BOARD MEETING – 11 April 2016 Title: FINANCE AND PROCUREMENT REPORT **Issue/ Purpose:** The purpose of this paper is to ask the **Board to note** the financial performance of the Agency for the first eleven months of financial year 2015/16. Summary: Income and Expenditure Measures Financial year 2015/16 Year to Date CPRD All figures rounded Regulator NIBSC Total Budget Variance £97.5 m £38.0 m £8.9 m £144.4 m £140.0 m £4.4 m **Operating Income Operating Expenditure** £88.5 m £32.5 m £6.5 m £127.5 m £124.2 m £(3.3)m **Operating Surplus / (Deficit)** £9.0 m £5.5 m £2.4 m £16.9 m £15.8 m £1.1 m Budgeted Surplus / (Deficit) £7.0 m £3.2 m £5.7 m £15.8 m £1.1 m Variance £2.0 m £2.4 m £(3.3)m **Dividend Payable** £0.0 m £(3.2)m £(3.7)m £0.0 m £(6.9)m £(6.9)m £0.0 m £0.4 m £0.0 m £0.4 m Financing £0.4 m £0.0 m **Retained Surplus / (Deficit)** £6.1 m £1.9 m £2.4 m £10.4 m £8.9 m £1.5 m % of 5 % of Estimated Cumulative 5 Year Rate of Return Years Target Target Figure Passed Attained Performance against estimate of Treasury financial objective 58% £45.0 m £53.6 m 119% since 1.4.13 Other Measures Max Min Year End Surplus 29-Feb-16 31-Mar-16 (Sep 17) (Apr 16) after Dividend Cash £212.5 m £210.1 m £127.5*m £105.9*m Previous One Year Two Years 29-Feb-16 Budgeted £9.0m Month Ago Ago Surplus Trade Receivables £30.1 m £18.9 m £29.7 m £21.7 m Forecast **Payments on Account - Non Iris** £15.1 m £13.9 m £14.8 m £15.9 m £8.8m Surplus **Payments on Account - Iris** £1.5 m £1.9 m £1.8 m £2.1 m PL Deferred Revenue £18.8 m £18.3 m £16.4 m £14.4 m Regulator NIBSC CPRD Total Budget Balance Capex 2015/16 £1.8 m £3.6 m £1.9 m £7.3 m NIBSC CPRD Variance Regulator Total Budget 1,293 FTEs (rounded) 887 335 41 1,262 31 15/16 14/15 No of Transactions **5 Day Payment Target** Average Feb-16 Average Paid (YTD) 151 BPR - in house 92% 1,299 of 1,547 84% 89% 72% Shared Services – Porton Down 77% 682 of 946 72% 82% 79% Combined 86% 1.981 of 2.493 Author(s): Richard Humphreys – Deputy Director – Finance Can paper be published on INsite? (List any deletions required): No CET Sponsor: Peter Commins

Medicines and Healthcare Products Regulatory Agency

Item 12

FINANCE AND PROCUREMENT REPORT

1. Highlights

The key points in this paper include the:

- 2015/16 Management Accounts for February 2016 -
 - Income exceeding budget driven by NIBSC Flu Standards and DCP RMS and CMS see 2.2 below;
 - **Operating Expenditure** above budget, due to **ICT**, **refunds of prioryear service fees and possible reclassification of capital into revenue** (partially offset by **Staff Costs**) – see 2.3 below;
- Forecast to the end of the financial year 2015/16;
- Statement of Financial Position as at 29th February 2016;
- March 2016 Cash Report; and
- Income Risk Assessment.

2. Management Accounts

2.1 Summary

The Management Accounts for the first eleven months of 2015/16 are attached as **Appendix 1**, they show that after rounding, the whole Agency was £4.4m (3%) above its income budget and operating costs were £3.3m (3%) above budget; the operating surplus (before Dividends) for the year of £16.9m is £1.1m (7%) above budget.

The summary Management Accounts for the whole Agency are shown in Table 1:

£000s (rounded)	<u>Actual</u>	<u>Budget</u>	<u>Variance</u>
MHRA (Regulator)	8,959	6,976	1,893
NIBSC	5,540	3,186	2,355
CPRD	2,420	5,679	(3,259)
Agency	16,920	15,841	1,079

Table 1- Summary Management Accounts

Schedule 1 of the Management Accounts shows, following budget and corporate cost reallocations, that after eleven months of the financial year 2015/16:

- MHRA (Regulator) has a surplus of £9.0m: it is £6.6m (7%) above its budget for income; it has under-spent its staff budget by £2.0m (4%); other operating costs are £6.7m (19%) above budget; giving a £2.0m overall favourable variance.
- **NIBSC** has a surplus of £5.5m: it is £0.6m (3%) above budget for operational income; it has under-spent its staff budget by £1.5m (8%); and, other operating costs are £0.3m (2%) below budget; giving a £2.4m overall favourable variance.
- **CPRD** has a surplus of £2.4m; it is £2.8m (24%) below budget for income; it has under-spent its staff budget by £0.4m (14%); whilst other operating costs are £0.9m (27%) above budget; giving a £3.3m (57%) overall unfavourable variance.

2.2 Income

Total income recognised in February 2016, at £12.1m is: £1.4m (10%) below budget; \pounds 1.1m (8%) below January 2016; and \pounds 1.4m (10%) below February 2015 – for details please see section 3.1 and particularly Figure 1 in the Management Accounts commentary.

The summary income year-to-date for the whole Agency is shown in Table 2 below:

	Table 2- Summary Income		
£000s (rounded)	Actual	Budget	Variance
MHRA (Regulator)	97,499	90,857	6,642
NIBSC	38,002	37,432	571
CPRD	8,924	11,738	(2,814)
Agency	144,425	140,027	4,398

The major component of this performance is MHRA (Regulator) income, particularly income from **DCP RMS** which is £1.2m (18%) above budget, **DCP CMS** which is £1.6m (28%) above budget; and, **NIBSC** income, particularly income from **Standards** - **Flu** which is £1.7m (62%) above budget.

2.3 Expenditure

Total operating costs for the year to the end of February 2016 at ± 127.5 m are ± 3.3 m (3%) above budget.

There is a significant expenditure variance in **Staff Costs** which are £3.9m (6%) below budget driven by all three centres being below staff complements. Other operating costs are £7.2m (14%) above budget due to an unfavourable variance on **ICT** which is £4.0m above budget in the Regulator and £1.2m above budget in CPRD. Additionally "other costs" are £4.3m above budget, due to **periodic fees received in prior years that have been refunded and the possible reclassification of capital into revenue**. These variances are being partly offset by favourable variances in other areas. This is discussed in detail in Section 4.2 of the Management Accounts commentary.

2.4 Deferred Revenue

In February 2016 the revenue deferred from PL applications increased by £0.6m (3%) when compared to the end of January 2016. Deferred revenue when compared to the end of February 2015 is £2.4m (15%) higher at £18.9m. Please see the graph in Schedule 6 of the Management Accounts which shows actual PL deferred revenue over the last two years.

Section 6 of the commentary includes a table which analyses the components of PL deferred revenue into various lead categories. This shows that $\pm 10.6m$ (56%) of PL deferred revenue is attributable to DCP applications.

NIBSC defers revenue mainly on its projects and grants income. At the end of February 2016, the deferred revenue balance was $\pounds 3.6m$, a $\pounds 0.5m$ (12%) decrease from January 2016.

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3 2015/16 Forecast

The forecast outturn position for the financial year 2015/16 is included in this report as **Appendix 2.** In summary the Agency is expected to deliver a surplus after dividends of between $\pounds7.2m$ and $\pounds11.6m$. The main driver of this is expected to be the Regulator (MHRA) in a range of $\pounds4.1$ and $\pounds7.2m$, with NIBSC expected to contribute between $\pounds2.2m$ and $\pounds3.2m$ and CPRD between $\pounds0.9m$ and $\pounds1.3m$ before the corporate recharge.

The best estimate is an overall surplus after dividends etc. of £8.8m.

4 Statement of Financial Position (SFP)

4.1 Summary and monthly movement in balances

The Statement of Financial Position (SFP) is attached as **Appendix 3**, which shows the position at the end of February 2016 compared to the position at the end of January 2016 and the final published position at the end of March 2015.

The main monthly movements in balances between February 2016 and January 2016 are detailed in the notes to the SFP. The most significant movements to note include the $\pounds 2.5m$ decrease in 'Assets Under Construction' due to the expensing of previous expenditure in the month and the increase in accrued income due to the inclusion of the DH 'circular flow' no-cash income. An increase of $\pounds 2.7m$ in 'other' receivables was due to annual invoicing for CPRD $\pounds 2.3m$ and RAMA XL $\pounds 0.6m$.

4.2 The SFP Annex

The SFP Annex shows an analysis of the net debtor aging; number of debtor accounts; average gross debt; payments held on account by age; and, outstanding debt by division.

5 March Cash Report

The March Cash Report is attached as **Appendix 4**. The chart shows the movement in the Agency's actual cash position from the end of December 2015 to the end of February 2016 and provides a forecast through to the end of September 2017.

However, since this was published DH has indicated a 'dividend' of could be requested. This hasn't been reflected in any part of this document apart from on the face of the report, the 'dashboard' on the front page where two forecast figures are marked with * as the forecast cash balance have been reduced to reflect a potential payment to DH.

6 Income Risk Assessment

Appendix 5, the Income Risk Assessment, was discussed in detail by the Finance Sub Committee (FSC) at the March meeting, with the Risks being assessed against the grid shown at the top of the first page. The risk ratings are shown as short and medium term, with all short term risks assessed as 'green'. The medium term risks are shown both before and after corrective action, with DH funding (for both Devices and NIBSC) assessed as 'red' over the medium term after corrective action, black before action. The medium term risks from Periodic fee are also assessed as 'red' after corrective action due to the potential impact of EU PV fees.

Richard Humphreys 6th April 2016



Management Accounts 2015/16 February 2016

Commentary	
Income & Expenditure Account	Schedule 1
Income Analysis by Type	Schedule 2
Expenditure Analysis by Type	Schedule 3
FTE Schedule	Schedule 4
Capital Expenditure	Schedule 5
Deferred Revenue	Schedule 6

Date Issued: April 2016

- Issued by: Management Accounts Team
- Issued to: Agency Board

1. Introduction

These are the Management Accounts for the year to the end of February 2016. All financial figures are in £m rounded to one decimal place and FTEs are rounded to the nearest whole number. These figures are draft and unaudited.

After rounding, the operating surplus at $\pounds 16.9m$ is $\pounds 1.1m$ (7%) above budget. This is a result of income being $\pounds 4.4m$ above budget combined with a $\pounds 3.3m$ overspend on operating costs.

2. Highlights (Schedule 1)

Year to date (YTD) overview (after rounding):

• The operating surplus for the Agency segmented into the Regulator, NIBSC and CPRD is shown in Table 1.

