

Medicines and Healthcare products Regulatory Agency

12 December 2016

Finance and Procurement Report

<u>Issue/Purpose:</u>	The purpose of this paper is to ask the Board to note the financial performance of the Agency for the first seven months of the financial year.
<u>Summary:</u>	After allowing for Dividends and Financing, after seven months of the year the Agency has a retained surplus of £2.2m which is £2.5m above budget. The Agency is forecast to deliver a retained surplus in 2016/17 of £5.6m which is £5.1m above budget, but the CET should note that the forecast expenditure of ICT is being further reviewed.
<u>Resource Implications</u>	See paper
<u>EU Referendum implications:</u>	Dependent on outcome of negotiations
<u>Timings</u>	Work in progress
<u>Action required by the Board</u>	To note
<u>Links</u>	
<u>Author(s):</u>	Daren Jones – Head of Business Analysis Richard Humphreys – Deputy Director, Finance and Procurement
<u>Which of the themes in the Corporate Plan does the paper support?</u>	All
<u>Which Business Plan strategic activity does it support?</u>	All
<u>CET Sponsor:</u>	Jon Fundrey – Chief Operating Officer

Finance and Procurement Report - Highlights

1. In-Year Performance

After seven months of the year, in-year performance shows that the Agency has an operating surplus of £5.4m which is £0.6m above budget. All three centres have an operating surplus: CPRD and NIBSC are both ahead of their budgeted operating surplus positions while the Regulator (Operate + Corporate) is £0.5m below its budgeted position at this stage of the year.

After allowing for dividend, after seven months of the year the Agency has a retained surplus of £2.2m which is £2.5m above budget.

2. 2016/17 Forecast

After allowing for dividends, the Agency is forecast to deliver a retained surplus of £5.6m which is £5.1m above budget.

The Regulator is forecast to deliver a retained surplus of £4.7m (£4.6m above budget) which is driven by: a £3.5m reduction in the Regulator's share of the dividend payment (due to the effect of the £100m super-dividend which was decided after the budget of £5m had been set) and operating income forecast to be £2.7m above budget (including a forecast of £1.5m for e-cigarette notification fees). This is offset by ICT costs being forecast at c£2m above budget due to: centralisation of NIBSC IT costs; and, expensing of operational transformation costs that had been budgeted as capital.

The forecast for ICT costs is being reviewed further to determine the timing of delivery of existing projects which may bring forward expenditure into 2016/17. The Agency is ahead (by c£66m) of its financial objective target in the five year period 2013-18 and has £129m cash, so it is advantageous to bring forward ICT Operational Transformation expenditure, where feasible and appropriate, into the remainder of the current 5 year period. Once the review has been completed, additional budget will be approved if appropriate.

NIBSC is forecast to deliver a retained surplus of £0.3m (£0.8m above budget) and CPRD is forecast to deliver a retained surplus of £0.6m (£0.3m below budget). The CPRD forecast includes an expectation that the second £1m of income from the DECIDE clinical trial will now be received in 2017/18.

Further detail on the forecast is included in the Dashboard on the next page.

3. Cash Report

The bank balance at the end of October 2016 was £128.8m, £1.3m higher than at the end of September 2016 and £7.2m higher than forecast. Receipts were higher in October than anticipated due to higher receipts from the European Medicines Agency and targeted debt recovery by the Accounts Receivable team. Payments were lower than anticipated due to not receiving the invoice from the DH for the 2015/16 dividend payment of £3.2m. The minimum cash balance over the next 18 months is forecast to be £96.9m in April 2018 just prior to the 2018/19 periodic fees being despatched. The ICT forecast review will be incorporated into the cash-flow forecast as more is known.

4. Statement of Financial Position

The most significant movement in the Statement of Financial Position (Schedule 6) during October was a reduction in trade receivables of £1.6m (12%).

5. Forward Look

The usual schedules on the IT portfolio and the Regulator financial model are not included this month as there has been relatively little change since the last report. Working with the Chief Operating Officer, these are being redesigned and will be included on a quarterly basis, plus there will be some further improvements to the whole report that are currently being developed.



Medicines & Healthcare products Regulatory Agency

CET - 6 December 2016 Board - 12 December 2016 Finance and Procurement Report

<u>Income & Expenditure</u>	Year to 31 October 2016						
	Regulator		NIBSC	CPRD	Total	Budget	Variance
All figures rounded	Operate	Corporate					
Operating Income	£60.6 m	£2.6 m	£25.2 m	£5.3 m	£93.6 m	£93.5 m	£0.2 m
Operating Expenditure	£31.1 m	£30.8 m	£22.4 m	£4.0 m	£88.2 m	£88.6 m	£0.4 m
Operating Surplus / (Deficit) - ACTUAL	£29.6 m	£(28.2)m	£2.8 m	£1.3 m	£5.4 m	£4.8 m	£0.6 m
Operating Surplus / (Deficit) - BUDGET	£29.6 m	£(27.7)m	£2.2 m	£0.8 m			
Variance		£(0.5)m	£0.6 m	£0.5 m			£0.6 m
Dividend Payable		£(1.0)m	£(2.3)m	£0.0 m	£(3.4)m	£(5.3)m	£1.9 m
Financing		£0.2 m	£0.0 m	£0.0 m	£0.2 m	£0.1 m	£0.0 m
Retained Surplus / (Deficit)		£0.5 m	£0.5 m	£1.3 m	£2.2 m	£(0.3)m	£2.5 m
Year-End Budget		£0.1 m	£(0.5)m	£0.9 m	£0.5 m		
Year-End Forecast		£4.7 m	£0.3 m	£0.6 m	£5.5 m		
<u>5 Year Rate of Return</u>	2013-2018				2018-2023		
	Estimated Target	Current Return	Forecast	Exceeds Target By	Estimated Target	Modelled	
Performance against estimate of HM Treasury financial objective	£34.1 m	£92.0 m	£99.8 m	£65.7 m	£27.5 m	£37.5 m	
<u>Cash</u>	31-Oct-16	30-Nov-16	Max (Sep 17)	Min (Apr 18)			
	£128.8 m	£124.4 m	£122.6 m	£96.9 m			
<u>Year-End Forecast</u>							See Schedule
1. The year-end forecast assumes the early-year performance in the Regulator continues for the remainder of the year and recognises that the Regulator share of the dividend payment has been reduced by £3.5m due to the effect of the £100m super-dividend which was decided after the 2016/17 budget of £5m had been set. The forecast also includes an estimate of £1.5m of income from e-cigarette notification fees and an increase in ICT costs in 2016/17 when compared to budget (c£2m). The forecast is before any post-referendum impact both in terms of potential early income reductions and making further strategic investments. Overall, the Regulator is forecasting a retained surplus of £4.7m compared to a budget of £0.1m but this is subject to change pending further review of ICT costs for 2016/17 and the potential to bring forward delivery, and therefore costs, of projects into 2016/17.							Dashboard and 1 and 3
2. The year-end forecast for NIBSC assumes expenditure continues at the same rate for the remainder of the year and that income continues at a lower rate reflecting the seasonal fluctuations in income from flu standards.							Dashboard and 1 and 3
3. The year-end forecast for CPRD includes an expectation that the second £1m of income from the DECIDE clinical trial will now be received in 2017/18. Partially offsetting this, is a forecast underspend on pay costs of £0.7m while CPRD continues to grow to its full complement of staff. Overall, CPRD is still forecast to achieve a 2016/17 retained surplus of £0.6m against a budget of £0.9m.							Dashboard 1 and 3

