



# Medicines & Healthcare products Regulatory Agency

## Minutes (FINAL)

<b>Title of meeting</b>	Corporate Executive Team formal monthly meeting
<b>Date</b>	05 January 2016
<b>Time</b>	09.00 – 13.00
<b>Venue</b>	R-T-503, BPR
<b>Chair</b>	Ian Hudson
<b>Attendees</b>	CET
<b>Apologies</b>	Jonathan Mogford, Gerald Heddell, Rachel Bosworth, John Wilkinson

Ian Hudson	Chief Executive (Chair)
Peter Commins	Chief Operating Officer and Director of Finance
[Redacted]	deputising for Director of Communications
Stephen Inglis	Director of National Institute for Biological Standards & Control
Christian Schneider	Director (designate) of National Institute for Biological Standards & Control
Patience Wilson	deputising for Director of Policy
Sam Atkinson	deputising for Director of Inspection, Enforcement and Standards
Vanessa Birchall-Scott	Director of Human Resources
Siu Ping Lam	Director of Licensing
[Redacted]	deputising for 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 redacted under section 40 of the FOIA (personal data)]

### 1. Apologies and Announcements

1.1 The Chief Executive welcomed Dr Christian Schneider, Director (designate) of NIBSC, to his first formal CET meeting. A three-month handover period is in place leading to Dr Stephen Inglis' retirement on 31 March.

### 2. Draft minutes of the 8 December Corporate Executive Team meeting (CET/16/001) including table of actions and final minutes of the 4 November Corporate Executive Team (CET/16/002)

2.1 The CET agreed the draft minutes of the 8 December CET meeting and noted the final minutes of the 4 November meeting.

### 3. Draft minutes of the Board meeting of 9 December (CET/16/003) and final minutes of the Board meeting of 20 November (CET/16/004)

3.1 The CET noted the draft minutes of the 9 December Board meeting and the final minutes of the 20 November meeting.

## **STRATEGY**

### **4. Corporate Plan review, Business Plan 2016/2017 and planning for the Awayday (CET/16/005)**

4.1 Patience Wilson presented a draft programme for the 15 January Board/CET Awayday for agreement. The proposed approach involves short presentations and detailed discussions on: strategic finance objectives; emerging material for the corporate plan refresh; how to optimise the synergies of the agency's three centres and the services that are provided across all business areas to deliver strategic outcomes in terms of our public health role ; ongoing exploratory work about how to develop the agency's services and business in a rapidly changing environment; and, finally, emerging business planning material for 2016/17.

4.2 The CET endorsed the proposed programme and agreed lead directors to present briefly each section. It was agreed that the lead presenters would spend no more than 5-10 minutes outlining key issues and highlights in order to maximise the discussion time. Highlights would cover the activities to be delivered in the remaining period of the current Corporate Plan (i.e. to 2018) as well as the longer term aspirations that might be worked into the following Corporate Plan covering 2018-2023. The CET agreed that in some areas it might be helpful for the lead presenter to discuss informally the areas to be covered with the designated NED topic leads.

4.3 A separate update was presented on the development of the agency's Business Plan 2016/17. The CET noted the material that was circulated, which comprised a proposed list of strategic activities, targets and metrics. It was noted that the overall Business Plan format and the need for targets, activities and metrics is set by DH; DH required a first draft of the business plan to be shared with them by Friday 29 January. The CET agreed that the need for a clear distinction between metrics (which measure, for example, the frequency or volume of events and activities) and targets (which provide a specific performance objective) – even if both exist in the same subject area and also for consistency. The CET also thought that a dashboard style illustration of the most important metrics would be a useful addition to the quarterly monitoring reports in the next business year. The CET noted the importance of continuing to develop outcome based measures. The CET agreed to forward any specific comments on the business planning material to Policy division by Thursday 7 January.

**Action:** directors to forward specific comments on the business planning material to Policy by Thursday 7 January; Policy to incorporate changes and send by Monday 11 January to Directorate for circulation to the CET and Board for the away day. Policy to develop a dashboard of key metrics

### **5. Growth Strategy (CET/16/006)**

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

## **GOVERNANCE & DELIVERY**

### **6. Building academic relationships (CET/16/007)**

6.1 Stephen Inglis and [Name redacted under section 40 of the FOIA (personal data)] presented an update on the progress in the four areas identified by the agency for building academic links, which are: regenerative medicines; clinical trial design; use of real world data to inform medicines evaluation; and supporting emergency response to disease.