Table 1

Operating Surplus / (Deficit)							
Year to the end of February 2016							
£000's Actual Budget Variance							
REGULATOR	8,959	6,976	1,983				
NIBSC	5,540	3,186	2,355				
CPRD	2,420	5,679	(3,259)				
Agency	16,920	15,841	1,079				

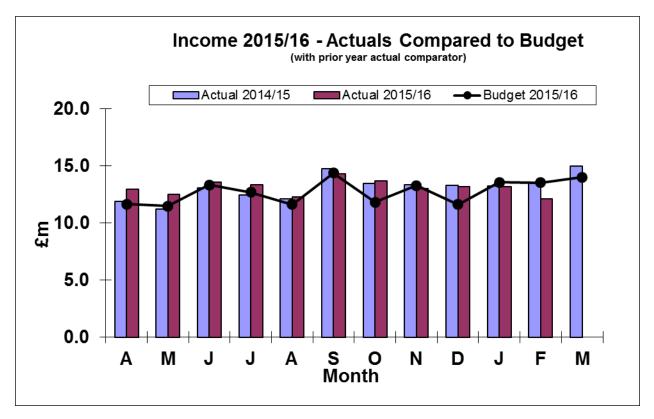
- Operating income for the Agency at £144.4m is £4.4m (3%) above budget (section 3);
- Total operating costs at £127.5m are £3.3m (3%) above budget.
- FTEs (Full Time Equivalents all figures rounded) in February were 1,262 (with 163 short term contracts and 56 Non-Payroll employees). This is 31 FTEs below the February budget of 1293 FTEs.
- Capital Expenditure for the year to the end of January 2016 is £7.3m.
- Total Product Licensing deferred revenue at the end of February 2016 is £18.9m (section 6).

3. Income (Schedule 2)

3.1 Income Summary

Figure 1 below shows actual recognised income compared against budget for 2015/16 and also includes a comparison against income recognised in 2014/15.

Figure 1



Income recognised in February 2016, at £12.1m is:

- £1.4m (10%) below budget
- £1.1m (8%) below January 2016
- £1.4m (10%) below February 2015

Income for the Agency for the year to the end of February 2016 segmented into the Regulator, NIBSC and CPRD is shown in Table 2. This is £4.4m (3%) above budget:

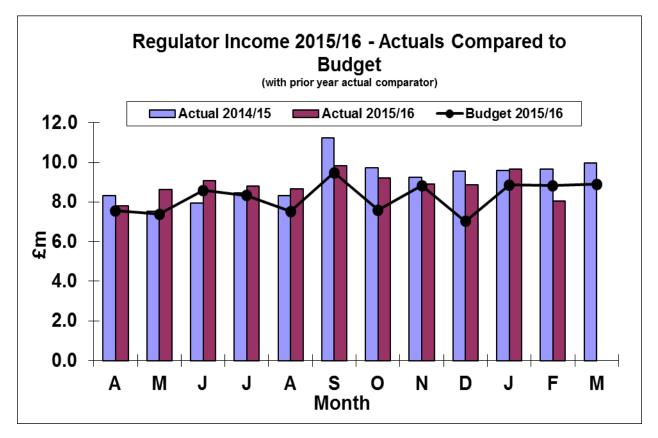
Income							
Year to the end of February 2016							
£000's	Actual	Budget	Variance				
REGULATOR	97,499	90,857	6,642				
NIBSC	38,002	37,432	571				
CPRD	8,924	11,738	(2,814)				
Agency	144,425	140,027	4,398				

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3.2 <u>Regulator Income</u>

Figure 2 below shows actual recognised income compared against budget for 2015/16 for the Regulator and also includes a comparison against income recognised in 2014/15.

Figure 2



Regulator income recognised in February 2016, at £8.1m is:

- £0.8m (9%) below budget for the month;
- £1.6m (17%) below January 2016.
- £1.6m (17%) below February 2015.

Regulator income for the year to the end of February 2016 at £97.5m is £6.6m (7%) above budget.

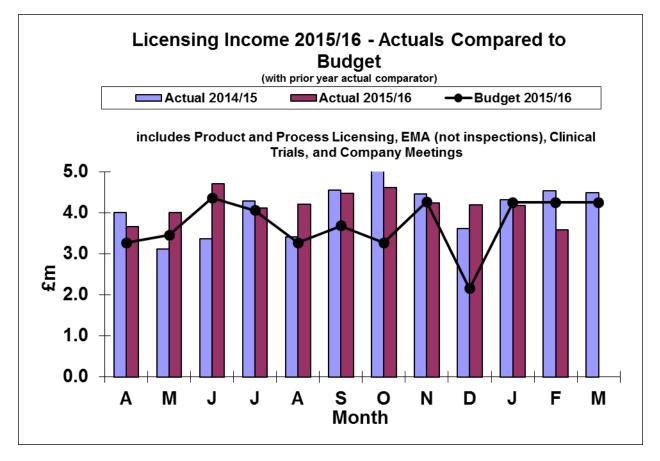
The major components of this performance are:

- Licences Product Licences which is £5.2m (20%) above budget;
- Other Regulation Income (which includes, BP, Rama XL and Seminar Income) which is £1.6m (24%) above budget

3.2.1 Licensing Income

Figure 3 below shows actual recognised income compared against budget for 2015/16 for Licensing and also includes a comparison against income recognised in 2014/15.

Figure 3



Licensing income recognised in February 2016, at £3.6m is;

- £0.7m (16%) below budget:
- £0.6m (14%) below January 2016;
- £0.9m (21%) lower than February 2015

Licensing income for the year to the end of January 2016 at £46.0m is £5.7m (14%) above budget.

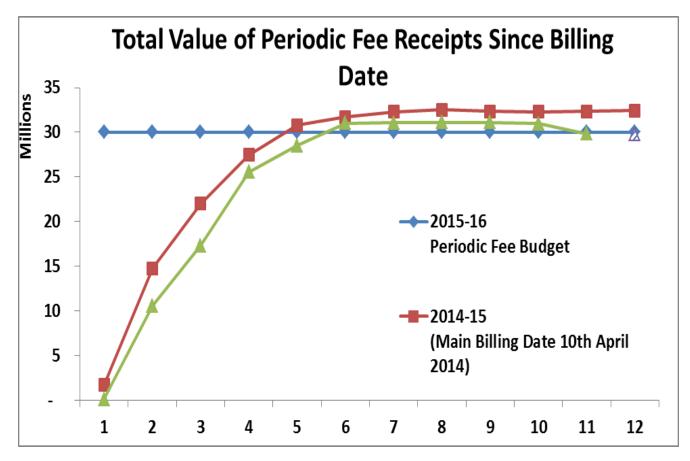
The major components of this performance are:

- Decentralised Applications CMS which is £1.6m (28%) above budget
- Decentralised Applications RMS which is £1.2m (18%) above budget
- Variations PL which is £1.0m (15%) above budget
- Labels & Leaflets which is £0.6m (29%) above budget

3.2.2 Periodic Fee Recognised Income and Receipts

Figure 4 (below) shows the value of periodic fee receipts since the billing date with a comparator to the cash collection performance in the previous financial year.

Figure 4



Total cash received in February relating to 2015/16 periodic fees amounted to £7k. However this has been offset by the refunding of credit notes amounting to £1.2m which brings the total cash received for the year to £29.8m. This is £2.5m lower than for the same period last year

Total debt at the end of February is £367k. This is £0.3m higher than for the same period last year.

Of the total debt outstanding, £43k relates to Process Licensing and £324k relates to Product Licensing. Of this, £201k relates to 100% unpaid invoices and £165k relates to part paid invoices.

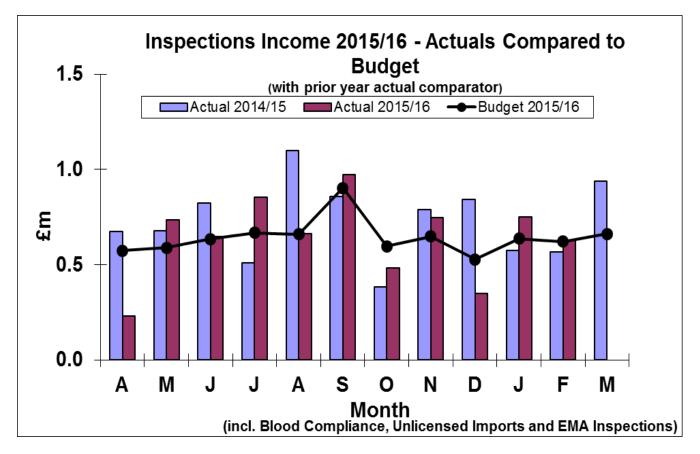
There is £17k of part allocated credit notes outstanding at the end of February 2016

The forecast for the year is $\pounds 29.8$ m.

3.2.3 Inspections

Figure 5 (below) shows actual recognised income compared against budget for 2015/16 for Inspections and also includes a comparison against income recognised in 2014/15. The graph excludes income from Travel & Subsistence charges to customers (T&S).





Inspection fee income (including EMA but excluding T&S) for February 2016 at £0.6m is;

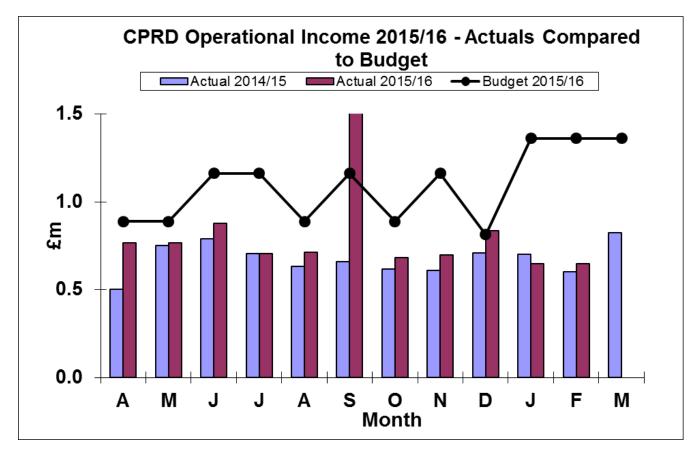
- in line with budget;
- £0.1m (17%) lower than January 2016;
- nearly £0.1m (10%) higher than February 2015

Inspection income (excluding income from T&S) for the year to the end of February 2016 at £7.1m is in line with budget.

3.3 Clinical Practice Research Datalink (CPRD)

Figure 6 below shows actual recognised operational income (excludes the investment from the Department of Health) compared against budget for 2015/16 for the CPRD and also includes a comparison against operational income recognised in 2014/15.

Figure 6



CPRD operational income recognised in February 2016, at £0.7m is;

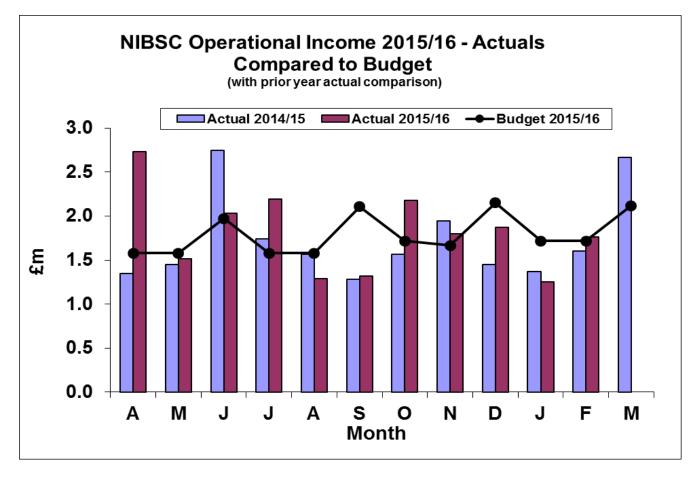
- £0.7m (52%) below budget;
- in line with January 2016;
- less than £0.1m (7%) lower than February 2015.

CPRD income for the year to the end of February 2016 at £8.9m is £2.8m (28%) below budget.

3.4 <u>National Institute of Biological Standards and Control (NIBSC)</u>

Figure 7 below shows actual recognised operational income (excludes the funding from the Department of Health) compared against budget for 2015/16 for NIBSC and also includes a comparison against operational income recognised in 2014/15.





