

MHRA Board meeting

Audit & Risk Assurance Committee (ARAC) meeting March 14 2016 REPORT TO THE BOARD

Issue/purpose:

The purpose of this paper is to give an overview of some of the discussions at the March 14th ARAC meeting.

The minutes of the meeting will be circulated in due course.

Summary/Key points: Please see below.

Timings: N/A

Action required:

The Board is recommended to note the discussions from the March 14th ARAC meeting.

Links: N/A

Author(s):

Dotun Adepoju (Secretary - ARAC)

FOI/publication issues: N/A

Sponsor: Deborah Oakley (Chair – ARAC)

The Audit and Risk Assurance Committee met on 14th March 2016. The main business of the meeting was as follows:

1. Internal Audit - PwC – good progress against 2015/16 plan was noted, with almost all the audit reviews planned for the year now completed. The draft plan for 2016/17 was reviewed and approved with some changes suggested.
2. Payroll - The internal audit review of the agency's HR Payroll Processes and Data Flows conducted in October 2015 had been given a 'Limited' assurance. ARAC had at a previous meeting requested additional assurance from the HR Director that the transition approach to the new payroll system mitigates the risks highlighted in the audit report. The assurance was received at this meeting which was welcomed by ARAC. ARAC requested further updates when the move to the new payroll provider is embedded.
3. CPRD - The CPRD KPI Follow Up internal audit review's 'Substantial' Assurance rating was noted. ARAC was pleased to acknowledge the improvement in CPRD and congratulated CPRD management for all their efforts in bringing about the positive changes highlighted in the report.
4. External Audit – NAO thanked the Finance team for providing an early draft of the new annual report and accounts content and reported that there were no issues identified during their interim audit. ARAC noted the good progress and was pleased to hear that the NAO found no issues. ARAC congratulated the Finance team for their efforts.
5. Corporate Risk Register – The Agency's Corporate Risk Register has been updated to the 5x5 risk matrix format, overhauled and risks consolidated as advised by ARAC. ARAC was pleased to note this new format and expressed the view this was more useful.
6. Information security update – A number of the recommendations from the Cyber Security internal audit review conducted in June 2015 which had been given a 'Limited' assurance have since been implemented. Good progress is being made. The move from Accenture to new suppliers was showing good progress and ARAC was pleased to hear that this would be completed on schedule.
7. External fraud – The reports on incidents of regulatory fraud were noted as was the review of the agency's external fraud risk registers. ARAC commended the presentation of both external fraud risk register and the reported incidents of regulatory fraud noting that the presentation of both items for review was good practise. It was noted that the external fraud risk register captured the risks involved in the agency's regulatory work. The reported incidents of regulatory fraud happen at low rates. Staff were continuously being trained to detect incidents.
8. Internal Fraud – The internal fraud risk register was noted as was the agency's revised internal fraud policy paper. ARAC has concern over gaps in the overall responsibility for fraud awareness and prevention and a lack of visibility in respect of training. It was agreed that a further paper on fraud policy would be presented at the next ARAC meeting.
9. Whistleblowing – The Policy paper was reviewed and recommended that the Agency consider whether the NED whistleblowing champion be the final point of escalation within the Agency before escalation to DH and then the Civil Service Commissioners. ARAC requested information from the last staff survey to assess staff awareness of the Civil Service Code which addresses issues around whistleblowing.

The ARAC minutes of January 2016 were agreed and are included below as Annex A for information. The next Audit and Risk Assurance Committee will meet on 17 June 2016.