6.2 On regenerative medicines the CET noted the key academic connections already established with UCL, Imperial College London and the UK Regenerative Medicines Platform (UKRMP). The relationships with UCL were very well established with a number of measures of success already being demonstrated. For example, the agency (through NIBSC) has a formal MoU with UCL and this is supported by the

secondment of [redacted] to NIBSC to lead the Advanced Therapies Division. The CET heard that the aim for both NIBSC and UCL is for this very productive relationship to continue, with the possibility of additional cross appointments when recruiting to key positions, including the appointment of [redacted]'s successor. The CET noted the progress in developing partnerships with Imperial and the UKRMP.

6.3 The CET noted the progress in clinical trial design, with key academic institutions continuing to play an active role in providing advice through the CHM structure and through interactions with the agency's regulatory divisions, particularly in relation to use of novel clinical trial designs and developments in the field of stratified medicines and genomics. For example, the 10<sup>th</sup> MISG Forum, to which academia makes an important contribution, discussed the use of Basket and Umbrella trials and their regulatory impact. Further discussions are planned with key academic institutions, including MRC, CRUK, UCL and the Oxford Trials Unit. On stratified medicines the key point of interaction is through the Pharmacovigilance and Stratified Medicines Network, based at the University of Liverpool, which meets 2-3 times per year to consider and progress innovative approaches in this area. The CET noted the interactions in the field of genomics.

6.4 The CET heard that the theme on use of real world data would be progressed when the CPRD structural transition is complete. On supporting emergency response to disease, the CET heard that the agency's leading role in supporting the UK Vaccine R&D initiative, which was established in 2015, is the main focus for developing links in this area. This work is co-sponsored by DH, the MRC, the BBSRC and the Wellcome Trust. The agency sits on the central steering group, which is chaired by Chris Whitty (LSHTM). The broad focus is to support the development of technologies and products that may be needed for future emergency response. The group's report is due this year and it is anticipated that it will lead to some specific R&D initiatives involving partnerships between academic laboratories and industry.

6.5 The CET welcomed the considerable work to date and the opportunities that were emerging for wider and deeper collaboration. It was clear that there was great appetite in the academic research community for more collaboration with the agency. The CET thought that securing cross appointments in NIBSC was particularly attractive and might be extended to a number of other areas. It was noted that IE&S already benefit from undergraduate and post graduate placements in the agency to work in areas of mutual advantage. On emergency response the CET agreed that the strategy should incorporate the role of British Pharmacopeia and the links it has established with academia. Further consideration would be given by NIBSC and LD to the future oversight of this work from 1 April, when Dr Inglis retires.

**Action:** NIBSC and IE&S to add BP emergency response activities to the strategy

## **7. Health and wellbeing proposal CET/16/008)**

7.1 [Name redacted under section 40 of the FOIA (personal data)] presented a proposal for a more systematic approach to supporting staff health and wellbeing, with the introduction of an overarching Health and Wellbeing Policy and a co-ordinated action plan, supported by an annual programme of staff activities. The CET heard that the agency can draw on a number of high level indicators to provide an insight into the general health and wellbeing of the workforce. The CET noted the People Survey responses to the wellbeing questions, the main recorded causes of sickness absence and the average rate per employee per year, when compared to other private and public sector organisations. The CET was encouraged by the very positive impact of the Health and Wellbeing Days at BPR and NIBSC in September, with over 250 staff attending the personal resilience sessions included. In October, 349 members of staff also attended a Flu clinic offering free Flu jabs. Feedback from attendees of these various sessions indicated a number of areas for future consideration and the CET noted the proposal to incorporate these in the annual action plan.

7.2 The CET fully supported the proposal for an overarching policy and an annual workplan, and agreed to set aside a budget with which to commission health and wellbeing activities and establish a Health and Wellbeing portal, which provides advice, resources and information. The policy and action plan will ideally be developed by an existing group (possibly the People Survey WG). The CET asked for mental health training to be incorporated and noted the plans for the new Oracle HR system to provide improved sickness absence recording. The overarching policy and action plan would be considered by CET when developed, along with a deeper analysis of the sickness absence statistics. The CET agreed the importance of the

Return to Work discussion with staff following any period of absence so that additional support measures can be put in place at a local or indeed organisational level should any patterns emerge and the need for reasons for absence recording.