NIBSC operational income recognised in February 2016, at £1.8m is;

- Less than £0.1m (3%) below budget;
- £0.5m (40%) higher than January 2016;
- £0.2m (10%) higher than February 2016.

NIBSC operational income for the year to the end of February 2016 at £19.9m is £0.6m (3%) above budget.

The major component of this performance is:

• Standards - Flu which is £1.7m (62%) above budget.

Offset by

• Research Grants - Flu which is £1.3m (24%) below budget.

COMMENTARY TO THE FEBRUARY 2015/16 MHRA MANAGEMENT ACCOUNTS

4. Expenditure (Schedules 3 and 4)

Total operating costs for the year to the end of February 2016 at £127.5m are £3.3m (3%) above budget.

4.1 <u>Staff Costs</u>

Staff costs for the year to the end of February 2016 at £66.7m are £3.9m (6%) below budget. (See schedule 3). Staff costs for the Agency segmented into the Regulator, NIBSC and CPRD are shown in Table 3.

Table 3

Staff Costs									
Year to the end of February 2016									
£000's	Actual	Budget	Variance	Var %					
REGULATOR	47,548	49,563	2,014	4%					
NIBSC	16,705	18,209	1,504	8%					
CPRD	2,441	2,850	409	14%					
Agency	66,694	70,621	3,927	6%					

FTEs (Full Time Equivalents – all figures rounded) in February were 1,262 (with 163 short term contracts and 56 Non-Payroll employees). This is 31 FTEs below the February budget of 1,293 FTEs:

- Regulator is 3 FTEs below budget
- NIBSC is 13 FTEs (4%) below budget
- CPRD is 15 FTEs (28%) below budget

The average number of FTEs in post for the year to the end of February 2016, for the Agency segmented into the Regulator, NIBSC and CPRD are shown in Table 4.

Table 4

Average Staffing - Full Time Equivalents (FTEs) Year to the end of February 2016									
Actual Budget Average Average £000's YTD YTD Variance Var %									
REGULATOR	853	890	37	4%					
NIBSC	322	348	26	7%					
CPRD	44	56	12	21%					
Agency	1,219	1,294	76	6%					

4.2 Other Operating Costs

Other Operating costs for the year to the end of February 2016 at £60.8m are £7.2m (14%) above budget (see schedule 3).

Other operating costs for the Agency segmented into the Regulator, NIBSC and CPRD are shown in Table 5.

Table 5

Other Operating Costs									
Year to the end of February 2016									
£000's	Actual	Budget	Variance	Var %					
REGULATOR	40,991	34,318	(6,673)	(19%)					
NIBSC	15,757	16,037	280	2%					
CPRD	4,063	3,209	(853)	(27%)					
Agency	60,811	53,565	(7,246)	(14%)					

Other operating costs within the Regulator at \pounds 41.0m are \pounds 6.7m (19%) above budget. The main components are:

- Other costs which are £4.3m above budget and consist of the expensing of items previously held as a Capital Asset under construction and the payment of periodic fees which were received in prior years but have been refunded this year.
- ICT which is £4.0m above budget with adverse variances across the Portfolio for IT change, Services from external providers and Software & licensing.

This is partly offset by favourable variances on all other non-pay expenditure categories.

Other operating costs within NIBSC at £15.8m are $\pm 0.3m$ (2%) below budget. The main components are:

- Other costs which are £0.8m below budget.
- Externally provided services which are £0.3m (58%) below budget.

Offset by

• Lab and Other lab Consumables is £0.6m (11%) above budget

Other operating costs within CPRD at £4.1m are £0.9m (27%) above budget. The main components are:

• ICT which at £2.4m is £1.2m (91%) above budget. A review of the statements of work supporting ICT expenditure, has led to work previously classified as capital expenditure being re-classified to non-capital.

5. Capital Expenditure (Schedule 5)

Capital Expenditure for the Agency (after rounding) for the year to the end of January 2016 was \pounds 7.3m. \pounds 1.8m was in the Regulator, with \pounds 3.6m in NIBSC and \pounds 1.9m in CPRD.

Schedule 5 has been developed to also include the revenue (non-capital) expenditure element of individual projects.

6. Deferred Revenue (Schedule 6)

6.1 <u>Total Product Licensing Deferred Revenue</u>

The graph showing the movement in total revenue deferred from Product Licensing (PL) applications, and how revenue deferred from aged applications has moved, is shown in Schedule 6.

In February 2016 the revenue deferred from PL applications increased by £0.6m (3%) when compared to the end of January 2016. Deferred revenue when compared to the end of February 2015 is £2.4m (15%) higher at £18.9m.

Table 6 below shows deferred revenue broken down into various lead categories. The table shows that $\pm 10.6m$ (56%) of deferred revenue is attributable to Decentralised Applications (DCP).

Previous								
Month	Parent £'000s	2015/16	2014/15	2013/14	2012/13	2011/12	Total	%
9,971	Decentralised Application	8,002	2,328	194	71	28	10,624	56%
3,329	Variations PL	2,169	562	283	161	59	3,234	17%
1,484	Standard Applications	1,157	221	81	17	33	1,509	8%
1,497	Complex Applications	1,043	238	149	40	18	1,487	8%
710	PLPIAPP	686	6	-	1	-	692	4%
309	Labels/Leaflets	303	8	4	4	2	321	2%
-	New Active Substance	-	-	-	-	-	-	0%
994	Other	420	235	125	153	62	995	5%
18,294	Grand Total	13,780	3,598	837	446	201	18,862	

Table 6

Table 7 below shows deferred revenue on decentralised applications broken down into Reference Member State (RMS) and Concerned Member State (CMS) categories.

Table 7								
Previous								
Month	£'000s	2015/16	2014/15	2013/14	2012/13	2011/12	Total	%
4,416	RMS	3,272	1,344	123	49	14	4,802	45%
5,556	CMS	4,730	984	72	22	15	5,822	55%
9,971	TOTAL	8,002	2,328	194	71	28	10,624	

In February 2016, out of a total of £10.6m of decentralised deferred revenue, 45% was attributable to RMS and 55% to CMS. In February 2016, RMS deferred revenue increased by £0.4m (9%), with CMS also increasing by £0.3m (5%).

6.2 NIBSC Deferred Revenue

NIBSC defers revenue, mainly on its projects and grants income. At the end of February 2016, the deferred revenue balance was £3.6m, a £0.5m (12%) decrease from January 2016.

2016-OB-15 Appendix 1

MANAGEMENT ACCOUNTS

Year to 29th Feb 2016

£'000s

Schedule 1

Income and Expenditure Account

	20003						
		Feb 16				Full Year	
<u>Regulator</u>	Actual	Budget	Variance)	%YTD	Budget	Balance
Income	97,499	90,857	6,642	7%	98%	99,748	2,249
Staff Cost	47,548	49,563	2,014	4%	88%	54,021	6,473
Other Operating Costs	40,991	34,318	(6,673)	(19%)	112%	36,627	(4,364)
Total Operating Costs	88,539	83,881	(4,659)	(6%)	98%	90,648	2,109
Regulator Contribution	8,959	6,976	1,983	28%	98%	9,100	141
NIBSC			·				
DH Funding	18,059	18,059	0	0%	92%	19,700	1,641
Operational Income	19,943	19,373	571	3%	93%	21,483	1,540
Total Income	38,002	37,432	571	2%	92%	41,183	3,181
Staff Cost	16,705	18,209	1,504	8%	82%	20,273	3,568
Other Operating Costs	15,757	16,037	280	2%	91%	17,263	1,506
Total Operating Costs	32,462	34,246	1,784	5%	86%	37,536	5,074
NIBSC Contribution	5,540	3,186	2,355	74%	152%	3,647	(1,893)
CPRD							
Income	8,924	11,738	(2,814)	(24%)	68%	13,100	4,176
Staff Cost	2,441	2,850	409	14%	79%	3,104	663
Other Operating Costs	4,063	3,209	(853)	(27%)	87%	4,696	634
Total Operating Costs	6,503	6,059	(444)	(7%)	83%	7,800	1,297
CPRD Contribution	2,420	5,679	(3,259)	(57%)	46%	5,300	2,880
MHRA							
Regulator Contribution	8,959	6,976	1,983	28%	98%	9,100	141
NIBSC Contribution	5,540	3,186	2,355	74%	152%	3,647	(1,893)
CPRD Contribution	2,420	5,679	(3,259)	(57%)	46%	5,300	2,880
Operating Surplus/(Deficit)	16,920	15,841	1,079	7%	94%	18,047	1,127
Financing:							
Interest Receivable	441	275	166	60%	147%	300	(141)
Interest Payable	(43)	(318)	275	(87%)	12%	(346)	(304)
Dividend Payable	(6,875)	(6,875)	0	0%	92%	(7,500)	(625)
	(6,477)	(6,918)	441	(6%)	86%	(7,546)	(1,070)
Surplus/(Deficit)	10,443						
Retained surplus b/forward MHRA	144,291						
Retained surplus c/forward	154,734						
Capital Expenditure							
	Feb 16 £000's						
Capital Expenditure	Actual						
Regulator	1,813						
NIBSC	3,635						
CPRD	1,856						
Total Capital Expenditure	7,304						
FTE (rounded, as at 29 February 2016)			<u></u>				
Devideter	Actual	Budget	Variance				
Regulator	887	889	3	0%			
NIBSC	335	348	13	4%			
CPRD MHRA FTE	41 1,262	56 1,293	15 31	28%			
	1,262	1,293	31	2%			

Year to 29th Feb 2016

MANAGEMENT ACCOUNTS

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Income - Analysis by fee type