Finance and Procurement Report

Year to 31 October 2016

Schedule 1

Income and Expenditure Account

£'000s

Regulator	Oct 16				Full Year		
	Actual	Budget	Variance		Forecast	Budget	Variance
DH Funding	4,725	4,725	0	0%	8,100	8,100	0
Operational Income	55,885	56,213	(328)	(1%)	96,352	93,826	2,526
Total Income	60,610	60,938	(328)	(1%)	104,452	101,926	2,526
Staff - Direct Cost	26,433	26,442	10	0%	45,486	45,173	(314)
Other Direct Operating Costs	4,622	4,906	284	6%	7,924	8,432	508
Total Direct Costs	31,055	31,349	294	1%	53,410	53,604	194
Income less Direct Costs	29,555	29,590	(35)	(0%)	51,042	48,322	2,720
NIBSC							
DH Funding	11,899	11,899	0	0%	19,700	19,700	0
Operational Income	13,291	12,657	634	5%	22,421	22,048	373
Total Income	25,190	24,556	634	3%	42,121	41,748	373
Staff - Direct Cost	10,998	11,125	127	1%	19,267	19,958	691
Other Direct Operating Costs	11,403	11,275	(128)	(1%)	18,560	18,291	(269)
Total Direct Costs	22,401	22,400	(1)	(0%)	37,827	38,249	422
Income less Direct Costs	2,789	2,156	633	29%	4,294	3,499	795
CPRD							
Operational Income	5,279	5,610	(330)	(6%)	9,500	10,500	(1,000)
Staff - Direct Cost	1,765	2,307	542	24%	3,216	3,955	739
Other Direct Operating Costs	2,251	2,517	266	11%	5,645	5,645	0
Total Direct Costs	4,016	4,824	808	17%	8,861	9,600	739
Income less Direct Costs	1,263	786	477	61%	639	900	(261)
Corporate							
DH Funding	1,342	1,342	0	0%	2,300	2,300	0
Operational Income	1,223	1,014	210	21%	2,997	2,774	223
Total Income	2,565	2,355	210	9%	5,297	5,074	223
Staff - Direct Cost	5,879	6,042	163	3%	10,087	10,527	440
Other Direct Operating Costs	24,894	24,026	(868)	(4%)	40,087	37,768	(2,319)
Total Direct Costs	30,773	30,068	(705)	(2%)	50,174	48,296	(1,879)
Income less Direct Costs	(28,208)	(27,713)	(495)	(2%)	(44,877)	(43,222)	(1,655)
Whole Agency							
DH Funding	17,966	17,966	0	0%	30,100	30,100	0
Operational Income	75,679	75,494	185	0%	131,270	129,148	2,122
Total Income	93,645	93,460	185	0%	161,370	159,248	2,122
Staff Cost	45,075	45,917	842	2%	78,056	79,613	1,557
Other Operating Costs	43,170	42,724	(446)	(1%)	72,216	70,136	(2,080)
Total Cost	88,245	88,641	396	0%	150,272	149,749	(523)
Operating Surplus/(Deficit)	5,400	4,819	581	12%	11,098	9,499	1,599
Financing:							
Interest Receivable	199	175	24	13%	300	300	0
Interest Payable	(27)	(27)	(0)	(0%)	(46)	(46)	0
Dividend Payable	(1,021)	(2,917)	1,896	65%	(1,750)	(5,000)	3,250
Dividend Payable - NIBSC	(2,333)	(2,333)	0	0%	(4,000)	(4,000)	0
	(3,183)	(5,102)	1,919	38%	(5,496)	(8,746)	3,250
Surplus/(Deficit)	2,217						
Retained surplus b/forward MHRA	56,266						
Retained surplus c/forward	58,483						

Capital Expenditure

Capital Expenditure

Oct 16 £000's	
Actual	
Regulator	234
NIBSC	2,060
CPRD	891
Corporate	3,158
Total Capital Expenditure	6,342

FTE (rounded, as at 31 October 2016)

	Actual	Budget	Variance	
Regulator	701	755	55	7%
NIBSC	334	368	34	9%
CPRD	52	69	17	24%
Corporate	182	197	15	7%
MHRA FTE	1,269	1,390	121	9%