ANNEX A

Medicines and Healthcare products Regulatory Agency

Audit and Risk Assurance Committee meeting

Thursday, 14th January 2016

Members in attendance:

Ms Deborah Oakley	Non-Executive Director (Chair)
Prof Sir Alex Markham	Non-Executive Director
Mr Martin Hindle	Non-Executive Director

Also in attendance

Medicines and Healthcare products Regulatory Agency

Dr Ian Hudson	Chief Executive
Mr Peter Commins	Chief Operating Officer and Director of Finance
Mr John Quinn	Chief Information Officer (for item 8 – Information Security update)
Mr Richard Humphreys	Deputy Director of Finance
Mrs Kerry McEyeson	Deputy Director of Human Resources (for item 6 – HR Payroll Process and Data internal audit report)
Mr Salim Master	Chief Financial Accountant
Ms Marie Donatantonio	NIBSC Head of Corp Affairs
Mr Dotun Adepoju	Corporate Risk Manager (Secretary)

National Audit Office (NAO)

Ms Felicia Wright	Director
Mr Nicholas Todd	Audit Manager

Health Group Internal Audit Service (HGIAS) / PricewaterhouseCoopers (PwC)

Ms Karen Finlayson	Head of Internal Audit
Ms Naima Ishaq	Engagement Manager

Apologies

Apologies were received from Stephen Lightfoot (ARAC member). He had sent his comments to the Chair ahead of the meeting and these would be incorporated as appropriate. Helen Batty (senior policy manager, DH Sponsor) also sent her apologies but the DH Sponsor team had also sent their comments for the meeting to the Secretary prior to the meeting.

1. Welcome and announcements

As Kerry McEyeson was attending her first ARAC meeting she was introduced to members.

2. Declarations of interests

- 2.1. Martin Hindle (MH) had prior to the meeting declared to the Chair his interest as Chairman of Porton Biopharmaceuticals Ltd and would not take part in relevant papers / discussions although none were expected.
- 2.2. There were no other declarations of interests.

3. Minutes of the last ARAC meeting: 14th October 2015

- 3.1. The minutes were agreed.
- 3.2. Karen Finlayson (KF) observed that the Agenda for the meeting had reflected PwC internal audit final reports “for noting”. She was of the view that these should be shown as “for discussion”.
- 3.3. The Chair replied that they were for noting as discussions on them could not result in changes to the final reports. However there will be discussions if there were internal audit report issues that needed to be addressed by ARAC.

4. Matters arising/Actions list

- 4.1. Item 1 - A standing item - “*IMD to provide updates on the implementation of the Cyber Security review action plan*” Update to be presented by John Quinn at this meeting under the ‘Progress Made against Previous Audit Recommendations’. Paper 16/07.
- 4.2. Item 2 - “*Finance to provide paper setting out how the £30m liability (self-insurance) has been calculated and comparing the MHRA approach with that used in other public sector bodies*”. -Paper 16/16.
- 4.3. Item 3 - “*Richard Humphreys to review other models of governance in government departments with similar arrangements as CPRD*”. Paper 16/12.
- 4.4. Item 5 - Richard Humphreys to review the presentation format of audit tracker and advise ARAC. Paper 16/08.
- 4.5. PwC and NAO to provide clarification to the Agency on whom the ARAC is accountable. Paper 16/02 (Revised copy of ARAC TOR for information).
 - 4.5.1. Feedback from DH Sponsor sent to the meeting via the Secretary drew attention to para 3.6 of the ARAC TOR which listed those who should routinely attend ARAC meeting. This list included a representative from DH. DH advised that it could not commit to this. However as they have access to all the ARAC papers prior to the meetings they will forward any comments/concerns to the ARAC secretariat when a DH rep is unable to attend.
 - 4.5.2. The committee’s view was that the ToR should not be changed as DH’s presence was important.

External Audit (National Audit Office)

5. 2015/16 Draft Audit Plan

- 5.1. Felicia Wright (FW) gave an update informing members that there was little to report for now until the Period 9 audit review commenced. Planning meetings had taken place and a timetable agreed with the Finance team. Field work for P9 to start on 1 February and would last for three weeks. It was also intended that more time would be set aside to spend at South Mimms to review NIBSC processes.