		<u>income - Analy</u> £'000s		<u>ypc</u>				
		20003	Feb	16		[Full Year	
<u>Sum</u>	mary	Actual	Budget	Vari	ance	%YTD	Budget	Balance
1	Licences	37,609	31,775	5,834	18%	107%	35,101	(2,509)
2 3	EMA Inspections	9,062 6,943	9,151 7,374	(88) (431)	(1%) (6%)	89% 86%	10,152 8,079	1,090 1,136
4	Periodic fees	27,317	27,587	(270)	(1%)	91%	30,000	2,683
5	Devices	8,246	8,268	(22)	(0%)	91%	9,048	802
6	Other Regulator	8,322	6,702	1,620	24%	113%	7,368	(953)
	Regulator	97,499	90,857	6,642	7%	98%	99,748	2,249
7	NIBSC	38,002	37,432	571	2%	92%	41,183	3,181
8	CPRD	8,924	11,738	(2,814)	(24%)	68%	13,100	4,176
	Total Income	144,425	140,027	4,398	3%	94%	154,031	9,607
			Feb	,			Full Year	-,
Brea	<u>kdown</u>	Actual	Budget	Varia	ance	%YTD	Budget	Balance
1a li	cences - Product Licences							
10. 21	Decentralised Applications RMS	7,800	6,602	1,197	18%	107%	7,297	(503)
	Decentralised Applications CMS	7,360	5,729	1,631	28%	116%	6,332	(1,028)
	Variations PL	7,315	6,355	960	15%	104%	7,024	(291)
	PLPI	2,411	2,145	266	12%	102%	2,371	(40)
	National Applications	3,431	2,832	598	21% 29%	110%	3,130	(300)
	Labels & Leaflets Other Product Licensing	2,550 481	1,980 694	570 (213)	29% (31%)	117% 64%	2,188 748	(362) 267
	PL/PLPI COA	401	255	(213)	68%	152%	282	(147)
	EAM APPLICATIONS	38	0	38	0%	0%	0	(38)
	Sub-Total	31,814	26,592	5,222	20%	108%	29,372	(2,442)
1b. Li	cences - Clinical Trials							
	CT Applications	2,730	2,295	435	19%	108%	2,536	(194)
	CT Variations	681	574	107	19%	107%	635	(46)
	Sub-Total	3,411	2,869	542	19%	108%	3,171	(240)
1c. Li	cences - Other							
	ML/WDL	957	890	67	8%	97%	983	26
	Company Meetings	963	938	25	3%	93%	1,037	73
	PIM MEETING Export certificates	28 436	0 486	28 (50)	0% (10%)	0% 81%	0 537	<mark>(28)</mark> 101
	Sub-Total	2,384	2,314	70	3%	93%	2,557	173
		-						
	Licences - Total	37,609	31,775	5,834	18%	107%	35,101	(2,509)
2. EN								
	EMA Variations	3,374	3,710	(337)	(9%)	82%	4,101	727
	EMA Applications EMA PHV	1,439 1,109	1,247 543	192 566	15% 104%	104% 185%	1,378 600	(61) (509)
	EMA FIV EMA Scientific Advice	1,109	1,577	(507)	(32%)	61%	1,766	(509) 697
	EMA - Renewals	32	90	(58)	(64%)	32%	100	68
	EMA Inspections	622	639	(17)	(3%)	89%	702	80
	EMA Annual Fee	1,356	1,296	59	5%	93%	1,452	96
	EMA Attendance Allowance	61	48	13	27%	115%	53	(8)
	EMA - Total	9,062	9,151	(88)	(1%)	89%	10,152	1,098
3. In:	spections							
	Inspection Income	6,310	6,427	(117)	(2%)	90%	7,026	716
	Income from T & S Fees Falsified Medicines Directive	497 136	947	<mark>(450)</mark> 136	<mark>(48%)</mark> 0%	47%	1,053	556 (136)
	Faisified Medicines Directive	6,943	7,374	(431)	(6%)	86%	8,079	1,136
4 0-	•	-				91%		2,683
	riodic Fees	27,317	27,587	(270)	(1%)	91%	30,000	∠,७४১
5. De		821	843	(00)	(20()	87%	948	127
	Operating Income DH Funding for Devices	821 7,425	843 7,425	(22) 0	(3%) (0%)	87% 92%	948 8,100	127 675
	DH Funding for Depreciation	0	0	0	0%	0%	0,100	0/5
	Devices - Total	8,246	8,268	(22)	(0%)	91%	9,048	802
6. Ot	her Regulator Income							
	DH Funding for NIBSC Corporate costs	2,108	2,108	0	0%	92%	2,300	192
	British Pharmacopoeia	3,244	2,658	586	22%	112%	2,900	(344)
	RAMA XL Revenue	1,268	985	283	29%	116%	1,089	(179)
	Seminar Income	1,066	603	463	77%	156%	685	(381)
	Misc Regulator Income Other Regulator Income - Total	635 8,322	347 6,702	288 1,620	83% 24%	161% 113%	395 7,368	(241) (953)
.	•	0,322	0,702	1,020	24 /0	11376	1,300	(555)
7. NI		0.050	0.050	0	00/	000/	10 000	050
	DH Funding for NIBSC - revenue DH Funding for NIBSC - depreciation	9,350 5,042	9,350 5,042	0 0	0% 0%	92% 92%	10,200 5,500	850 458
	DH Funding for NIBSC - dividend	3,667	3,667	0	0%	92%	4,000	333
	Standards - WHO ISs	2,200	2,402	(202)	(8%)	84%	2,620	420
	Standards - Flu	4,520	2,795	1,726	62%	148%	3,049	(1,471)
	Standards - Clinical Diagnostics	650	738	(88)	(12%)	81%	805	155
	Standards - Shipping/ Other RSRU SLA DH	845 915	680 917	165 (2)	24% (0%)	91% 92%	926 1,000	81 85
	Certification Fees	4,512	4,400	(2) 112	3%	92% 94%	4,800	288
	Research Grants	4,181	5,492	(1,311)	(24%)	69%	6,052	1,871
	Contract	1,770	1,900	(130)	(7%)	79%	2,231	461
	Other Income	350	49	301	614%	0%	0	(350)
	NIBSC - Total	38,002	37,432	571	2%	92%	41,183	3,181
8. CF								
	CPRD - Observationals	7,951	10,405	(2,454)	(24%)	69%	11,500	3,549
	CPRD - Clinical Trials	973 8 924	1,333	(361) (2 814)	(27%)	61%	1,600	627
	CPRD - Total	8,924	11,738	(2,814)	(24%)	68%	13,100	4,176
Total	Income	144,425	140,027	4,398	3%	94%	154,031	9,607

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2016-OB-15 Appendix 1

MANAGEMENT ACCOUNTS

Year to 29th Feb 2016

Schedule 3

Expenditure - Analysis by Segment and Type

£'000s

		Feb 16		Full Year								
	Actual	Budget	Variano	ce	%YTD	Budget	Balance					
MHRA												
Staff Costs	66,383	70,238	3,855	5%	86%	76,979	10,596					
Overtime	311	383	72	19%	74%	419	107					
ICT	20,696	15,534	(5,162)	(33%)	128%	16,119	(4,577)					
Accommodation	8,366	8,715	348	4%	88%	9,518	1,152					
Depreciation	9,900	10,072	173	2%	90%	11,016	1,117					
Staff Related Costs	3,455	3,822	367	10%	83%	4,159	704					
Training	756	858	102	12%	82% 72%	927	171					
Externally Provided Services	3,433 8,646	4,357 8,221	924 (425)	21% (5%)	72% 96%	4,740 9,031	1,306 385					
Medicines Testing and Laboratory Marketing	0,040 70	170	(425)	59%	39%	9,031	112					
Cost of Seminars	420	215	(204)	(95%)	171%	245	(175)					
Other	5.070	1.601	(3.469)	(217%)	191%	2.649	(2.421)					
MHRA Operating Costs	127,505	124,186	(3,319)	(3%)	94%	135,984	8,479					
	,000		(0,0.0)	(0,0)	0170	,	0,0					
Regulator												
Staff Costs	47,346	49,278	1,932	4%	88%	53,710	6,364					
Overtime	202	285	83	29%	65%	312	109					
ICT	17,917	13,871	(4,046)	(29%)	125%	14,305	(3,612)					
Accommodation	4,596	5,269	672	13%	80%	5,747	1,151					
Depreciation	4,059	4,268	208	5%	87%	4,652	593					
Staff Related Costs	2,995	3,246	251	8%	85%	3,536	542					
Training	495	576	81	14%	80%	620	125					
Externally Provided Services	2,641	3,067	427	14%	79%	3,333	692					
Medicines Testing and Laboratory	2,436	2,616	180	7%	84%	2,898	462					
Marketing	33	83	50	61%	38%	87	54					
Cost of Seminars	417	215	(201)	(93%)	170%	245	(172)					
Other Regulator Operating Costs	5,404 88,539	1,108 83,881	(4,295) (4.659)	(388%) (6%)	449% 98%	1,204 90,648	(4,200) 2,109					
Regulator operating coold	00,000	00,001	(4,000)	(070)	0070	00,040	2,100					
NIBSC												
Staff Costs	16,596	18,111	1,515	8%	82%	20,166	3,570					
Overtime	109	98	(11)	(11%)	102%	107	(2)					
ICT	371	406	35	9%	84%	442	71					
Accommodation	3,770	3,446	(324)	(9%)	100%	3,771	1					
Depreciation	5,004	5,012	8	0%	91%	5,500	496					
Staff Related Costs	352	420	68	16%	77%	457	105					
Training	188	179	(9)	(5%)	96%	195	7					
Lab & Other Lab Consumables	6,210	5,605	(605)	(11%)	101%	6,133	(77)					
Externally Provided Services	207	497	290	58%	38%	542	335					
Other	(345)	472	817	173%	(155%)	223	568					
NIBSC Operating Costs	32,462	34,246	1,784	5%	86%	37,536	5,074					
CPRD												
Staff Costs	2,441	2,850	409	14%	79%	3,104	663					
Overtime	0	0	0	0%	0%	0	0					
ICT	2,408	1,258	(1,151)	(91%)	176%	1,372	(1,036)					
Accommodation	0	0	0	0%	0%	0	0					
Depreciation	836	793	(43)	(5%)	97%	864	28					
Staff Related Costs	108	156	47	30%	65%	166	57					
Training	73	103	30	29%	65%	112	39					
Externally Provided Services	586	793	207	26%	68%	865	279					
Medicines Testing and Laboratory	0	0	0	0%	0%	0	0					
Marketing	38	87	50	57%	39%	95	58					
Cost of Seminars	3	0	(3)	0%	0%	0	(3)					
Other	11	20	9	46%	1%	1,222	1,211					
CPRD Operating Costs	6,503	6,059	(444)	(7%)	83%	7,800	1,297					

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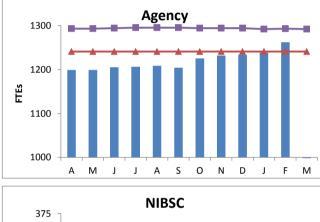
MANAGEMENT ACCOUNTS

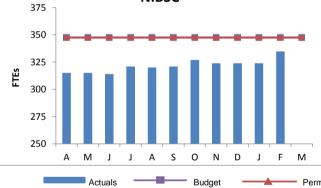
As at 29th Feb 2016

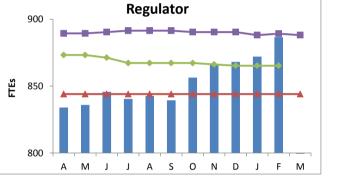
Schedule 4

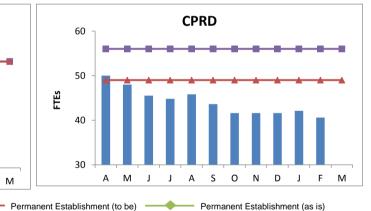
Full Time Equivalent (FTE) Schedule

		Casual	Employees	Payroll Employees	Grand Total	Budget	(payroll- only)	Variance	Average YTD	Perm Est 'As Is'	Perm Est 'To Be'
	211.0	14.0	225.0	4.0	229.0	241.9	16.9	12.9	220.2	240.9	240.9
Licensing VRMM	-	-		-		-			-		
	107.8	24.5	132.3	-	132.3	126.3	(6.0)	(6.0)	126.2	120.3	119.3
IE&S	160.2	18.8	179.0	2.6	181.6	192.3	13.3	10.7	180.0	185.5	182.3
Policy	18.6	1.8	20.4	3.0	23.4	23.0	2.6	(0.4)	22.5	19.9	20.9
Information Management	81.8	1.0	82.8	26.0	108.8	104.8	22.0	(4.0)	101.8	106.8	91.8
Finance & Procurement	27.5	2.0	29.5	3.8	33.3	32.5	3.0	(0.8)	32.8	31.2	28.2
Facilities	4.3	3.0	7.3	1.0	8.3	7.0	(0.3)	(1.3)	7.7	7.0	6.0
Human Resources	16.6	6.0	22.6	4.0	26.6	23.3	0.7	(3.3)	25.0	16.8	17.8
Directorate	6.5	-	6.5	1.0	7.5	6.9	0.4	(0.6)	7.8	6.9	6.9
Devices	92.3	5.0	97.3	1.0	98.3	95.0	(2.3)	(3.3)	93.0	95.0	95.0
Communications	30.6	5.0	35.6	2.0	37.6	36.2	0.6	(1.4)	36.4	35.0	35.0
REGULATOR	757.1	81.1	838.2	48.4	886.6	889.2	50.9	2.5	853.4	865.3	844.0
NIBSC	257.9	72.9	330.8	4.0	334.8	347.9	17.1	13.1	321.8	347.6	347.6
CPRD	27.6	9.0	36.6	4.0	40.6	56.0	19.4	15.4	44.1	49.0	49.0
Total	1,042.6	163.0	1,205.6	56.4	1,262.0	1,293.1	87.4	31.0	1,219.3	1,261.9	1,240.6









"As is" — represents the Divisions's permanent establishment at the end of P1 where specific posts have been identified and removed.