Average
2016/17
In Post
704
334
48
179
1,264

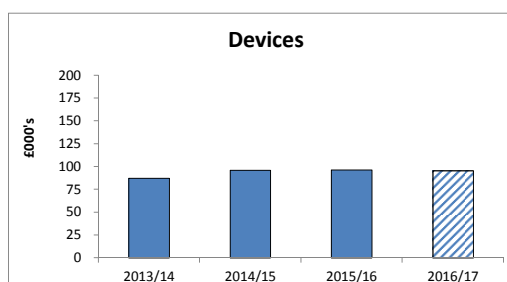
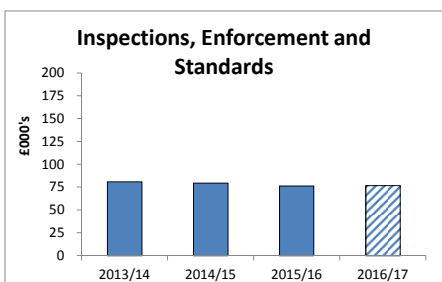
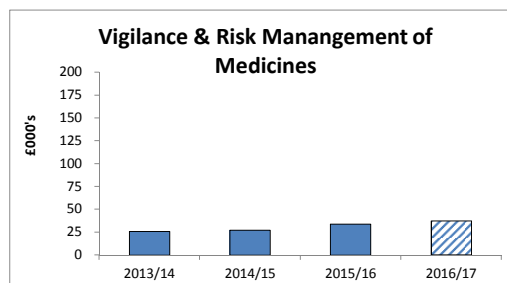
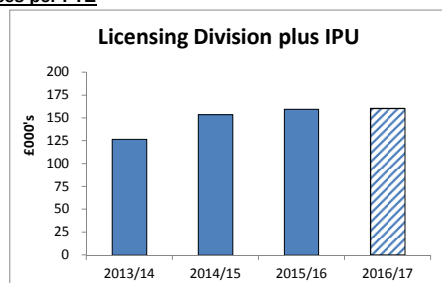
Finance and Procurement Report

Year to 31 October 2016

Schedule 2

Income and Expenditure Account - Regulator

£'000s	Oct 16				Full Year		
	Actual	Budget	Variance		Forecast	Budget	Variance
Licensing Division plus IPU							
Operational Income	27,444	25,628	1,816	7%	47,567	41,716	5,850
Staff - Direct Cost	11,242	11,647	405	3%	19,272	19,880	607
Other Direct Operating Costs	359	412	53	13%	615	700	85
Total Direct Costs	11,601	12,059	458	4%	19,888	20,580	692
Income less Direct Costs	15,843	13,569	2,274	17%	27,679	21,137	6,542
Vigilance & Risk Management of Medicines							
Operational Income	3,171	2,528	643	25%	4,710	4,067	643
Staff - Direct Cost	5,176	5,307	131	2%	8,913	9,044	131
Other Direct Operating Costs	513	413	(99)	(24%)	879	694	(185)
Total Direct Costs	5,689	5,720	32	1%	9,791	9,738	(54)
Income less Direct Costs	(2,518)	(3,193)	675	21%	(5,081)	(5,670)	589
Inspections, Enforcement and Standards							
Operational Income	8,420	8,057	363	5%	14,434	13,824	610
Staff - Direct Cost	7,030	7,479	449	6%	12,174	12,804	630
Other Direct Operating Costs	3,502	3,781	279	7%	6,004	6,524	520
Total Direct Costs	10,532	11,260	728	6%	18,178	19,328	1,150
Income less Direct Costs	(2,112)	(3,203)	1,091	34%	(3,744)	(5,504)	1,760
Devices							
DH Funding	4,725	4,725	0	0%	8,100	8,100	0
Operational Income	478	666	(189)	(28%)	1,073	1,073	0
Total Income	5,203	5,391	(189)	(3%)	9,173	9,173	0
Staff - Direct Cost	2,984	3,077	93	3%	5,127	5,275	148
Other Direct Operating Costs	249	300	51	17%	426	514	88
Total Direct Costs	3,233	3,377	144	4%	5,553	5,789	236
Income less Direct Costs	1,970	2,014	(45)	(2%)	3,619	3,384	236
Other							
National Periodic Fee Income	16,373	16,373	0	0%	28,568	28,068	500
Total - Regulator							
DH Funding	4,725	4,725	0	0	8,100	8,100	0
Operational Income	55,885	53,251	2,634	5%	96,352	88,748	7,603
Projected Income Variance	2,962		(2,962)	(100%)	0	5,078	(5,078)
Total Income	60,610	60,938	(328)	(1%)	104,452	101,926	2,526
Staff - Direct Cost	26,433	27,510	1,077	4%	45,486	47,003	1,517
Projected Staff Cost Variance	(1,068)		(1,068)			(1,830)	(1,830)
Total Staff - Direct Cost	26,433	26,442	10	0%	45,486	45,173	(314)
Other Direct Operating Costs	4,622	4,906	284	6%	7,924	8,432	508
Total Direct Costs	31,055	31,349	294	1%	53,410	53,604	194
Income less Direct Cost	29,555	29,590	(35)	(0%)	51,042	48,322	2,720
FTE (rounded, as at 31 October 2016)							
Licensing Division plus IPU	287	316	29	9%	Average 2016/17 In Post		
Vigilance & Risk Management of Medicines	127	132	5	4%			
Inspections, Enforcement and Standards	193	208	15	7%			
Devices	94	100	6	6%			
Regulator FTE	701	755	55	7%			