**Action:** HR to take forward this work, considering whether the People Survey WG can progress this and incorporating the CET's comments; HR and LD to arrange a deeper statistical analysis of the sickness absence statistics; HR and IMD to consider the Oracle implications

## **8. Civil Service People Survey: text responses and draft agency-wide action plan (CET/16/009)**

8.1 Vanessa Birchall-Scott presented an analysis of the free text responses to the People Survey together with a detailed agency-wide action plan for agreement. The individual free text comments had been sent to CET separately. The CET noted the additional analysis of the free text comments. The updated action plan had been developed following discussions in the Senior Leadership Group and the more detailed analysis of the results, including the free text comments. The CET agreed the action plan, subject to: (i) the addition of further actions on recognising achievements (ii) further consideration of actions to ensure that the 'golden thread', linking staff objectives to the agency's Mission, can act as a source of motivation; and (iii) the addition of some context around the action on training for staff in lower pay grades. Linking reward and recognition to the agency's values would also be considered further.

**Action:** HR to reflect CET's comments in an updated action plan to be agreed by CET in March, along with divisional action plans

## **9. Investors In People update (CET/16/010)**

9.1 [Name redacted under section 40 of the FOIA (personal data)] presented the results of the informal IIP 'health check', which took place in November with the results available in December, together with further reflections on the value of IIP and the status of IIP with other organisations. A proposal for ensuring that the agency has the necessary tools for ongoing organisational improvement was presented for agreement.

9.2 The CET heard that the status of IIP has declined over time, with most of the other government departments and arm's length bodies contacted so far confirming that they no longer use IIP. The CET heard that the IIP health check identified a range of exemplary practices throughout the agency. The main opportunity for improvement was in the demonstration of consistency of approach across a number of areas. The health check indicated that the agency could aim to retain the Bronze standard but that it would probably not be possible by the current March 2016 deadline. It was noted that the agency could be granted 'retainer recognition' for a further 12 months if reaccreditation was not obtained in March, leading to a second assessment the following year. It was also noted that the approach taken by IIP appeared quite mechanistic, being based on documentation rather than itself adding real value to our policies and processes.

10.3 The CET considered the value, advantages and disadvantages of several options, including continuing with IIP, using other organisational audits or awards, and pursuing alternative mechanisms for ensuring continuous improvement. The CET agreed that by and large the agency does not currently use IIP as a business improvement tool. The focus now is on other mechanisms, such as: the People Survey and the divisional and agency-wide action plan; staff engagement initiatives; L&D strategies including Talent Management, career pathways and leadership activities. The forthcoming focus on Health and Wellbeing is another example of business improvement being driven not by IIP status, but from within the organisation. Additionally, all of these mechanisms apply to the agency as a whole and as CET agreed at an earlier meeting, NIBSC and CPRD have no experience of IIP and are not yet in position to join the agency's Bronze accreditation assessment. The CET acknowledged the tremendous effort and time that is required to prepare the evidence needed to support an IIP assessment.

10.4 The CET agreed the recommendation that, on balance, it was not in the agency's best interests to pursue IIP. In addition, the value of using an alternative accreditation body was not clear at present. The CET agreed that the more effective approach would be to continue to use the People Survey as the

principal tool with which to drive action and measure progress, using comparisons with other public sector organisations. The CET did however ask for consideration to be given to an external audit/peer review process, perhaps as a reciprocal arrangement with another organisation. The CET also asked for clarity on the relationship between the agency's business improvement planning and the ISO quality standard and whether they can be more formally linked.

**Action:** HR to prepare materials to communicate to staff and to consider options for a light touch peer review via reciprocal arrangement and look into a potential link with the ISO quality standard

## **10. Skills capability planning (CET/16/011)**

10.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on skills capability planning, which is a cross-Government initiative to build skills and capacity across the civil service in some core transferable areas. The four areas of focus for the agency are: digital skills; project delivery; leading and managing change; and commercial skills and behaviours. Each of these topics has a CET lead director working with existing agency experts and HR L&D to develop proposals to build the agency's capability over the next 12 months. The CET noted progress and agreed the proposal for a staff survey on digital skills, to be sent to all staff in the coming weeks. The CET also noted the approach on project delivery, which is to establish a community of practitioners in the agency to share knowledge and best practice.