"To be" - represents the permanent establishment at the end of 2015/16 when each division has identified and removed all its required posts as part of the headcount reduction.

	Permanent	Casual	Total Payroll Employees	Non Payroll Employees	Grand Total	Budget	Variance (payroll- only)	Variance	Average YTD	Full Year Perm Est 'As Is'	Full Year Perm Est 'To Be'
In Devices	92.3	5.0	97.3	1.0	98.3	95.0	(2.3)	(3.3)	93.0	95.0	95.0
Devices Enforcement (in											
IE&S)	6.0	-	6.0	-	6.0	7.0	1.0	1.0	7.0	7.0	7.0
Total Devices	98.3	5.0	103.3	1.0	104.3	102.0	(1.3)	(2.3)	100.0	102.0	102.0

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MANAGEMENT ACCOUNTS

Year to 29th Feb 2016

Schedule 5

TABLE 1 : Summarv

		Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Planned Expenditure 2015/16	Total Capital Expenditure	Total Revenue Expenditure	Total Expenditure to date	Balance Available	
Regulator		6,351	15,164	10,293	31,807	17,121	1,813	6,537	8,350	23,397	
NIBSC		8,413	0	0	8,413	8,413	3,635	499	4,134	4,279	
CPRD		2,000	0	0	2,000	2,000	1,856	0	1,856	144	
Gross Tot	al	16,764	15,164	10,293	42,220	27,534	7,304	7,036	14,340	27,820	
TABLE 2 : Regulator By proje £'000s	<u>ct</u>										
List of Projects:	Governance	Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Planned Expenditure 2015/16	Total Capital Expenditure	Total Revenue Expenditure	Total Expenditure to date	Balance Available	Status
Business Intelligence	IMGB	3,198	431	574	4,203	3,121	1,322	54	1,376	2,827	Development / implementation
Information & Records Management	IMGB	0	4,221	499	4,720	3,679	180	1,355	1,534	3,186	Development / implementation
IO Service Transition	IMGB	600	3,324	6,036	9,960	4,940	0	3,237	3,237	6,723	Development / implementation
Superdome Hardware	IMGB	100	0	0	100	100	32	0	32	68	Development / implementation
Digital Service Transformation / Application Refresh	IMGB	423	3,118	360	3,901	2,158	54	1,129	1,184	2,717	Development / implementation
FMD Logo	IMGB	125	0	0	125	125	93	0	93	32	Development / implementation
DAP Performance Enhancements	IMGB	0	115	0	115	115	0	36	36	79	Development / implementation
Oracle R12 - ERP	IMGB	0	3,905	840	4,745	998	5	665	670	4,075	Development / implementation
Certificate for Free Sales	IMGB	90	0	0	90	20	16	0	16	74	Development / implementation
Centralised Spreadsheet	IMGB	202	0	0	202	202	87	37	124	78	Development / implementation
UK Haemovigillance joint (SHOT/SABRE) reporting system	IMGB	50	0	0	50	50	0	0	0	50	Not Yet Started
Website Content Migration	IMGB	0	50	0	50	50	0	6	6	44	Ongoing
E-Cigarettes	IMGB	330	0	1,984	2,314	330	0	18	18	2,296	Ongoing
Devices		1,000	0	0	1,000	1,000	3	0	3	997	Ongoing
Other IT Hardware/Software		0	0	0	0	0	44	0	44	(44)	Ongoing
Lab Equipment / Enforcement Vehicles	Budget & Business Cases	232	0	0	232	232	37	0	37	195	Ongoing
151 BPR Refurb							(60)	0	(60)		Completed
Regulator T	otal	6,351	15,164	10,293	31,807	17,121	1,813	6,537	8,350	23,397	

TABLE	3:	NIBSC	
£'000s			

List of Projects:	Governance								
іт	Budget								
Accommodation	Budget								
Equipment	Budget								
NIBSC Total									
TABLE 4 : CPRD									

Capital Approved	One-Off Revenue Approved	Other Revenue Approved	
808	0	0	
5,535	0	0	
2,070	0	0	
8,413	0	0	11

ner enue oved	Total Business Case Approved
0	808
0	5,535
0	2,070
0	8,413

Planned Expenditure 2015/16

808

5,535

2,070

8,413

Total Capital Expenditure	Total Revenue Expenditure	Total Expenditure to date
314		314
2,490	499	2,989
831	0	831
3,635	499	4,134

Expenditure (to the end of Feb 2016)

	Status	
Ongoing		
Ongoing		
Ongoing		

List of Projects:	Governance		Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Planned Expenditure 2015/16	Total Capital Expenditure	Total Revenue Expenditure	Total Expenditure to date
Trial Viz / Trial Form	Budget	[[2,000	0	0	2,000	2,000	1,856	0	1,856
CPRD Total			2,000	0	0	2,000	2,000	1,856	0	1,856

Balance Available	Status
144	Implementation
144	

Г

Balance Available

494

2,546

1,239

4,279

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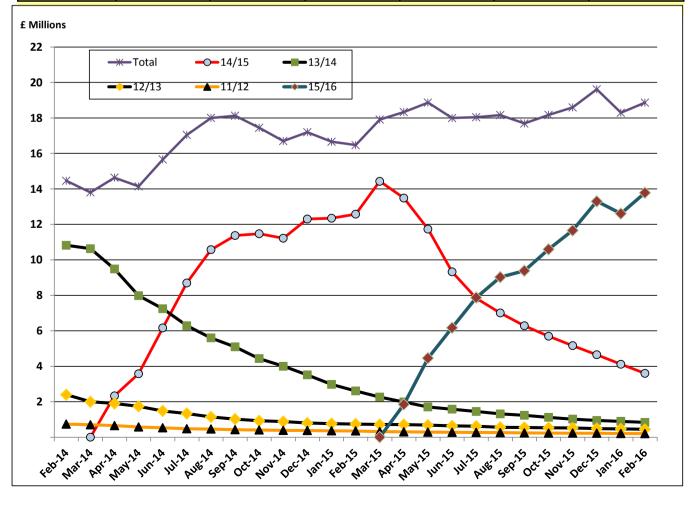
Management Accounts

Year to 29 Feb 2016

Schedule 6

PL - Deferred Revenue - Movement Monitoring

£'000s			Deferred Revenue	e - Product Licens	sing	
Date	Total	15/16	14/15	13/14	12/13	11/12
Feb-14	14,457			10,822	2,395	741
Mar-14	13,804			10,629	1,999	701
Apr-14	14,635		2,334	9,483	1,902	653
May-14	14,142		3,578	7,982	1,741	579
Jun-14	15,661		6,159	7,244	1,483	533
Jul-14	17,040		8,697	6,288	1,337	476
Aug-14	18,002		10,571	5,599	1,148	461
Sep-14	18,122		11,370	5,094	1,018	422
Oct-14	17,444		11,473	4,433	925	405
Nov-14	16,695		11,216	4,002	885	385
Dec-14	17,194		12,299	3,512	799	378
Jan-15	16,661		12,346	2,980	768	363
Feb-15	16,470		12,577	2,610	742	351
Mar-15	17,910		14,430	2,267	717	313
Apr-15	18,336	1,853	13,483	1,988	712	301
May-15	18,862	4,459	11,730	1,702	683	288
Jun-15	17,994	6,171	9,328	1,581	640	274
Jul-15	18,044	7,870	7,835	1,451	619	269
Aug-15	18,163	9,025	7,004	1,317	561	257
Sep-15	17,687	9,387	6,283	1,234	544	239
Oct-15	18,172	10,599	5,697	1,118	531	228
Nov-15	18,590	11,659	5,162	1,019	523	228
Dec-15	19,612	13,300	4,649	948	489	226
Jan-16	18,294	12,608	4,115	896	469	205
Feb-16	18,862	13,780	3,598	837	446	201



2015/16 Forecast Summary

		Published	1	Maximum		Maximum	Range
		Budget		Unfavourable		Favourable	%
		£000s		Outcome £000's		Outcome £000s	
			Regulator	6,422		7,370	
			NIBSC	(230)		350	
			CPRD	(3,484)		(3,414)	
	Income	154,031	or ne	2,708		4,305	1.0%
	income	104,001		2,700		4,303	1.0 %
			Regulator	2,044		2,133	
			NIBSC	1,615		1,715	
			CPRD	415		418	
	Pay	77,398		4,074		4,266	0.2%
			Regulator	(9,873)		(7,938)	
			NIBSC	1,150		1,533	
	Non		CPRD	147		347	
	Pay	58,586		(8,576)		(6,058)	4.3%
				R8			
In-Year Operating Surplus /	<u>.</u>						4 50/
(Deficit) Forecast		18,047		16,253		20,560	1.5%
	less Dividen	d Payments	Regulator	(5,000)		(5,000)	
			NIBSC	(4,000)		(4,000)	
				Maximum		Maximum	Range
				Unfavourable		Favourable	%
		-		Outcome £000s		Outcome £000s	
In-Year Retained Surplus /							1.6%
(Deficit) Forecast				7,153		11,660	
				Max Unfavourable	F	Max Favourable	
			Comprising		Forecast		
			Comprising	Surplus	Surplus	Surplus	1.6%
			Regulator NIBSC	4,093	5,179	7,165	
			-	2,182 878	2,714	3,245	1.4%
			CPRD	ŏ/ŏ	905	1,251	1.3%
			Total Farage	of Sumplue	0 700	7	
			Total Foreca	si surpius	8,798		

2015/16 Forecast - Regulator

Notes

				Unfavou	rable	Favou		
Note	In-year performa	ance 2015/16	Budget	Variar		Varia		Range
			£000s		£000s		£000s	%
	Surplus / (Deficit)							
		Opening Planned Surplus - Regulator			9,100		9,100	
	Income	Regulator	99,748					
		P11 Variance			6,642		6,642	
1		DCP		0		200		
2		EMA Income		0		100		
3		Periodic Fees		0		0		
4		Inspections (inc Blood and Unlicensed Med)		(100)		0		
5		Others Projected Variance		(120)		428		
		P11-12 Forecast variance		_	(220)	-	728	
	Income Year-End Fo	precast Variance	99,748		6,422		7,370	1.0%
	Expenditure	Regulator						
		P11 Pay Variance	54,021	1,955		1,955		
		P11 Pay Variance Extrapolated		89		178		
		Pay Variance			2,044		2,133	
		P11 Non Pay Variance	36,627	(6,673)		(6,673)		
6		Other Non Pay Extrapolated		(2,000)		(455)		
7		Bad Debt & Credit Note Provision		(250)		0		
8		Accommodation Asset Re-Lifeing		(950)		(810)		
		Non Pay Variance			(9,873)		(7,938)	
	Expenditure Year-E	nd Forecast Variance	90,648	_	(7,829)	-	(5,805)	2.2%
			Published Budget	Max. Unfav			avourable	Range
				Outcome		Outcome	£000s	%
	In-Year Operating S	urplus / (Deficit) Forecast	9,100		7,693		10,665	1.6%
9		less Regulator dividend payment		Ľ	(5,000)		(5,000)	Ì
10		add Net recharge to other centres		Ľ	1,400	[1,500	
	In -Year Retained S	urplus / (Deficit) Forecast			4,093		7,165	1.6%
					.,		.,	

Forecast Surplus

5,179

1 Favourable assumes DCP performance in P12 is above budget by £0.2m. Unfavourable assumes that it is in line with the budget.