Fees per FTE

Finance and Procurement Report

Year to 31 October 2016

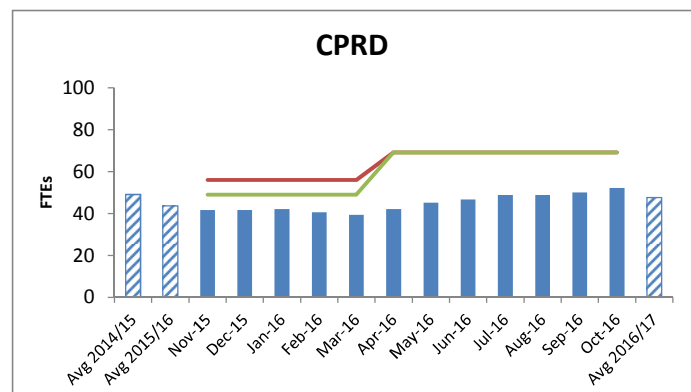
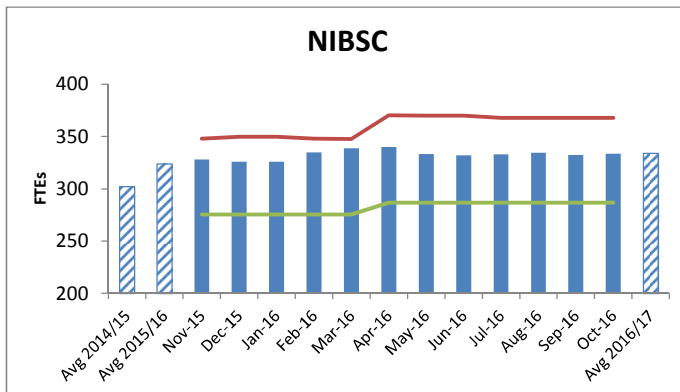
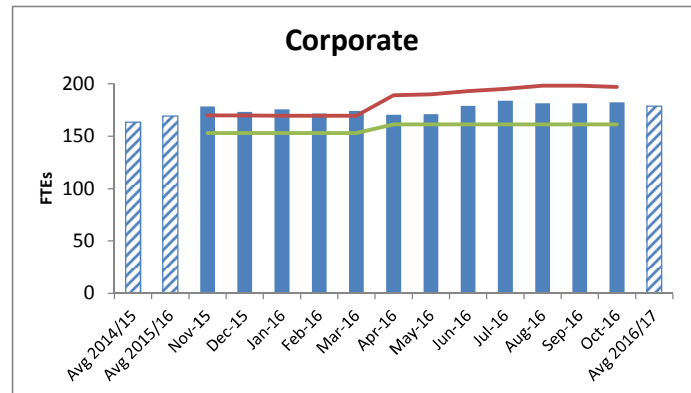
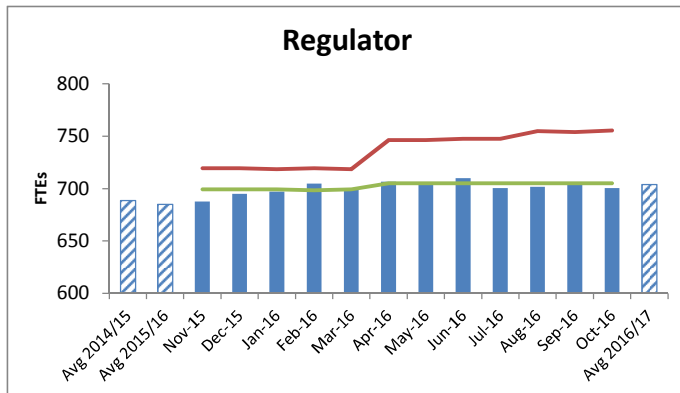
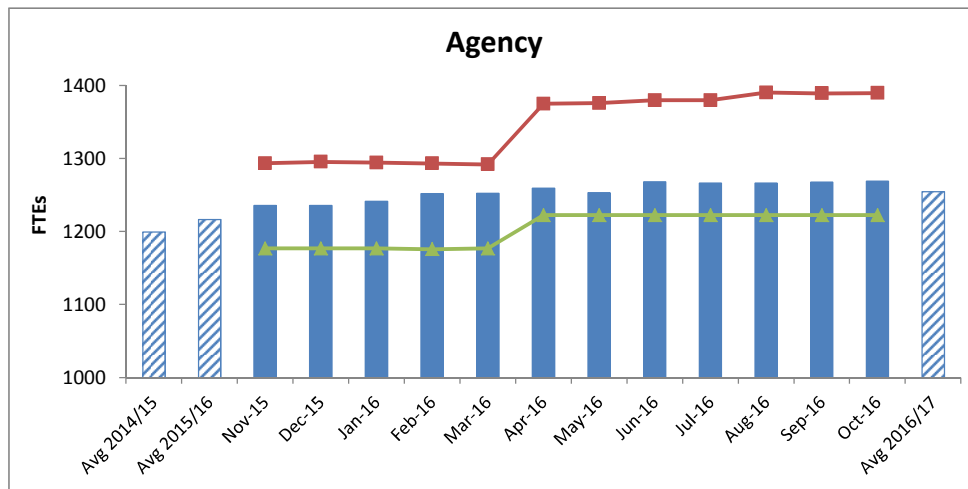
Schedule 3

