

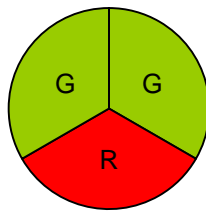
Internal Audit



Sample testing of ABPI data and compliance with NHS Lothian policies

June 2017

Report Assessment



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Introduction

In May 2016, Counter Fraud Services (CFS) issued a bulletin to all Health Boards to highlight the publication of payment details by pharmaceutical companies to health care organisations (HCO) and professionals (HCP).

On 30 June 2016, the Association of British Pharmaceutical Industry (ABPI) published the information, which has been analysed to Board specific level by CFS. CFS has highlighted the importance of all Boards carrying out sufficient checks on the data to ensure that action has been taken in accordance with local policies.

Scope

A sample was selected from the ABPI payments spreadsheet provided by the CFS, based on large/unusual values and frequently occurring individuals/departments. For the sample selected we considered against the following criteria:

- The approvals process it went through
- How and when it was declared
- The individual/department understanding of business conduct policies and procedures
- Record keeping (in accordance with procedures)

Acknowledgements

We would like to thank all staff consulted during this review, for their assistance and cooperation.

Executive Summary

Conclusion

We have noted significant gaps within the framework of control for the receipt and recording of payments by pharmaceutical companies to healthcare professionals. These should be addressed to comply with the Board's principles of good business conduct and improve transparency across the organisation. In particular, there is a need for additional training directly related to this area, to improve understanding and ensure personal ownership and accountability for declaring activities in accordance with procedures.

Summary of Findings

The table below summarises three specific areas of review. Definitions of the ratings applied to each action are set out in Appendix 1.

No.	Objective	Control objective assessment	Number of actions by action rating			
			Critical	Significant	Important	Minor
1	Confirm payments specifically relate to the named individual (or department) and were retained by them.	Green	-	1	-	-
2	Confirm that payments were processed in accordance with the Board's Standing Financial Instructions (SFIs) and policies & procedures.	Red	1	-	-	-
3	Where payments relate to specific HCPs with procurement and/or prescribing influence. Review the subsequent use of donor organisation products and services.	Green	-	-	-	-

Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above)
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)

Main findings

Based on our review of the APBI data collated and our sample testing we did not identify the Healthcare professionals we sampled, who received payments, as having significant influence within prescribing or procurement activity. We have identified several weaknesses within the framework of control governing the receipt of payments and therefore scope for further improvements. Our findings are summarised below:

We identified one critical and one significant issue during this review:

- Some payments listed in the APBI data have not identified the recipient.
- Requirements of the Board's procedures governing good business conduct are not being followed or applied.

Further details of the two issues are set out in the Management Action Plan.

Management Action Plan

Control Objective 1: Confirm payments specifically relate to the named individual (or department) and were retained by them.	
1.1 Some payments listed in the APBI data have not identified the recipient	Significant
<p>Observation and Risk:</p> <p>Analysis of the data provided by the Association of British Pharmaceutical Industry identified 196 individuals with NHS Lothian payroll numbers and therefore Board employees. These individuals had received a total of 367 payments to the value of £288,255.22.</p> <p>A further 80 payments had been made where the Healthcare Professionals were considered to be NHS Lothian employees, totalling £179,045. However, for each of these payments the individual's details had not been disclosed. This is an option that is available for selection by the healthcare professional when agreeing payment with the pharmaceutical company, although choosing this option prevents investigation by NHS Lothian of the payments being made.</p> <p>Also the APBI guidance states that its hope is that Healthcare Professionals will recognise the benefits of greater transparency and grant consent to disclose the data when asked.</p>	
<p>Recommendation:</p> <p>Employees should be reminded of the requirement under the principles of good business conduct to ensure all activities are carried out fairly, transparently and are available for scrutiny.</p> <p>To ensure this they should be advised to approve disclosure of their details when receiving payments from pharmaceutical companies.</p>	
<p>Management Response:</p> <p>The Standing Financial Instructions set out high level principles for all employees to follow, to observe the values of conduct, openness and accountability. One of those principles is that employees shall "demonstrate appropriate ethical standards of personal conduct". This is a key principle, as transparency provides confidence that the other aspects of the values are being observed in practice.</p> <p>This principle does however need to be balanced with the rights of individuals under the Data Protection Act 1998, and to consider what information is actually necessary for employees to demonstrate appropriate conduct.</p> <p>There are existing procedures which expect employees to discuss and agree any proposed secondary employment with his or her line manager before entering into any such engagement. This is a key control which should always operate, and is preferable to being notified of remuneration for secondary employment after the event. This together with</p>	

another existing requirement to declare interests as and when it is pertinent to the conduct of business should be sufficient. Ideally the annual disclosure from ABPI should not refer to activities that the organisation was not already aware of.

Management Action:

In response to another audit report, it has already been agreed to develop a communication plan to raise awareness of business conduct issues, and that process will consider this point.

Responsibility: Corporate Governance Manager

Target date: 31 August 2017

Control Objective 2: Confirm that payments were processed in accordance with the Board's Standing Financial Instructions (SFIs) and policies & procedures.

2.1 Requirements of the Board's procedures governing good business conduct are not being followed or applied.

Critical

Observation and Risk:

Section 2 of the NHS Lothian Standing Financial Instructions sets out the broad expectations of all employees on good business conduct. According to the SFIs, employees are required to demonstrate appropriate ethical standards of personal conduct and should not undertake outside employment that could compromise their NHS duties, or seek to advantage or further their private business or interest in the course of their official duties.