- 2 Favourable assumes Income performance from the EMA (through Applications, Variations, PHv, Scientific Advice, Annual Fee and Renewals) in P12 will improve by £0.1m Unfavourable assumes EMA will be in line with budget.
- 3 Periodic Fees Based on latest review of cash collections so far in 2015/16 Favourable and unfavourable assumes performance in P12 will be in line with budget.
- 4 Favourable assumes that income performance for Inspections in P12 will be in line with budget. Unfavourable assumes that the performance will be £0.1m below budget.
- 5 Favourable assumes that the rate of performance in P12 in the remaining income streams within the regulator is in line with P1-11 meaning a £0.8m positive variance. Unfavourable assumes that performance is approximately £0.5m worse than the favourable.
- 6 Favourable assumes that the non pay variance will worsen by £0.5m from P12. The unfavourable scenario assumes that the non pay variance will worsen by £2.0m from P12.
- 7 Due to the the current level of (and provision for) outstanding debt, the favourable and unfavourable scenario assumes that there will be changes to the Bad Debt / Credit Note provision reducing the surplus by £0.3m for the unfavourable. There is no effect on the surplus in the favourable scenario.

8 The favourable assumes £0.8m adverse effect the unfavourable a £1.0m adverse effect, based on the view that the departure from 151 BPR will be in Dec 2017 (under the favourable scenario) and March 2018 (under the unfavourable scenario).

9 The Regulator must make a 3.5% return on Capital employed. This is currently estimated at £5.0m for 2015/16 financial year.

10 Favourable scenaro suggests £1.5m will be recharged out of the Regulator into the other centres. Unfavourable scenario suggests that this will only be £1.4m.

2015/16 Forecast - NIBSC

				Unfavoura	able		ourable	
Note	In-year performan	ce 2015/16	Budget	Varianc	e	Var	iance	Range
			£000s		£000s		£000s	%
	Surplus / (Deficit)							
		Opening Planned Surplus - NIBSC			3,647		3,647	
	Income	NIBSC	41,183					
		P11 Variance			570		570	
1		Research Grants variance		(300)		(300))	
2		Research Grants EC Overheads		(900)		(720	0)	
3		Standards Sales (incl shipping) variance		500		900)	
4		Certification Fees variance		(100)		(100))	
5		DHSSPS SLA		0		C)	
		Total Income Forecast Variance			(800)		(220)	
	Income Year-End For	ecast Variance	41,183		(230)		350	1.4%
	Expenditure	NIBSC	37,536					
		P11 Pay Variance	,	1,515		1,515	5	
6		P11 Pay Variance Extrapolated		100		200)	
		Pay Variance			1,615		1,715	
		P11 Other operating costs variance		269		269	9	
7		Accommodation costs		(200)		(100		
8		Laboratory costs		(200)		(
9		Project cost adjustment		586		469		
10		Release of GRNI accrual		695		695	5	
11		VAT Refund		0		200		
		Non Pay Variance			1,150	200	1,533	
	Expenditure Year-End	l Forecast Variance	37,536		2,765		3,248	1.3%
			Published				-, -	
			Budget	Max. Unfavo	urable	Max. I	Favourable	Range
			-	Outcome		Outcome	£000s	%
	In-Year Operating Sur	rplus / (Deficit) Forecast	3,647	Outcome	6,182	Outcome	7,245	[%] 1.4%
12		less NIBSC dividend payment	•	·	(4,000)	1	(4,000)	
								1
		add corporate recharge			0		0	
	In -Year Retained Sur	plus / (Deficit) Forecast			2,182		3,245	1.4%
					Forecast Surplus	2,714]	

Notes

1 Research Grants forecast to fall short of the budget of £7.1m by £1.6m due to no cost extensions on Barda, Gates Macadam and UKSCB grants with revised forecasting on other grants.

2 Research grants may need to be adjusted for the write off of the income on the EC FP7 grants - at worst this will be £0.9m, with an outturn of £5.2, favourable assumes only 80% of this in 15/16

3 Standards Sales (includes shipping): Favourable assumes that income performance for P12 will exceed the monthly budget by £0.9m delivering an outturn of £9.7m.

Unfavourable assumes that income performance in P12 will be £0.5m abov the monthly budget of £0.6m delivering an outturn of £9.3m.

4 Certification fees - assumes this will be in line with the budget giving an outturn of £4.8m. The current favourable variance of £0.1m will reverse.

5 DH Funding will remain in line with the budget, but the £0.4m for NI Department of Health, Social Services and Public Safety (DHSSPS) is reflected in the YTD variance.

6 Assumes pay variance will be at £0.2m in P12, the unfavourable £0.1m in P12.

7 Accommodation costs could be as much as £0.5m over budget for the year due to refurbishments classed as revenue instead of capital, and favourable would be estimated at half of this.

8 Laboratory costs are over budget and this is likely to continue. The unfavourable assumes the overspend will be £0.5m, the favourable that it will be at it's current level of £0.3m above budget.

9 Project cost adjustment - these are the project costs for the grants in Note 1

10 Release of GRNI (Goods Received Not Invoiced) - Accrual Purchase orders receipted but invoices have been paid and not matched to the PO.

11 VAT refund for the remaining quarter is likely to be at least in line with budget but could be as much as £0.3m above budget.

12 Projected NIBSC dividend payment for 2015/16.

2015/16 Forecast - CPRD

Note	In-year performa	ance 2015/16	Budget	Unfavour Variane	ce	Favoura Varian	ce	Range
			£000s		£000s		£000s	%
	Surplus / (Deficit)	On an in a Bloom of Ourseling OBBD						
		Opening Planned Surplus - CPRD CPRD	40.400		5,300		5,300	
	Income		13,100		(0.04.4)		(0.04.4)	
		P11 Operational Variance		(100)	(2,814)	(000)	(2,814)	
1		Observationals		(400)		(330)		
2		Clinical trials income		(270)	(070)	(270)	(000)	
		P11-12 Forecast variance			(670)	—	(600)	
	Income Year-End F	orecast Variance	13,100		(3,484)		(3,414)	0.5%
	Expenditure	CPRD						
		P11 Pay Variance	3,104	409		409		
		P11 Pay Variance Extrapolated		6		9		
		Pay Variance			415		418	
		P11 Non Pay Variance	4,696	(853)		(853)		
3		P11-12 Non-Pay Variance		(100)		0		
4		Non Pay reserves		1,100		1,200		
		Non Pay Variance			147		347	
	Expenditure Year-E	nd Forecast Variance	7,800	_	562	_	765	2.6%
			Published					
			Budget	Max. Unfavo	ourable	Max. Fav	ourable	Range
			-	Outcome		Outcome	£000s	%
	In-Year Operating S	Surplus / (Deficit) Forecast	5,300		2,378	outoonic	2,651	1.3%
5			add corporate r	echarge	(1,500)		(1,400)	
					Forecast Surplus	905		

1 Favourable assumes observationals will perform in P12 at a similar rate the same rate as in P1-11. Unfavourable assumes performance will be aproximately £0.1m worse than the favourable.

2 The Favourable and the unfavourable scenario assumes that no further Clinical trials income will be received in P12.

3 The favourable position assumes that spend is in line with the forecast budgets. The unfavourable position assumes spending will exceed reforecast budgets by £0.1m.

4 The unfavourable position assumes we use £0.1m of the remaining £1.2m of non pay reserves. The favourable assumes there is no utilisation of these reserves.

5 The unfavourable suggests that the Corporate recharge from the Regulator will be £1.5m. The favaourable suggests that £1.4m will be recharged to CPRD.

2016-OB-15 Appendix 3

STATEMENT OF FINANCIAL POSITION

		29 Februa		31 Januar Fina		31 March	
		Dra	Draft		I	Final	
Notes		£'000	£'000	£'000	£'000	£'000	£'000
	NON-CURRENT ASSETS						
	Plant and Equipment		95,507		95,153		96,726
	Intangible Assets		12,231		13,171		10,930
1	Assets Under construction		3,671		6,164		8,541
	TOTAL NON-CURRENT ASSETS		111,409	_	114,488	_	116,197
	CURRENT ASSETS						
	TRADE AND OTHER RECEIVABLES						
	Inventories	6,818		6,818		6,827	
2	Other Trade Receivables	6,592		3,892		7,392	
3	DH Receivables	2,310		2,310		9,500	
	Service Fee credit note	(1,741)		(1,860)		0	
	Credit note and bad debt provision	(1,111)		(1,291)		(1,618)	
4	Pre-payments	1,991		2,224		1,984	
5	Accrued Income	14,686		6,553		3,114	
	Other Receivables	560		259	L	1,863	
	TOTAL TRADE AND OTHER RECEIVABLES		30,104		18,906		29,062
6	Cash and Cash Equivalents	_	212,539		218,348	_	192,534
	TOTAL CURRENT ASSETS		242,643		237,254		221,596
	CURRENT LIABILITIES						
7	Payments on Account - non iRIS	(15,083)		(13,909)		(12,386)	
7	Payments on Account - iRIS	(1,482)		(1,892)		(1,650)	
	Trade payables	(399)		(1,702)		(4,767)	
	Proceeds of Crime Reserve	(92)		(98)		(7)	
8	DH payables (including short-term borrowings)	(7,162)		(6,549)		(14,366)	
9	Accrued Expenses	(11,528)		(9,047)		(9,456)	
	Provisions for liabilities and charges	(350)		(350)		(350)	
	Tax and N.I.	(2,810)		(2,809)		(2,648)	
	Other payables	(105)		(98)	L L	(2)	
	TOTAL CURRENT LIABILITIES		(39,011)	_	(36,455)	_	(45,632
	Net current (Liabilities)/assets	_	203,632		200,800	_	175,964
	Total Assets less Current Liabilities		315,041		315,288		292,161
	Borrowings		(1,328)		(1,328)		(1,328
	Provisions for liabilities and charges		(1,963)		(2,216)		(2,236
	DEFERRED REVENUE						
	Licence fees (applications and variations)	(18,832)		(18,264)		(17,603)	
10	Service Fees	(2,483)		(4,853)		0	
11	Other fees	(15,915)		(9,861)		(6,926)	
	CPRD	(13,145)		(13,145)		(13,145)	
	TOTAL DEFERRED REVENUE	_	(50,376)		(46,124)	_	(37,674
	NET ASSETS	_	261,375	_	265,621	_	250,923
	FINANCED BY TAXPAYER'S EQUITY						
	Public dividend capital		1,329		1,329		1,329
	Revaluation Reserve		61,888		61,888		61,879
	General Reserve		42,470		42,470		42,470
	Income & Expenditure Reserve		954		954		954
	Retained earnings	_	154,734	_	158,981	_	144,291
	TOTAL TAXPAYER'S EQUITY		261,375		265,621		250,923

Notes:

1	Assets Under Construction decrease due to impairment of £2.4m BI project investment.
2	Trade receivables increased by a £2.7m over last month. See SFP annex for further analysis.
3	DH receivables £2.3m is invoicing for revenue funding (NIBSC £1.5m and Devices £0.8m), relate to January invoices not yet paid.
4	Prepayments include: £1.1m for computing costs; £0.5m misc prepayments and £0.3m for NIBSC.
5	Accrued income includes: £7.7m DH (circular flow); £1.9m EMA; £2.0m pending cases, £0.6m NIBSC and £2.5m other misc income.
6	The cash and cash equivalents at the end of the month was £212.5m, a decrease of £5.8m from the previous month. See Cash Report for details.
7	Payments on account increased by £0.8m during the month. See SFP Annex for details.
8	DH payables includes £5.9m for 2015/16 dividends.
9	Accrued expenses include: £2.0m annual leave provision; £3.1m (£1.7m last month) for computing costs; £1.9m for accomodation; £1.5m misc accruals and £3.1m for NIBSC (£2.6m last month).
10	Service fees income deferred at the start of the year.
11	Includes CPRD (£2.3m) and RAMAXL (£0.6m) annual invoices raised in February and £6.8m DH circular flow.