Expenditure - Analysis by Segment and Type**£'000s**

	Oct 16				Full Year		
	Actual	Budget	Variance		Forecast	Budget	Variance
Whole Agency							
Staff Costs	44,840	47,739	2,899	6%	77,634	82,021	4,387
Projected Staff Cost Variance		(2,068)	(2,068)			(2,830)	(2,830)
Overtime	235	245	10	4%	423	423	0
ICT	9,451	9,275	(175)	(2%)	15,629	14,259	(1,370)
ICT - Operational Transformation	8,360	8,360	0	0%	11,784	11,000	(784)
Accommodation	5,187	5,856	669	11%	9,915	10,934	1,020
Depreciation	7,217	7,092	(125)	(2%)	11,320	11,426	106
Staff Related Costs	2,164	2,678	514	19%	3,691	4,476	785
Training	654	696	42	6%	1,335	1,151	(183)
Externally Provided Services	2,647	3,636	989	27%	4,846	5,983	1,137
Medicines Testing and Laboratory	6,258	5,765	(492)	(9%)	10,728	9,888	(840)
Marketing	87	122	35	29%	513	680	167
Cost of Seminars	101	134	33	25%	243	245	2
Other	1,045	708	(337)	(48%)	2,213	2,833	620
Projected Other Direct Costs Variance		(1,598)	(1,598)		0	(2,740)	(2,740)
Whole Agency Operating Costs	88,245	88,641	396	0%	150,272	149,751	(522)
Regulator							
Staff Costs	26,271	27,332	1,062	4%	45,180	46,696	1,517
Projected Staff Cost Variance		(1,068)	(1,068)	100%		(1,830)	(1,830)
Overtime	162	177	16	9%	307	307	0
ICT	88	57	(31)	(54%)	151	96	(55)
Accommodation	52	53	1	1%	89	90	1
Depreciation	55	117	62	53%	94	200	106
Staff Related Costs	1,354	1,600	246	15%	2,320	2,741	420
Training	376	198	(178)	(90%)	645	312	(332)
Externally Provided Services	543	697	154	22%	931	1,155	224
Medicines Testing and Laboratory	1,790	1,756	(33)	(2%)	3,068	3,016	(52)
Marketing	10	2	(7)	(308%)	16	4	(12)
Cost of Seminars	13	15	1	8%	23	25	2
Other	342	412	70	17%	586	793	207
Regulator Operating Costs	31,055	31,349	294	1%	53,410	53,604	194
NIBSC							
Staff Costs	10,926	12,063	1,137	9%	19,161	20,852	1,691
Projected Staff Cost Variance	0	(1,000)	(1,000)	100%		(1,000)	(1,000)
Overtime	72	62	(10)	(16%)	106	106	0
ICT	213	393	180	46%	673	673	0
Accommodation	2,206	2,110	(96)	(5%)	3,782	3,618	(164)
Depreciation	3,616	3,616	0	0%	5,496	5,496	0
Staff Related Costs	273	392	119	30%	468	573	105
Training	63	197	134	68%	300	338	38
Medicines Testing and Laboratory	4,468	4,009	(459)	(11%)	7,659	6,872	(787)
Externally Provided Services	123	528	405	77%	389	928	539
Other	441	30	(411)	(1370%)	(207)	(207)	0
NIBSC Operating Costs	22,401	22,400	(1)	(0%)	37,827	38,249	422
CPRD							
Staff Costs	1,765	2,307	542	24%	3,216	3,955	739
Overtime	0	0	0	0%	0	0	0
ICT	1,146	1,183	37	3%	2,084	2,084	0
Accommodation	0	0	0	0%	0	0	0
Depreciation	648	746	98	13%	1,250	1,250	0
Staff Related Costs	73	69	(5)	(7%)	106	106	0
Training	28	41	13	31%	70	70	0
Externally Provided Services	305	431	126	29%	654	654	0
Medicines Testing and Laboratory	0	0	0	0%	0	0	0
Marketing	33	41	8	20%	71	71	0
Cost of Seminars	2	0	(2)	0%	0	0	0
Other	15	6	(9)	(156%)	1,410	1,410	0
CPRD Operating Costs	4,016	4,824	808	17%	8,861	9,600	740
Corporate							
Staff Costs	5,878	6,037	158	3%	10,077	10,517	440
Overtime	1	6	5	78%	10	10	0
ICT	8,004	7,642	(362)	(5%)	12,721	11,406	(1,315)
ICT - Operational Transformation	8,360	8,360	0	0%	11,784	11,000	(784)
Accommodation	2,929	3,694	765	21%	6,044	7,226	1,182
Depreciation	2,898	2,613	(285)	(11%)	4,480	4,480	0
Staff Related Costs	465	618	153	25%	796	1,056	260
Training	187	260	73	28%	320	431	111
Externally Provided Services	1,675	1,980	304	15%	2,872	3,246	374
Medicines Testing and Laboratory	0	0	0	0%	0	0	0
Marketing	44	78	34	44%	425	605	180
Cost of Seminars	85	119	34	29%	220	220	0
Other	247	260	13	5%	424	837	413
Projected Other Direct Costs Variance		(1,598)	(1,598)	100%		(2,740)	(2,740)
Corporate Operating Costs	30,773	30,068	(705)	(2%)	50,174	48,296	(1,878)

Finance and Procurement Report

Schedule 3a

Staffing

Actuals

Budget

Permanent Establishment

Graphs show average staff in post figures for the previous two financial years, monthly staffing post figures for each of the last 12 months against permanent establishment and budget, and also shows the year to date average for the current financial year

Budgeted FTE numbers exclude projection of underspending against fully funded issued staff budgets

CPRD's permanent establishment has been increased to 69 following approval of its organisational restructure, the financial budget has been phased in from the start of Q2

Year to 31st Oct 2016

Schedule 4

MANAGEMENT ACCOUNTS

Expenditure (to the end of October 2016)

TABLE 1 : Summary

	Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Prior Years Expenditure	Total Capital Expenditure	Total Revenue Expenditure (One-Off and Other)	Total Revenue Expenditure Operational	Total Expenditure to date
Regulator	13,061	18,684	10,695	42,346	9,615	3,391	8,375	2,787	14,552
NIBSC	8,922	0	0	8,922	0	2,059	259	0	2,318
CPRD	4,000	0	0	4,000	0	891	0	0	891
Gross Total	25,983	18,684	10,695	55,268	9,615	6,341	8,634	2,787	17,761