## **11. Management & Leadership Development Opportunities (CET/16/012)**

11.1 [Name redacted under section 40 of the FOIA (personal data)] presented an update on some work completed in response to feedback from the People Survey and last year's Managers' Conferences, to provide more clarity to staff on the management and leadership development opportunities available to staff. The CET noted a very helpful summary of the development opportunities within each grade, from AO through to SCS2, which would be promoted across the agency and placed on the refreshed L&D INsite pages. In response to a question about focus on developing those from minority groups, the CET heard that specific opportunities would be considered by the Equality and Diversity Steering Group.. The CET supported the proposal for HR L&D to attend divisional SMT meetings to discuss training needs with a view to updating the summary and generally fill any training needs gaps identified. The CET asked for management and leadership training to be considered alongside the professional development opportunities available to staff.

## **12. CPRD Quarterly Report (CET/16/013)**

12.1 Janet Valentine presented the CPRD Quarterly Report, covering: staff restructure; data acquisition; information governance; partnerships; business development; and observational research. The CET heard that considerable positive progress had been made in all areas. This was particularly impressive in the light of the considerable work and focus to support the staff restructure.

## **13. Finance and Procurement Report (CET/16/014)**

13.1 [Name redacted under section 40 of the FOIA (personal data)] presented the monthly Finance and Procurement report for the month of November and for the first eight months of the 2015/2016 financial year. The CET noted the agency's total operating surplus for the year to 30 November of £17.2m against a budgeted surplus of £9.9m. The operating surplus comprised £9.5m, £4.7m and £2.9m for the regulator, NIBSC and CPRD respectively. Following payment of dividends the overall retained surplus is £12.5m against a budget of £4.9m. The cash position at 30 November stood at £217.4m and trade receivables were at £19.8m. The forecast surplus at year end of £18.0m against a budgeted surplus of £10.5m was noted. The CET also note the detailed income and expenditure accounts including the continuation of the significant expenditure variance on staff costs, which are now £3.1m (6%) below budget

13.2 The CET noted the statement of financial position including the debtors' analysis, deferred revenue and cash positions and the Income Risk Assessment. The CET agreed to review the medium term risk to NIBSC funding received from DH from status Black (very highest risk) to Red (high risk).

**Action:** F&P to review the medium term risk to NIBSC funding received from DH from status Black (very highest risk) to Red (high risk)

## **INFORMATION**

### **14. Quinquennial Review of the Bacteriology Department by external review panel and response from the Head of the Division (CET/16/015)**

14.1 This was noted by the CET

### **15. NIBSC SMT update (CET/16/016)**

15.1 The CET noted the latest NIBSC SMT update

### **16. CPRD minutes:**

a. **SMT minutes (CET/16/017a)**

b. **CPRD Executive Committee minutes (CET/16/017b)**

16.1 The CET noted these minutes

### **17. Draft minutes of the 22 December Regulatory Group meeting (CET/16/018) and final minutes of 24 November Regulatory Group (CET/16/019)**

17.1 The CET noted these minutes

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

18.1 The CET noted these updates

Information Management Governance Board (19 Nov. final)	CET/16/020	Peter Commins
Information Management Governance Board (2 Dec. draft)	CET/16/021	Peter Commins
Finance Sub Committee meeting (15 October final)	CET/16/022	Peter Commins
SOP Working Group (next meeting 11 Jan.)		Gerald Heddell
Health and Safety Working Group (3 Dec. draft)	CET/16/023	Stephen Inglis
Audit and Risk Assurance Committee (next meeting 14 Jan.)		Peter Commins
Risk Management & Audit Liaison Group (11 Nov. draft)	CET/16/024	Peter Commins

### **19. Agreement of 2 February CET agenda (CET/16/025)**

19.1 The CET agreed the agenda, subject to some minor revision.

### **20. AOB**

20.1 Sam Atkinson provided an overview of her visit in December, with Gerald Heddell, to India to speak at the Indian Pharmaceutical Congress and meet Dr Singh (Drugs Controller of India) and a number of regional regulatory heads. The CET heard that the visit was a success and that a full note of discussions will be circulated shortly.