	STATEMENT OF FINANCIAL POSITION ANNEX - 29 February 2016 ANALYSIS OF DEBTORS, CASH RECEIPTS AND PAYMENTS ON ACCOUNT							
	Table 1 - MHRA	Debtors Analysis	at 29 February 20	016				
		Feb	-16	Jan	-16	Mar-1	5	
Notes		Di	raft	Fi	nal	Final		
			£000		£000		£000	
1	Other Trade receivables (per SFP)		6,592		3,892		7,392	
	DH receivables (per SFP)		2,310		2,310		9,500	
	Total Debts		8,902		6,202		16,892	
2	Service fee credit note		(1,741)	(1,860)		(263)		
3	Provisions for credit notes, bad and doubtful debts		(1,111)	(1,291)		(1,356)		
4	Gross Trade Receivables		6,050		3,051		15,274	
	Payments on Account		(16,566)		(15,801)		(14,036)	
5	Net Trade Receivables (per Debtors Ledger)	(10,516)			(12,750)		1,237.76	
6	Gross Debt less than 6 months old	94%	8,380	92%	5,680	92%	15,541	
	Gross Debt between 6 and 12 months old	4%	366	7%	448	3%	507	
	Gross Debt greater than 12 months old	2%	157	1%	74	5%	845	

	Table 2 - MHRA Cash Receipts Analysis at 29 February 2016						
Feb-16		Year to February 2016		Year to February 2015			
		£000	%	£000		£000	%
7	Cash receipts	7,443		152,935		169,267	
8	Allocated	3,795	51%	141,846	93%	160,002	95%
	Unallocated	3,648	49%	11,089	7%	9,265	5%

	Table 3 - MHRA Payments on Account Analysis at 29 February 2016								
			Feb-16		,	Year end 2014/1	5	Movement since March 2015	
		£000	£000	%	£000	£000	%	£000	%
		iRis	Non iRis		iRis	Non iRis			
9	2011-12	3	132	1%	17	8	0%	110	-439%
	2012-13	9	207	1%	39	957	6%	(780)	78%
	2013-14	26	1,679	10%	174	4,896	27%	(3,365)	66%
	2014-15	131	3,291	21%	1,920	6,025	67%	(4,523)	57%
9	Sub total	169	5,309	33%	2,150	11,886	100%	(8,558)	
	2015-16 M1-3	472	803	8%					
	2015-16 M4-6	285	1,660	12%					
	2015-16 M7-9	389	1,890	14%					
	2015-16 M10-12	167	5,422	34%					
10	Total	1,482	15,083	100%					

Notes	
1	Trade Receivables increase due to annual invoicing for CPRD £2.3m and RAMAXL £0.6m.
2	Service fee credit note £1.7m is likely income adjustment to the invoicing issued in April 2015.
3	Provisions for credit note and bad debts £1.1m is provision created at year end for all unpaid service fees and other debts over six months.
4	Gross trade receivables at the end of February totalled £6.1m. This includes DH invoicing of £2.3m
5	Net receivables at the end of the month is -£10.5m as payments on accounts exceed all debts.
6	Gross debt less than six months is £8.4m (94%).
7	Cash receipts during the month were £7.4m making the total received so far this year £152.9m. This is £16.3m lower than at the same time last year.
8	£3.8m (51%) cash received during the month were allocated. The transition to the new banking service has resulted in loss of information delaying allocations.
9	The old payment on account balance which was £14.0m at the start of the year has reduced by £8.6m leaving a balance of £5.5m as further progress is made to refund these. The increase in 2011-12 figures are due to reallocating transactions where instructions for refunds are still outstanding.
10	The payments on account balance on the SFP at the end of the month was £16.6m an increase of £0.8m. £3.9m was received during the month.

FINANCIAL ACCOUNTS - MARCH CASH REPORT

1. FEBRUARY 2016

After rounding;

- The bank balance at the end of February was £212.5m (MHRA/CPRD: £192.9m; NIBSC £19.7m).
- This was £5.8m lower than last month (MHRA/CPRD: £4.9m lower; NIBSC: £0.9m lower) and £1.5m lower than forecast (MHRA/CPRD: £1.8m lower; NIBSC: £0.3m higher).
- The variance against the forecast was caused by receipts being £0.7m lower and payments being £0.8m higher than forecast.

1.1 <u>MHRA Regulator</u>

Receipts at £7.1m were £1.4m higher than forecast due to a €1.3m (£1.0m) receipt in relation to SCOPE and higher than forecast iRIS receipts.

Payments at £10.2m were £1.3m higher than forecast due to customer refunds made as a result of the focus by accounts receivable staff on clearing old payments on account.

1.2 <u>CPRD</u>

Receipts at £0.2m were £0.5m lower than forecast.

Payments at £0.5m were £0.2m lower than forecast.

1.3 <u>NIBSC</u>

Receipts at £1.5m were £1.6m lower than forecast due to payment for the last revenue funding invoice (£1.5m) for 15/16 not being received from DH as forecast.

Payments at £3.9m were £0.3m lower than forecast.

2. FORECAST 2015/16

The projected cash position at the end of March 2016 is forecast to be £210.1m.

3. PROJECTED FORECAST TO SEPTEMBER 2017

The balance at the end of September 2017 is projected to be £220.1m. A high point of £227.5m is expected in September 2016 and a low point of £205.9m is expected in April 2017.

4. <u>CONCLUSION</u>

The cash position of the MHRA remains healthy for the entire forecast period.

Cashflow Dec 2015 - Sep 2017

_ . . _

<u>£000's</u>	Dec-15	<u>Jan-16</u>	Feb-16	<u>Mar-16</u>	<u>Apr-16</u>	<u>May-16</u>	<u>Jun-16</u>	<u>Jul-16</u>	<u>Aug-16</u>	<u>Sep-16</u>	<u>Oct-16</u>	<u>Nov-16</u>	Dec-16	<u>Jan-17</u>	Feb-17	<u>Mar-17</u>	<u>Apr-17</u>	<u>May-17</u>	<u>Jun-17</u>	<u>Jul-17</u>	<u>Aug-17</u>	<u>Sep-17</u>
MHRA Accounts		ACTUAL											FORECAST									
MHRA Regulator Receipts	(including ov 6,322	verheads) 7,071	7,086	6,688	7,511	14,511	13,511	12,011	8,511	11,971	8,021	6,621	6,521	6,321	5,511	6,561	8,921	14,921	12,921	11,921	8,646	7,421
Payments	8,920	9,785	10,222	9,368	8,822	8,822	10,772	8,822	8,822	15,272	10,822	8,822	10,772	10,642	8,822	10,772	8,822	8,822	11,072	8,822	8,822	15,572
Subtotal	(2,598)	(2,714)	(3,136)	(2,680)	(1,311)	5,689	2,739	3,189	(311)	(3,301)	(2,801)	(2,201)	(4,251)	(4,321)	(3,311)	(4,211)	99	6,099	1,849	3,099	(176)	(8,151)
<u>CPRD (direct excl</u> Receipts	luding overhe 429	1eads) 990	237	800	875	875	875	875	875	875	875	875	875	875	875	875	950	950	950	950	950	950
Payments	433	946	504	700	740	600	600	740	600	600	740	600	600	740	600	600	855	715	715	855	715	715
Subtotal	(4)	44	(267)	100	135	275	275	135	275	275	135	275	275	135	275	275	95	235	235	95	235	235
NIBSC (direct exc	luding overh		0	4 500	0	•	0	6 000	1 500	9 700	4 500	1 500	1 500	4 500	0	0	0	0	•	6 000	1 500	9 700
Receipts Payments	1,467	8,700 1,510	0 1,530	1,500 1,500	0 1,550	0 1,550	1,550	6,000 1,550	1,500 1,550	8,700 1,550	1,500 1,550	1,500 1,550	1,500 1,550	1,500 1,550	0 1,550	0 1,550	1,550	1,550	0 1,550	6,000 1,550	1,500 1,550	8,700 1,550
Subtotal	(1,467)	7,190	(1,530)	0	(1,550)	(1,550)	(1,550)	4,450	(50)	7,150	(50)	(50)	(50)	(50)	(1,550)	(1,550)	(1,550)	(1,550)	(1,550)	4,450	(50)	7,150
Closing Balance	193,302	197,822	192,889	190,309	187,583	191,998	193,462	201,236	201,150	205,275	202,559	200,583	196,557	192,322	187,736	182,250	180,894	185,679	186,213	193,857	193,866	193,101
NIBSC Accounts																						
NIBSC (direct exc Receipts	luding overh 1,569	heads) 2,249	1,489	1,550	1,850	4 959	1,850	1,850	1,850	1,850	1,850	4 950	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850
Payments	1,569	2,249	2,365	1,550	1,850	1,850 1,450	1,850	1,850	1,850	1,850	1,850	1,850 1,450	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850	1,850
Subtotal	(140)	582	(876)	150	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400
Closing Balance	19,944	20,526	19,650	19,800	20,200	20,600	21,000	21,400	21,800	22,200	22,600	23,000	23,400	23,800	24,200	24,600	25,000	25,400	25,800	26,200	26,600	27,000
						040 500	214,462	222,636		007 475	225,159	223,583	219,957	216,122	211,936	206,850	205,894	211,079	212,013	220,057	220,466	220,101
Total	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,030	222,950	227,475	220,109	110,000	,	-1	,	200,000						
Total	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							,	200,000	200,001	211,010				
Total	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,030				ep 2017				200,000						
Total	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636														
Total	213,246	218,348	212,539	210,109																		
Total	213,246	218,348	212,539	210,109	207,783	212,598																
	213,246	218,348	212,539	210,109				222,030														
	213,246	218,348	212,539	210,109											Actual (Jan 16 - Fe							
235,000	213,246	218,348	212,539	210,109												. 16)						
235,000	213,246	218,348	212,539	210,109			214,402	222,536							- Actual (Jan 16 - Fe	. 16)						
235,000 230,000 225,000	213,246	218,348	212,539	210,109			214,402	222,536 							- Actual (Jan 16 - Fe	. 16)						
235,000 230,000 225,000	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)					Q=	0
235,000 230,000 225,000	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)					8	0
235,000	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)					8	
235,000 230,000 225,000 220,000 220,000	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)					8	0
235,000 230,000 225,000	213,246		212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)						
235,000 230,000 225,000 220,000 210,000	213,246	218,348	212,539	210,109	207,783	212,598	214,462	222,636							- Actual (Jan 16 - Fe	. 16)						0
235,000 230,000 225,000 220,000 220,000	213,246		212,539	210,109	207,783	212,598	214,462	222,030							- Actual (Jan 16 - Fe	. 16)						
235,000 230,000 225,000 220,000 210,000 205,000	213,246		212,539	210,109	207,783	212,598	214,462	222,030							- Actual (Jan 16 - Fe	. 16)					8	
235,000 230,000 225,000 220,000 210,000	213,246	218,348	212,539	210,109 Mar-16		212,598 May-16		Jul-16	Cashfl	ow Dec	2015 - S				- Actual (Jan 16 - Fe	- 16) Sep 17)		 May-17	0^	Jul-17		
235,000 230,000 225,000 220,000 210,000 205,000				· · · · · · · · · · · · · · · · · · ·				, , , , , , , , , , , , , , , , , , ,	Cashfl	ow Dec	2015 - S	ep 2017			- Actual (Jan 16 - Fe	- 16) Sep 17)			0^	Jul-17	Aug-17	
235,000 - 230,000 - 225,000 - 220,000 - 215,000 - 210,000 - 205,000 -				· · · · · · · · · · · · · · · · · · ·				, , , , , , , , , , , , , , , , , , ,	Cashfl	ow Dec	2015 - S	ep 2017			- Actual (Jan 16 - Fe	- 16) Sep 17)			0^	Jul-17	Aug-17	