TABLE 2 : Regulator By project
£'000s

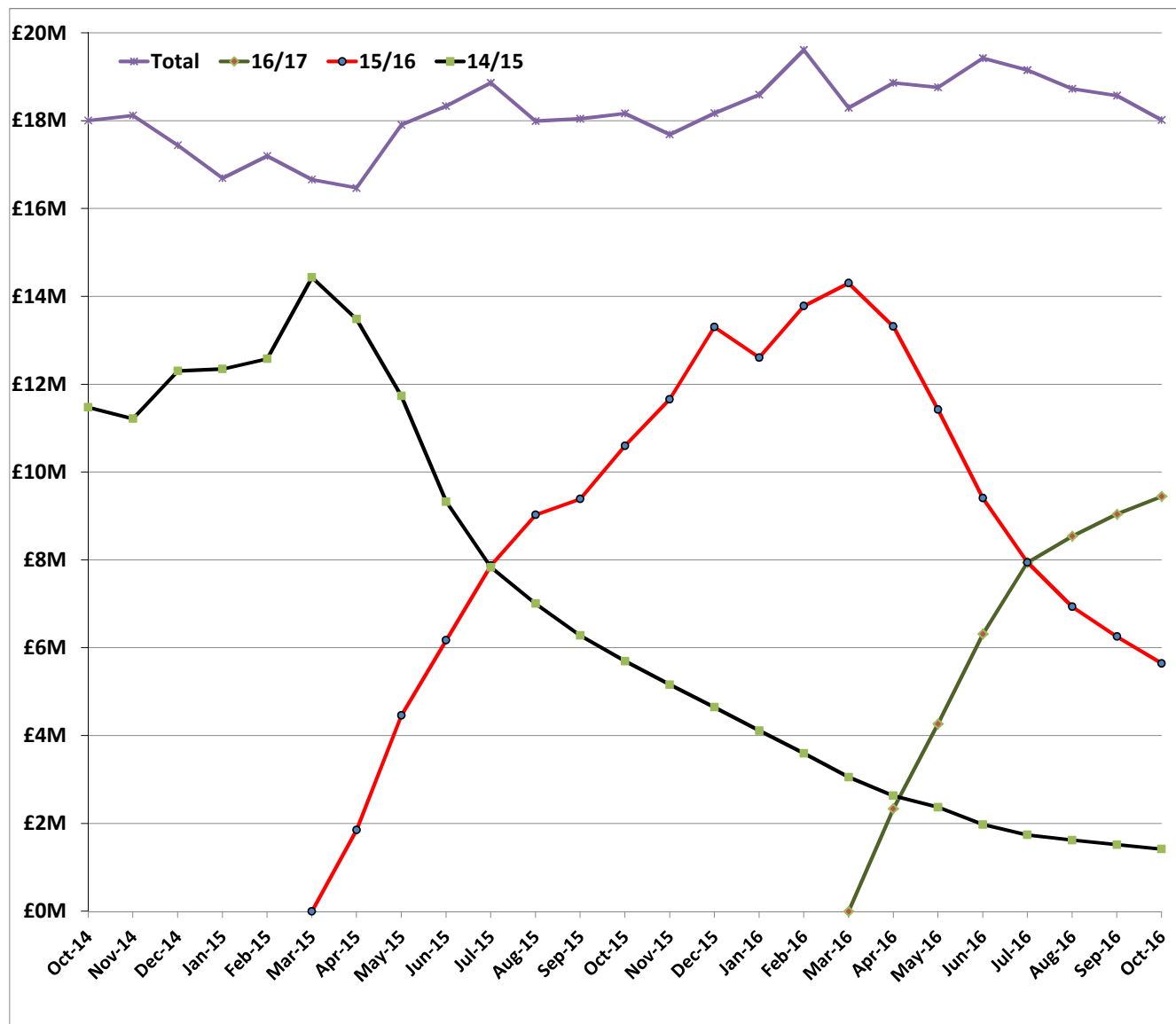
List of Projects:	Governance	Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Prior Years Expenditure	Total Capital Expenditure	Total Revenue Expenditure (One-Off and Other)	Total Revenue Expenditure Operational	Total Expenditure to date	Status
Business Intelligence	IMGB	3,198	431	574	4,203	1,432	239	416	0	655	Development / implementation
Information & Records Management	IMGB	0	4,221	499	4,720	1,325	1	1,067	0	1,068	Development / implementation
IO Service Transition	IMGB	600	3,324	6,036	9,960	4,566	249	1,354	2,787	4,389	Development / implementation
Digital Service Transformation / Application Refresh	IMGB	423	3,118	360	3,901	1,198	9	1,081	0	1,090	Development / implementation
Oracle Fusion - ERP	IMGB	0	3,905	840	4,745	446	5	2,383	0	2,388	Development / implementation
E-Cigarettes / Tobacco Products Directive	IMGB	330	0	1,984	2,314	85	88	384	0	472	Ongoing
Global Digital / Global Data Integration	IMGB	0	905	0	416	0	12	129	0	141	Ongoing
Desktop Lifecycle	IMGB	3,520	0	0	3,520	0	2,295	96	0	2,391	Ongoing
IPU Review	IMGB	0	1,683	0	1,683	15	0	192	0	192	Ongoing
Devices Transformation	IMGB	3,000	0	402	3,402	0	323	461	0	785	Ongoing
NIBSC Service Transition	Not Yet Approved	0	50	0	446	0	0	29	0	29	Ongoing
Devices (DH Capital Funding)		1,000	0	0	1,000	3	0	0	0	0	Ongoing
Lab Equipment / Enforcement Vehicles	Budget & Business Cases	402	0	0	402	105	234	0	0	234	Ongoing
Others <£250k	IMGB	588	1,048	0	1,635	439	(63)	781	0	718	
Regulator Total		13,061	18,684	10,695	42,346	9,615	3,391	8,375	2,787	14,552	

TABLE 3 : NIBSC
£'000s

List of Projects:	Governance	Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Prior Years Expenditure	Total Capital Expenditure	Total Revenue Expenditure (One-Off and Other)	Total Revenue Expenditure Operational	Total Expenditure to date	Status
IT	Budget	197	0	0	197	0	56	0	0	56	Ongoing
Accommodation	Budget	5,511	0	0	5,511	0	1,498	259	0	1,757	Ongoing
Equipment	Budget	3,214	0	0	3,214	0	505	0	0	505	Ongoing
NIBSC Total		8,922	0	0	8,922	0	2,059	259	0	2,318	