In response to the SFI requirements, NHSLothian has in place a documented procedure and guidance for all employees in applying the principles of good business conduct.

Through the Finance online intranet site, supplementary guidance and procedures is provided to ensure that the above principles are understood and applied in practice.

Of 361 payments identified for testing, 163 (valuing £99,586) were recorded in the APBI data as 'contribution to costs of events'. The payments involved either registration fees or travel and accommodation costs. Of the remaining 198 payments (valuing £187,238.88), all related to a 'fee for service and consultancy' and were either fees or related expenses agreed in the fee for services or consultancy contract.

The payments have been assessed by Internal Audit against the Board's Procedure and Guidance for Employees in Applying the Principals of Good Business Conduct. As the majority appear to be related to work not part of any normal duties and on behalf of other organisations, they are considered secondary employment and have been reviewed against NHSLothian's guidance governing this.

Contributions to costs of events, such as travel and/or accommodation, have also been considered against the Board's guidance on accepting support or funding from other organisations, recorded within Finance Online as Commercial Sponsorship.

If an employee is offered secondary employment, they have a duty to discuss it immediately with their line manager and consider whether it is appropriate according to policy. To be appropriate it has to adhere to a specific requirement:

- The work is carried out under the employee's own time (otherwise NHSLothian will be required to invoice the secondary employer for any income and any travel requirements organised through the Travel Procurement Team).

If the secondary employment is carried out during the employees own time then they are required by the Guidance to declare it as an interest and record made of this.

If however the payments are considered to be commercial sponsorship there should be a signed written agreement in place between NHS Lothian and the organisation. Also, all

bookings for travel and accommodation should be directed through the appropriate NHS Lothian department and the company invoiced for the amount.

Financial Services confirmed that of the 361 payments, ten had been received by NHS Lothian, totalling £4,368.87. Of those payments, details had been disclosed for two of them, to the value of £1,072.20.

Internal Audit identified 17 individuals with high value or frequent payments, across a number of clinical areas (92 payments in total, valuing £135,201.17). Contact was made with line/service managers and two questions asked around the nature of the payments:

1. The payments made specifically related to the named individual and were accepted and retained by them; and
2. Whether the payments had been discussed between the individual and their line manager and a declaration of interest recorded, or other actions taken, in accordance with the Board's Principles of Good Business Conduct.

Responses were received for 16 of the individuals.

Findings from the responses received are summarised below:

- Income from secondary employment is declared only as part of annual appraisal process.
- Activity categorised as study leave and funded by the pharmaceutical company.
- Secondary employment and likely payments etc are not always discussed at the outset with the line/service manager.
- One Clinical Service Manager confirmed that payment related to consultancy work and was carried out during the staff member's annual leave. This had been approved and signed-off by their Clinical Director and Service Manager.

Furthermore, one clinical service manager reported that there was documentation available locally to maintain a record of this activity and any declarations of interest required.

Also, it is unclear whether the payments relating to additional study have been assessed under the guidance on Commercial Sponsorship.

Recommendation:

In response to the findings of the review, several recommendations are made:

- The Medical Director should carry out an exercise to remind clinical staff of the Board's procedure and guidance for all employees in applying the principles of good business conduct. Specific mention should be made around how payments and contributions from pharmaceutical companies should be considered under the guidance available through the Finance Online intranet site, and should make specific reference to secondary employment and commercial sponsorship. Where necessary, companies should be invoiced for travel, accommodation and other costs.
- Advice and training should be targeted in the following clinical departments which account for 48% of the volume of payments to employees and 59% of the total cost of

<p>these payments:</p> <ul style="list-style-type: none"> ○ Diabetes & Endocrinology. ○ Gastroenterology. ○ Infectious Diseases. ○ Cardiology. ○ Haematology. ○ Respiratory Medicine. <ul style="list-style-type: none"> ● Standard documentation should be completed to record any discussions with line managers in accordance with the relevant guidance. Such as the Declaration of Interest form or the Commercial Sponsorship template. 	
<p>Management Response:</p> <p>The findings reflect the need to improve understanding of, and compliance with, our existing procedures and guidance. We do not agree that it is necessary to issue standard documentation to record discussions, however we will give further consideration as to how the intelligence from various processes can be systematically and efficiently brought together.</p> <p>Management Action:</p> <p>Progress this issue as part of the communication plan (referred to at 1.1).</p>	
<p>Responsibility: Medical Director, and Corporate Governance Manager</p>	<p>Target date: 31 December 2017</p>

Control Objective 3: Where payments relate to specific HCPs with procurement and/or prescribing influence. Review the subsequent use of donor organisation products and services

We found no significant weaknesses in relation to the above control objective.

Analysis has been carried out on 11 employees to determine whether they appear in any procurement activity relating to the pharmaceutical companies making payments to them. Of the 14 companies relevant to this test, only one (Bayer plc) had provided goods or services within the last year. Review of the transactions noted that the procurement requests and approvals had been made by individuals not recorded in the APBI submission.

Appendix 1 - Definition of Ratings

Management Action Ratings

Action Ratings	Definition
Critical	The issue has a material effect upon the wider organisation – 60 points
Significant	The issue is material for the subject under review – 20 points
Important	The issue is relevant for the subject under review – 10 points
Minor	This issue is a housekeeping point for the subject under review – 5 points

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