				lt	em 12		2016-OB-15		
				An	pendix 5	1 c	5 Critical 5 10 15 20 25		
184 A									4 4 8 12 16 20
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Medicines &	& Healthcare	products						Impact	2 2 Low 2 4 6 8 10
Regulatory	Agency								1 1 2 2 4 5
negulatory	Agency					ME RISK ASSESS	MENT	Insi	
					INCO	WIE RISK ASSESS			Rare Unlikely Possible Likely Almost Probability
		% Change during past year		<u>Short</u>		Key Monitoring Measures		funded by	
	Current Annual Value (Mar 15 - Feb 16)* (£m)	(Mar 14 - Feb 15)*		Term Risk	<u>Medium</u> Term Risk	and performance for month	Corrective Action	source of income	Analysis
Periodic fees	£30n			Green O	Red O	1. Value of payments	Red O	35%	Cash receipts to the end of February at £29.8m are £2.5m
(* 2014/15 draft statutory a/c)						made versus previous year 2. Value of outstanding			lower than for the same period last year. Total outstanding debt is £0.4m, £0.3m higher than at this
statutory a/c/						payments split between			stage last year.
						those part paid and those			The second state of the FULDY (second state of the second state of
						completely unpaid			The potential impact of the EU PV fees remain under review In the medium term aging of MAs means income expected to
									drop to £26m pa.
nspections	£8n	n (11%)) (19%)	Green 🔾	Amber Ο	1. Comparison against	Green Ο	10%	
						budget 2. Demand for Inspections			inspections is high. Corrective action: Recruitment strategy being developed to
									help ensure vacant posts are filled. Budget increased for
PL Variation	£8n	n 10%	0%	Green 🔵	Green 🔵	1. The value of monthly	Green 🔵	10%	2016/17 by £0.4m. Annual value is currently £0.7m higher than 14/15. Monthly
					· ·	earnings			earnings, deferred revenue and rate of receipts steady.
						Rate of receipts of applications			Medium term risk remains at Green.
						3. The value of deferred			
						revenue			
DH Funding for Devices	£8.1m	0%	(100/)	Green 🔾	Black	DH 16/17 funding	Red 😑	10%	DH have recently indicated cash flat funding for the first half 16/17 and are committed to supporting the agency in the even
Current Annual	20.111	0%	(10%)				neu 🧹	10%	that the new fee regime is delayed.
Value = Plan)					1		1		Corrective action: The Agency is planning a move to a Devic fees regime starting from 2016/17.
Capital Funding	<u>£1.0m</u>								Residual medium term risk is Red due to uncertainty of new
									fee regime.
DCP RMS	£9.1n £9n		35%	Green 🔾	Amber 🔵	1. RMS substitution -	Amber 🔵	10%	Annual value is currently £0.1m Lower than 14/15. DCP RM
	2.91	1 (176)) 35%	Gleen	Amber	average fee charged	Amber	10.%	deferred revenue has increased by £0.4m during February.
See DCP Measures below)						Rate of receipts of applications			Receipts in February have decreased to 18 from 23 in January.
below)						3. Value of deferred			January.
						revenue			Medium term risk remains at Amber as it is anticipated that t
									surge in DCP receipts arising from data exclusivity rule changes will reduce post 2016/17 although income is expect
									to be maintained through 16/17 and 17/18.
DCP CMS	£8n	n 4%	40%	Green 🔾	Amber <mark></mark>	1. CMS substitution - average fee charged	Amber <mark></mark>	9%	Annual value is currently £0.3m higher than 14/15. DCP CMS deferred revenue has increased by £0.3m during February.
(See DCP Measures						2. Rate of receipts			Receipts in February have increased to 36 from 34 in Januar
below)						 Value of deferred revenue 			Medium term risk remains at Amber as it is anticipated that th
						i o i o i do			surge in DCP receipts arising from data exclusivity rule
									changes will reduce post 2016/17 although income is expect to be maintained through 16/17 and 17/18.
EMA PL (excl	£9n	n (9%)) 17%	Green 🔾	Green 🔵	1. The value of monthly	Green 🔵	11%	Annual value is currently £0.1m below budget. Bidding for
nspections)	201	. (070)	,			earnings			scientific advice has temporarily reduced due to resource
						The level of new contracts			constraints.
						3. Sterling/Euro exchange			
						rate			
Other	£15n	n 8%	(7%)	Green Ο	Green 🔿	1. The value of monthly	Green 🔿	18%	Risk maintained at green. Annual value is curently £1m lowe
PL/PLPI/PcL/CT					1	earnings 2. The value of deferred	1		than in 2014/15.
		ļ			<u> </u>	revenue			
Other income	£9n			Green 🗢	Green 🗢		Green 🗢	11%	
Regulatory Total	£106n		000/	Green 🦰	Ambor	Compositore in i	Ambor	124%	
CPRD Operational Income)	£10n	n 19%	26%	Green 🔾	Amber <mark>O</mark>	Comparison against budget	Amber <mark></mark>	148%	Medium term risk maintained at amber while new CPRD strategy and pricing being implemented. 15/16 YTD
					1	-	1		performance is £1.6m greater than the equivalent period in
									14/15 and is higher than the last year of GPRD, by 44%.
CPRD Total	£10n						-	148%	
NIBSC (I&E)	£1011	1				+		140 /0	DH have recently indicated cash flat funding for 16/17 and
DH Funding		1			1		1		perhaps until 2020. There remains uncertainty over funding
excl. Capital)	040 -								from 16/17 onwards, especially with government plans to cu funding by 25/40%, and DH asking NIBSC to ensure that DF
Revenue funding	£10.2m	0%	n/a	Green 🔵	Black	DH 2016/17 Funding	Red 🔴	61%	funding requirement is not greater than is necessary.
Revenue funding for Corporate	£2.3m								
Dividend	£4.0m	n/a							Corrective action: Maintain pressure on DH.
Depreciation	£5.5m	n/a							
Capital	£6m	n/a							
SubTotal NIBSC Standards	£22n £8n			Green ဝ	Red 🔴	Comparison against	Red 🔴	22%	Potential loss of influenza standards income (worth £3.9m ir
	£on	. (2%)	, 13%			budget and assumptions in		22.70	2014/15) due to potential regulatory changes that could
		1			1	sustainability model	1		obviate the need for producers to use these standards.
NIBSC Certification	£4n	n 28%	28%	Green Ο	Green 🔵	Comparison against	Green 🔵	12%	Residual risk is Green. Annual value 14/15 is £1m higher the
ees		1			1	budget and assumptions in	1		13/14.
						sustainability model			
		ļ							
NBSC Other	£9n	n 44%	120%	Green Ο	Green 🔾	Comparison against	Green 🔾	24%	
					1	budget and assumptions in sustainability model	1		
								44001	
NIBSC Total	£43n	1						119%	
	£158n	.]	1					124%	

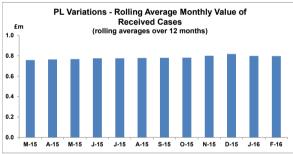
Item 12 Appendix 5

Periodic Fee Measures:

	Billing (£'000s)			Numbe	er of Licence	s Billed	Paid (£'000s)			
Periodic Fee Type (£'000s)	2014-15 (Billed)	2015-16 (Billed)	Difference	2014-15	2015-16	Difference	2014-15 Amount Received	2015-16 Forecast Outturn	Difference	
PL Prescription Only Medicine	30,488	30,187	(301)	11,928	11,811	(117)	19,579	18,084	(1,495)	
PL Abridged Complex	7,748	6,828	(920)	758	668	(90)	7,677	6,828	(849)	
PLPI Prescription Only Medicine	2,620	2,541	(79)	8,113	7,866	(247)	2,618	2,539	(79)	
PL General Sales List	397	383	(14)	1,230	1,186	(44)	395	381	(14)	
PL Pharmacy	400	395	(5)	1,238	1,222	(16)	400	395	(5)	
PL New Active Substance Major	447	447	0	18	18	0	447	447	0	
PL New Active Substance Additional Strength	117	90	(27)	17	13	(4)	117	90	(27)	
PL New Active Substance Additional Dosage	51	41	(10)	5	4	(1)	41	41	0	
PLPI Pharmacy	69	80	11	213	247	34	68	79	11	
National Homeopathic Product	40	19	(21)	505	236	(269)	35	17	(18)	
Herbal Remedy	28	28	0	352	351	(1)	27	27	0	
PLPI General Sales List	2	1	(1)	5	2	(3)	2	1	(1)	
PL No Status	1	1	0	2	3	1	1	1	0	
Pcl Billing - Broken down into:									0	
ML Licences	435	431	(4)	883	875	(8)	405	401	(4)	
WDL/WL Licences	682	724	42	2,345	2,477	132	631	670	39	
Total Billing	43,525	42,196	(1,329)	27,612	26,979	(633)	32,443	30,000	(2,443)	

PL Variation Measures:

	Average p	Deferred Revenue	
Period	Volume	Total Value £m	£m
2008/09	2,471	0.89	3.80
2009/10	1,310	0.78	3.70
2010/11	1,258	0.73	3.10
2011/12	1,396	0.83	3.20
2012/13	1,299	0.74	2.90
2013/14	1,227	0.71	3.00
2014/15	1,412	0.76	3.10
2015/16 YTD	1,477	0.79	3.20
Last 12 months	1,487	0.80	n/a
Last 6 months	1,466	0.79	n/a
Last 3 months	1,423	0.78	n/a
Last month (Feb)	1,364	0.72	n/a



DCP Measures:

	Average p	Deferred Revenue	
Period	Volume	Total Value £m	£m
2008/09	111	2.34	18.0
2009/10	95	2.02	18.4
2010/11	95	1.95	14.8
2011/12	63	1.27	11.9
2012/13	51	1.00	7.6
2013/14	54	1.11	7.3
2014/15	85	1.74	10.8
2015/16 YTD	73	1.47	10.6
Last 6 months	72	1.40	n/a
Last 3 months	59	1.23	n/a
Last month (Feb)	54	1.17	n/a