TABLE 4 : CPRD
£'000s

List of Projects:	Governance	Capital Approved	One-Off Revenue Approved	Other Revenue Approved	Total Business Case Approved	Prior Years Expenditure	Total Capital Expenditure	Total Revenue Expenditure (One-Off and Other)	Total Revenue Expenditure Operational	Total Expenditure to date	Status
Trial Viz / Trial Form	Budget	4,000	0	0	4,000	0	891	0	0	891	Implementation
CPRD Total		4,000	0	0	4,000	0	891	0	0	891	

Product Licensing - Deferred Revenue - Movement Monitoring

	Total	Year Application Made		
		In-year	Previous year	Previous year -1
2016-17	18,019	9,444	5,646	1,418
2015-16	18,163	10,599	5,697	1,118
2014-15	18,002	11,473	4,433	925

Deferred Revenue shows activity for which we have been paid but the effort to earn income has not been completed.

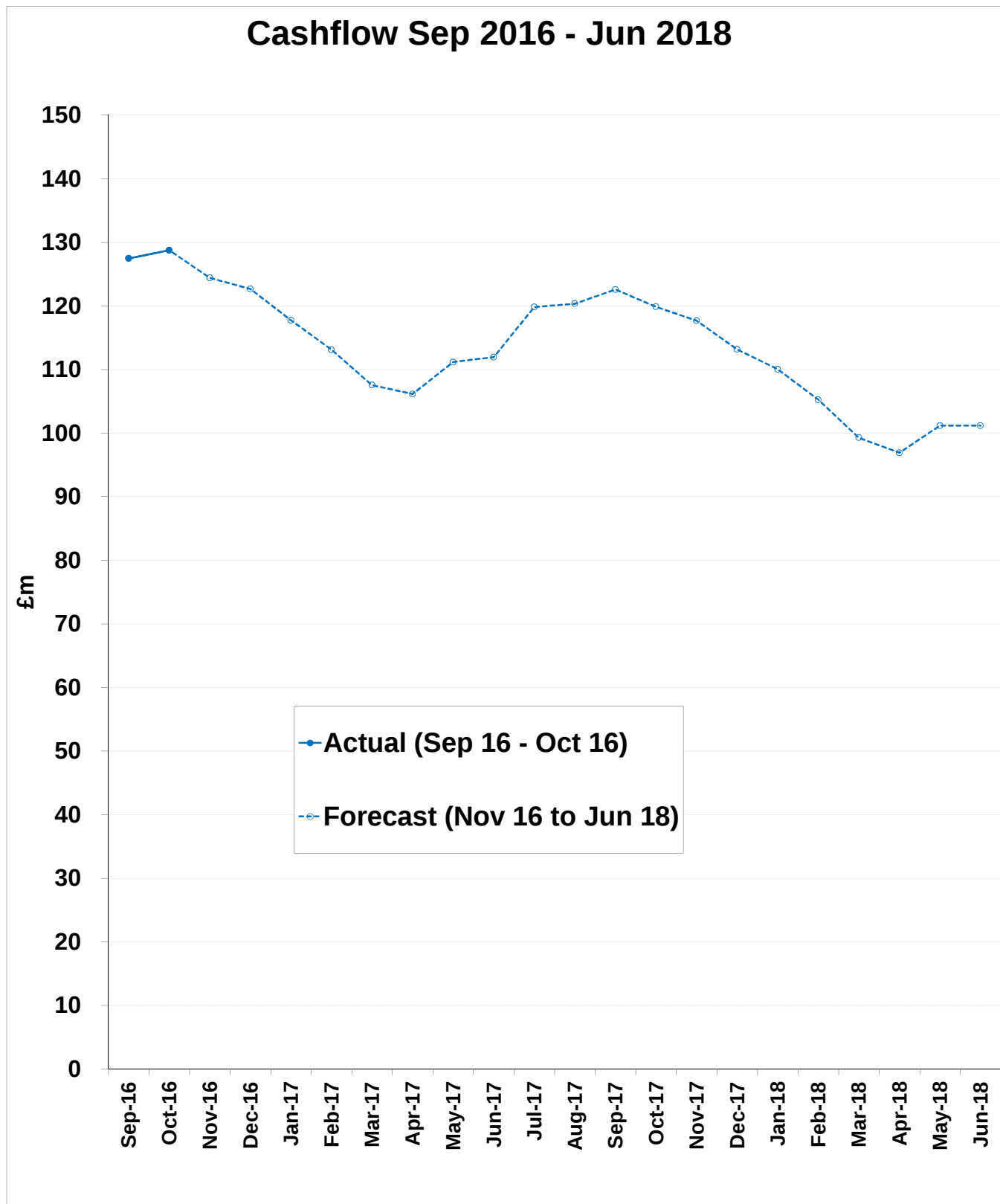
Schedule 6

STATEMENT OF FINANCIAL POSITION

Notes		31 October 2016		30 September 2016		31 March 2016	
		Draft		Final		Final	
		£'000	£'000	£'000	£'000	£'000	£'000
	NON-CURRENT ASSETS						
	Plant and Equipment		111,756		111,946		112,898
	Intangible Assets		8,902		8,914		8,990
	Assets Under construction		3,870		3,876		3,909
	TOTAL NON-CURRENT ASSETS		124,528		124,736		125,797
	CURRENT ASSETS						
	TRADE AND OTHER RECEIVABLES						
	Inventories		6,316		6,316		6,289
1	Other Trade Receivables		12,288		13,919		6,629
2	DH Receivables		0		2,310		10,182
3	Service Fee credit note		(6,379)		(7,591)		(208)
	Credit note and bad debt provision		(675)		(734)		(726)
4	Pre-payments		2,144		2,463		2,753
5	Accrued Income		9,892		8,164		3,966
	Other Receivables		481		701		1,256
	TOTAL TRADE AND OTHER RECEIVABLES		24,066		25,548		30,141
6	Cash and Cash Equivalents		128,772		127,482		211,428
	TOTAL CURRENT ASSETS		152,838		153,030		241,569
	CURRENT LIABILITIES						
7	Payments on Account - non iRIS		(13,341)		(15,690)		(13,272)
7	Payments on Account - iRIS		(1,754)		(1,510)		(1,490)
	Trade payables		(184)		(356)		(3,064)
	Proceeds of Crime Reserve		(62)		(62)		(102)
8	DH payables (including short-term borrowings)		(6,733)		(7,898)		(113,693)
9	Accrued Expenses		(7,261)		(5,434)		(11,269)
	Provisions for liabilities and charges		(922)		(922)		(992)
	Tax and N.I.		(2,995)		(3,103)		(2,780)
	Other payables		(860)		(62)		(105)
	TOTAL CURRENT LIABILITIES		(34,112)		(35,037)		(146,767)
	Net current (Liabilities)/assets		118,726		117,993		94,802
	Total Assets less Current Liabilities		243,254		242,729		220,599
	Borrowings		(1,328)		(1,328)		(1,328)
	Provisions for liabilities and charges		(2,129)		(2,129)		(2,120)
	DEFERRED REVENUE						
10	Licence fees (applications and variations)		(17,408)		(17,727)		(18,733)
	Service Fees		(11,695)		(14,034)		0
	Other fees		(15,178)		(12,240)		(5,118)
	CPRD		(14,184)		(14,184)		(14,184)
	TOTAL DEFERRED REVENUE		(58,465)		(58,185)		(38,035)
	NET ASSETS		181,331		181,086		179,116
	FINANCED BY TAXPAYER'S EQUITY						
	Public dividend capital		1,329		1,329		1,329
	Revaluation Reserve		78,097		78,097		78,097
	General Reserve		42,470		42,470		42,470
	Income & Expenditure Reserve		954		954		954
	Retained earnings		58,482		58,237		56,266
	TOTAL TAXPAYER'S EQUITY		181,331		181,086		179,116

Notes:

1	Debtors (Other trade receivables) decreased by £1.6m during the month.
2	DH receivables balance cleared as DH paid all outstanding invoices during the month.
3	Service fees adjustment created at start of year for anticipated fee reduction requests from customers.
