CET would be given yearly updates on the academic relationships work.

8.2 The CET noted that it is the responsibility of the operating divisions to ensure that there are good links to take forward the day to day work; and all operating teams should have this as part of their priority work. A cross-agency network should be established with members nominated from each division and area of interest. If strategic opportunities present themselves, it was proposed that the new colleague in the horizon scanning post should take these forward.

**Action:** Set up cross-Agency network to focus on academic relationships

## **9. Whistleblowing policy and procedure (CET/17/133)**

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on the whistleblowing policy and procedure. The document presented to CET contained a number of changes proposed as a result of learning from the last whistleblowing case, suggestions from NAO as well as changes to make the document clearer and more helpful. The format had also been changed to fit the Agency's new policies and procedures template. The option to offer whistleblowers the opportunity to be assigned a buddy, if they wished, was discussed. The CET commented that an appropriate buddy from within the Agency would be offered to whistleblowers, who would waive their anonymity to this buddy if they accepted. The CET discussed whether it would be appropriate for a whistleblower to be temporarily removed from their post for the duration of the investigation; the CET agreed that this should only be undertaken, if appropriate, if the identity of the whistleblower is known and it would not be possible or appropriate for them to continue their work – it was agreed that more active language should be used in the policy in this regard.

9.2 The CET considered whether it is appropriate for someone independent of the whistleblowing case to evaluate handling after the event. It was agreed that this would be appropriate; and that a senior member of staff with general management experience would be relevant for this role. It was noted that the policy states that concerns will be treated as alleged until proven; however this should be strengthened to make clear that managers also have a responsibility to look after the welfare of the person against whom the allegation is made. The CET noted the work on raising awareness of whistleblowing within the Agency. It was also noted that staff who are members of professional bodies may have a duty of care to report certain activities – this should be reflected in the policy but should only be contemplated after exhausting all internal/CS measures.

## **10. End of year monitoring report for the Agency's 2016-17 Business Plan targets, activities and metrics (CET/17/132)**

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented the end of year monitoring report for the Agency's business plan targets. 34 targets out of 39 were met from 2016-17; of the 103 activities due to be completed, 88 were completed and 15 were postponed, four of which were due to factors outside MHRA's direct control, which the CET noted. The CET gave comments on the outstanding targets.

## **11. Annual report 2016/17 (CET/17/134)**

11.1 Rachel Bosworth presented an updated draft of the Annual Report for 2016/17, which the CET noted and gave comments on. It was noted that colleagues in Comms division have been working on infographics to display some of the Agency's work, which will be included in a later draft of the report.

## **12. Annual pay guidance, 2017 (CET/17/135)**

12.1 Vanessa Birchall-Scott presented the annual pay guidance paper. The Civil Service Pay Guidance for delegated grades was published on 21st April 2017. The Senior Salaries Review Body (SSRB) report on SCS pay for 2017 has been delayed by the election related purdah and is now not expected until June 2017. The CET were presented with an outline of the key aspects of the delegated grade guidance and were asked to agree the Agency's approach for 2016/17, including an in principle discussion about SCS. The CET agreed the recommendations in the paper; including basing the remaining 1% award on the median of each pay band and paying this as a flat rate sum to all of those within each pay band, as was done in previous years. It was agreed that when the modelling is undertaken, the impact of market pay supplements should be considered. Any pay anomaly cases should be put forward for the SCS pay committee.

## **13. Finance and Procurement Report (CET/17/148)**

13.1 Richard Humphreys presented the draft financial performance of the Agency for the 2016/17 financial year; and noted that these figures are subject to audit. Before further year-end adjustments but after allowing for Dividends and Financing, the Agency has a draft retained surplus of £10.0m which is £3.2m above budget. After final year-end accounting adjustments, the Agency is forecast to deliver a retained surplus in 2016/17 of £9.5m which is £2.7m above budget. The forecast includes known changes that will be made before the final accounts are published but is subject to change. It was noted that the Agency has achieved the triennial review objective of bringing the regulator in to balance. The CET noted the report.

## **14. Agreement of team briefing notes**

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

## **INFORMATION**

### **15. CPRD SMT Partners Meeting Minutes (CET/17/137)**

20.1 The CPRD SMT Partners Meeting Minutes were noted.

### **16. NIBSC monthly briefing for CET (CET/17/146)**

21.1 The NIBSC monthly briefing report was noted.

### **17. Draft minutes of the 25 April Regulatory Group meeting & final minutes of the 21 March Regulatory Group meeting (CET/17/138)**

22.1 The draft minutes of the **25 April** Regulatory Group meeting and the final minutes of the 21 March Regulatory Group were noted.

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

23.1 These updates were noted by the CET:

Information Management Governance Board (IMGB)	CET/17/139
Finance Sub Committee meeting	CET/17/140
Policy and Procedures Committee	CET/17/141
Audit and Risk Assurance Committee	CET/17/142
Risk and Audit Liaison Group	CET/17/143

#### **19. Agreement of 6 June 2017 CET agenda (CET/17/145)**

24.1 The CET agreed reviewed and commented on the draft agenda for the 6 June CET meeting. It was agreed that a number of items had still to be confirmed; relevant directors would advise Directorate.

#### **20. AOB**

20.1 The CET discussed the DECIDE study.