Internal Audit (PwC/HGIAS)

6. 2015/16 Internal Audit Progress report

- 6.1. KF informed members that PwC (HGIAS) was on track to complete the 2015/16 audit plan. A new audit (TSO contract review) has been added to the plan and the ToR agreed. This replaces the planned HR review now pushed back until the new HR system has been implemented.
- 6.2. Naima Ishaq (NI) explained reasons for the including TSO contract review in the revised plan. The request had come from the British Pharmacopoeia (BP) Unit in I,E&S division. TSO (the former The Stationery Office) is responsible for the publication and sale of 'BP' – a publication of standards for UK medicinal substances comprising of six volumes and containing monographs for substances and articles used in the practice of human and veterinary medicines. There is an agreement with the Agency on payment of royalties for publications sold by TSO. The audit will review the current contract and agreement in place.
- 6.3. TSO had suggested a date in February for the audit fieldwork. As a result of the timing PwC (HGIAS) informed members that the audit report may not be ready for the ARAC meeting in March.
- 6.4. Furthermore the new HR New Payroll Process and System will not be in place until quarter 2 or 3 of the next financial year and therefore cannot be reviewed this year. As this audit review has now been deferred to the 2016/17 internal audit plan, the TSO contract review has taken the slot.
- 6.5. KF reported that she had met with the Board Chairman to discuss the terms of reference (TOR) for the Board Effectiveness review. The draft TOR was planned to go to the Board for agreement.
- 6.6. KF confirmed that Board members' views will also be sought. The review fitted into the Agency's own annual governance statement; however, it may not be completed before the next ARAC meeting in March. Nonetheless the report from the review can still feature in the governance statement when produced. KF advised that findings from the audit review can either be used by the Board as a baseline for moving forward or as a benchmark for standards.
- 6.7. Richard Humphreys (RH) asked the NAO to note that the Agency's 2014/15 governance statement reflected its progress with work evaluating Board Effectiveness.

(a) (HR Payroll Processes and Data Flows)

- 6.8. Kerry McEyeson (KM) gave an update of the work on the HR Payroll Processes and Data Flows action points; the audit review had resulted in Limited assurance. HR checked 100% of the Payroll and currently undertakes additional checks to ensure that any leavers moving to DH do not also get paid by the Agency. In addition, from 1st April 2016, Payroll function will be undertaken by another company and therefore the issue of payments to leavers will not be able to re-occur as MHRA will be on one database and the DH on a separate database. If someone left the Agency to join DH, the leaving date is entered on the Agency's system.

- 6.9. The committee were concerned about the limited conclusion particularly in the light of the issues which had arisen some time ago in relation to the transfer of data to the CS pension scheme. The committee enquired about the cleanliness of data moving to the new system. The committee were also concerned about the risks associated with the move to a new payroll provider followed by a new HR & Finance system.
- 6.10. The Chair enquired if a follow up review would be helpful to confirm that the new system was effective. She was assured by PwC (HGIAS) that there will be follow up audit review in due course.
- 6.11. FW informed members that the NAO will also be carrying out additional work on payroll data and this will complement the work done by the internal auditors.
- 6.12. Martin Hindle (MH) enquired about the July 2016 implementation date stated for the high risk recommendation in the audit report which stated "*A report of all changes to standing data should be produced from the payroll system and reviewed on a monthly basis*".
- 6.13. Peter Commins (PC) explained that a parallel running was scheduled for April to June 2016 which will provide further assurance hence the July 2016 implementation date stated for the audit recommendation.
- 6.14. The Chair asked about who was going to be responsible for ensuring the recommendations in the audit report were fully implemented and for the transfer to the new payroll provider. PC informed members that this will be Vanesa Birchall-Scott, Director of HR.
- 6.15. The committee concluded that this remained an area of high risk. The Chair asked that the Director of HR attend the next ARAC meeting for feedback and update to the committee.

(b) NISBC Income Review

- 6.16. The NIBSC Income review audit report Moderate Assurance rating was noted.

(c) Agency Business Continuity Planning

- 6.18. The Business Continuity Planning audit report Moderate Assurance was noted. SL had sent comments enquiring about the complexity and fragility of the Agency's IT systems and whether individual plans were required for each system. John Quinn (JQ) informed members that the complexity and integration of the current systems means that individual system recovery plans cannot be produced. Disaster recovery was based on the platforms not individual systems. As the Agency replaces its estate greater granularity will be possible. Activity was currently underway to identify priority systems to ensure business continuity plans and disaster recovery plans align.
- 6.19. MH drew the attention of JQ to para 3.8 of the Business Continuity audit report which said: "*IT Disaster Recovery Order: – The Agency's IT Disaster Recovery plan and procedures have not been reviewed in light of the refreshed business impact analyses. Therefore, the current recovery order may not be aligned to the Agency's requirements*".
- 6.20. JQ informed members that Information Asset Owners had now been identified, and they were currently assessing their data to respond to this requirement.

Actions Point:

- 6.21. *The Secretary to notify Director of HR of ARAC's request that she attend the next meeting in March and provide an assurance report on the transfer to the new payroll provider.*

Progress Made against Previous Internal Audit Recommendations

7. Audit Recommendations Tracker

- 7.1. SL had sent his comments and appreciation for the revised format of the audit tracker document. Members suggested that the document could be further enhanced if the grand total of audit recommendations yet to be implemented were summarised at the bottom of the paper.
- 7.2. Members observed that there was still an outstanding item from the NAO Interim Audit report of 2014-15 relating to with non-current assets. NAO had recommended that *“the Agency ensures all non-current assets are subject to the same level of oversight, and implement additional procedures if needed. The Agency should continue to investigate whether the integration of non-current asset reporting data is possible going forward”*. SM stated that this would be dealt with by the implementation of the new Oracle system. The Agency was currently awaiting the final plan for the implementation work.

8. Information Security update

- 8.1. JQ gave an update as follows:
 - 8.1.1. The IT Service Management tool and new contract has been completed.
 - 8.1.2. Central patching and maintenance of infrastructure has been done, and monitoring was now in place.
 - 8.1.3. Information Asset Owners were now in place.
 - 8.1.4. Annual protecting information training was due to be scheduled.
 - 8.1.5. There was also a need for wider set of digital skills and security specific training, which would need to be scheduled as part of the change programme.
- 8.2. The committee were informed that the transfer of IT infrastructure from Accenture was due to take place the last week of February.

Counter Fraud

9. Reported Cases of Fraud

- 9.1. RH explained to members that the delay at DH with concluding ongoing investigation of cases reported by the Agency was due to lack of resources.
- 9.2. Ian Hudson (IH) informed members that there were two elements to the reported cases of fraud. One was prevention which ensured that there was no repetition of reported incidents and this has been addressed by the Agency. The second was the delay with investigations by DH. The Agency was concerned with the delay by DH in dealing with investigations of cases reported by the Agency; this was taking too long. Members were in full agreement with him. This would be communicated back to DH.

Actions Point:

- 9.3. *Finance to communicate Agency's concerns to DH regarding delay by the department with investigations of reported fraud cases.*

Governance

10. Agency's draft Governance Statement

- 10.1. RH informed members that the paper presented was to show the new format in which the governance statement will be presented.
- 10.2. MH commented on the internal audit reviews section of the draft paper and suggested more details be added in relation to recommendations and agreed actions. RH replied that this section of the governance statement will be updated after the annual Follow Up review exercise. The Follow Up audit review will provide updates on outstanding action points from all the internal audits reviews conducted in the year.
- 10.3. SM informed members that the HR Payroll Processes and Data Flows high recommendations will be added in the next version.
- 10.4. The Chair advised that the Governance Statement should reflect that ARAC received updates on IT Cyber Security at each of the ARAC meetings held in the year.

Actions Point:

- 10.5. *Finance to ensure that the Agency's Governance Statement includes details of high level recommendations and action and also show that ARAC asked for and received updates on the implementation of the IT Cyber Security internal audit recommendations at its quarterly meetings in the year.*

11. CPRD Governance

- 11.1. The paper was reviewed and members were satisfied with the current arrangements in place.
- 11.2. The CPRD business case is to be reviewed at the beginning of the 2016/17 financial year. The Agency will take the opportunity to review governance arrangements and if deemed appropriate will seek to make changes to the Memorandum of Understanding (MoU) with DH. The current governance arrangements involving joint control have proven to be helpful to CPRD and the Agency would not want to jeopardise this. In addition, the current accounting treatment and presentation has been cleared by NAO and the process embedded in the production of the financial statements. There would be no tangible benefit in making any change now.
- 11.3. Feedback from DH Sponsor relayed through the Secretary, advised that if the Agency was going to be reviewing its accounting treatment of CPRD, then it would be helpful for DH Finance to be involved as it could affect the department. This would be either through Heather Suckling or Helen Gott from DH Finance.

12. Delegated Authority

- 12.1. The Chair had thought that members would see the internal delegated authority notes at the meeting.
- 12.2. RH explained to members that delegated authority in the Agency stems from the Accounting Officer delegating to his directors and managers.
- 12.3. Nick Todd (NT) informed members that the NAO also reviews the delegated authorities checking for discrepancies.
- 12.4. The Chair enquired about assurances in the delegated authority process.
- 12.5. IH referred to IMGB being responsible for the clearing of funded projects, the delegated authorities process also had financial spend limits. He added that IMGB,

for example, was a committee that provided robust checks on the process. As Accounting Officer he is ultimately responsible for ensuring that the assurances in the delegated authority process are in place and robust enough.

13. Report on the Corporate Risk Register (CRR).

- 13.1. The Chair enquired about the key risk items in the risk register.
- 13.2. RH informed members that there were 7 red risk items under the following headings: NIBSC, Information Technology, Financial, Enforcement and CPRD.
- 13.3. Members felt that some of the risks in the CRR were no more than the usual day-job type issues which need not necessarily be listed in the CRR. The Chair gave the example of risk 26(a) defined as “failure to communicate public health safety messages on use of devices” as being one of such listed risk items.
- 13.4. KF advised that ideally risks in the CRR should be no more than twenty items at most as anything more could be quite cumbersome for the Board.
- 13.5. NI suggested that PwC (HGIAS) could carry out an audit review of the Agency’s risk management process in the quarter 1 of next year if the Agency was interested in such a review. The review will assess the Agency’s risk appetite and advise on its risks compilation.
- 13.6. MH observed that besides the new risk items in the CRR presented for review there seemed little change in the document.
- 13.7. Sir Alex Markham (AM) felt that the covering note that accompanied the CRR seemed to separate CPRD and NIBSC from the Regulator. He wondered if all these could be presented as the Regulator without the separating identifier.
- 13.8. NT was of the view that the details of assurances stated for new risk 11 defined as - *“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”* - did not provide enough assurances to justify its reduction from the inherent red risk to a residual risk indicated as amber. RH replied that this will referred back to IMD.

Actions Point:

- 13.9. *Secretary to refer risk 11 back to IMD for review.*

14. Report on Whistleblowing

- 14.1. The Chair enquired about the role of ARAC in internal and external whistleblowing in terms of providing assurances that the processes worked.
- 14.2. IH informed members that external whistleblowing reports were routine matters. The Agency had an ARAC member, Stephen Lightfoot, as champion for internal whistleblowing matters.
- 14.3. The committee discussed whether ARAC should have a role in relation to external whistle-blowing i.e. where the agency receives reports about companies or other organisations.
- 14.4. KF advised that the risks around internal whistleblowing issues would normally be of concern to ARAC. Trends which result in increased risk would be identified by

management and if appropriate reflected in the risk registers. ARAC would need further assurances from management if the identified risks impacted on the Agency's reputation.

- 14.5. IH gave examples of how whistleblowing might be helpful in the Agency's Inspections and Enforcements roles. On the other hand internal whistleblowing issues can sometimes be generated from disaffected staff. ARAC may not need much involvement with the external whistleblowing process but may be involved in assurances that internal whistleblowing process works effectively.
- 14.6. The Chair had requested that the whistle-blowing policy be brought to this meeting as per the work plan. RH informed members that the new whistleblowing policy will be launched on January 20th and this will be come to ARAC at the next meeting in March.
- 14.7. The Chair noted that the work plan included a high level summarised feedback of internal whistleblowing to come to every meeting. A brief summary of actions taken and lessons learned should be included
- 14.8. MH informed management that ARAC should be informed of whistleblowing issues that could impact on the Agency. Secondly, members would also want to be informed if there was a high frequency of whistleblowing issues.
- 14.9. IH pointed out that there was a need to be clear about the role of SL as the Board's whistleblowing champion compared to the role of ARAC. This was in order to avoid duplication. He felt that the role of SL would be more of an oversight that gave assurances to ARAC. Further clarification would be sought
- 14.10. In conclusion it was agreed that:
 - 14.10.1. The ARAC's role was to provide assurance on the processes for internal whistle-blowing. External whistle-blowing was a business as usual activity for the agency. Any risks arising would be reflected in risk registers.
 - 14.10.2. The chair to discuss the role of the w/b champion with SL in order to provide assurance and avoid duplication.
 - 14.10.3. The whistleblowing policy to come to the next meeting.

15. Minutes of the Risk and Audit Liaison Group meeting of 11th November.

- 15.1. The minutes were noted.

Financial

16. Agency's Self-Insurance of £30m

- 16.1. At the June 2015 ARAC there was discussion about £30m cash set aside by the agency for potential future liabilities. Finance was asked at the June 2015 ARAC to provide a paper setting out how the £30m liability (self-insurance) has been calculated and comparing the MHRA approach with that used in other public sector bodies.
- 16.2. SM informed members that the costs breakdowns were based on gross costs as reflected in the agency asset register at 31 March 2015.

- 16.3. To the question raised by the Chair on whether the Agency had the Certificate of Exemption for employer's liability, RH informed members that NIBSC has an exemption that was confirmed by DH prior to the merger, however, no exemption has been issued to the Regular/CPRD and thus self-cover is required. FW noted that the arrangement of setting aside such a large sum for self-insurance purposes was quite unusual. IH replied that as the department will only cover the Agency for liability based on its regulatory function, the Agency needed to set aside funds to cover for its assets.
- 16.4. The committee noted that the agency seemed to be adopting a very prudent approach and that the sums in the paper did not amount to a full £30m. No comparable organisation had been found within the DH. It was noted that this was not a liability on the balance sheet. The Chair in closing felt the sum of £30m was still quite high. As the agency currently has over £200m in cash it is not an issue at present.

17. Review of the Agency's draft Remuneration Report

- 17.1. The report was noted with SM explaining that the changes to the report were in the last 3 pages of the document and these were items being moved from others sections of the annual report and accounts

18. Approve changes to accounting standards and/or policies

- 18.1. The paper was noted.

19. Write-Offs and Losses

- 19.1. The paper was noted.
- 19.2. The Chair will in future like a quarter by quarter feedback and year-to-date total to allow for comparisons.

Actions Point:

- 19.3. *Finance to provide quarter-by-quarter feedback and year-to-date total to allow for comparisons.*

ARAC

20. Work Plan for ARAC

- 20.1. The revised work plan was noted.

21. Agree process of Self-Assessment of ARAC effectiveness.

- 21.1. The evaluation questionnaire was noted and agreed as tool for the evaluation process.
- 21.2. The Chair advised that it should be circulated and completed by all members and attendees at ARAC.

Actions Point:

21.3. *Secretary to circulate the evaluation questionnaire and collate results for review at the next ARAC meeting in March.*

22. Private meeting of ARAC with Internal & External auditors

22.1. The Chair enquired from the auditors (Internal and external) if there was a need for a private meeting with members after the main meeting. The auditors confirmed that there was no need for one on this occasion.

23. Board Reporting - items to highlight to the Board

23.1. This was agreed amongst members at a closed meeting.

24. Any other Business

24.1. AM shared his views on the triennial review's recommendation of a unitary board for the Agency. Members agreed that the framework document when completed will inform further on the recommendation.

Date of next meeting.

The next ARAC meeting is scheduled for Monday 14th March 2016 at 10:30 a.m. Details have already been sent out by the Secretary via electronic diary notifications.