4	Prepayments include: £1.1m for computing costs; £0.4m misc prepayments and £0.6m for NIBSC.
5	Accrued income includes: £4.0m DH funding (including circular flow £1.3m) ; £2.4m EMA; £1.1m pending cases; £1.5m other misc income £0.2m NIBSC.
6	The cash and cash equivalents at the end of the month was £129.0m, an increase of £1.3m from the previous month.
7	Payments on account decreased by £2.1m during the month.
8	DH payables includes £2.4m dividend for 2016/17, circular flow £1.3m and £3.2m dividend for 2015/16.
9	Accrued expenses include: £3.8m for computing costs; £1.9m annual leave provision; £0.4m for medicines testing and laboratory expenses and £1.2m for NIBSC.
10	Service fees income deferred at the start of the year.



Impact ↑	5 Critical	5	10	15	20	25
	4 Major	4	8	12	16	20
	3 Moderate	3	6	9	12	15
	2 Low	2	4	6	8	10
	1 Insignificant	1	2	3	4	5
		1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost Certain

INCOME RISK ASSESSMENT

Income category	Current Annual Value (Nov 15 - Oct 16)* (£m)	% Change during past year since (Nov 14 - Oct 15)*	% Change during past two years since (Nov 13 - Oct 14)*	Short Term Risk	Medium Term Risk	Key Monitoring Measures and performance for month	Residual Medium Term Risk on Income After Corrective Action	Proportion of cost base funded by source of income	Analysis
Periodic fees (* 2015/16 draft statutory a/c)	£30m	(3%)	(2%)	Green ●	Red ●	1. Value of payments made versus previous year 2. Value of outstanding payments split between those part paid and those completely unpaid	Red ●	35%	In the medium term aging of MAS means income expected to drop to £28m pa. Cash receipts to the end of October at £26.4m are £5m lower than for the same period last year. Total outstanding debt is £5.5m, £4.4m higher than the same period last year. In most scenarios except 'fast follower' worse case, unlikely to be adversely affected by BREXIT.
Inspections	£9m	(3%)	(12%)	Green ●	Amber ●	1. Comparison against budget 2. Demand for inspections	Green ●	10%	Annual value is currently £0.3m lower than 15/16. Demand for inspections is high. Corrective action: Recruitment & retention strategy being developed to help ensure vacant posts are filled. Budget increased for 2016/17 by £0.4m. Unlikely to be adversely affected by BREXIT.
PL Variation	£7m	(4%)	(2%)	Green ●	Green ●	1. The value of monthly earnings 2. Rate of receipts of applications 3. The value of deferred revenue	Green ●	9%	Annual value is currently £0.3m lower than 15/16. Monthly earnings have remained steady, but the rate of receipts has declined over the last 3-6 months. Deferred revenue has reduced 10% since May 2016. In most scenarios except 'fast follower' worse case, unlikely to be adversely affected by BREXIT.
DH Funding - for Devices (Current Annual Value = Plan) - Capital Funding	£8.1m £1.0m	0%	(10%)	Green ●	Black ●	DH 16/17 funding	Black ●	10%	DH have recently confirmed cash flat funding for 2016/17. The threat to DH Funding remains over the long term but the Agency is still looking to implement a fee regime to substitute DH Funding from April 2018. This was previously April 2017 and as no verbal indication has been received that DH will provide funding in absence of fees the risk has been changed to Black.
DCP RMS (See DCP Measures below)	£8m	(16%)	(3%)	Green ●	Red ●	1. RMS substitution - average fee charged 2. Rate of receipts of applications 3. Value of deferred revenue	Red ●	9%	The 12 month rolling annual value is currently £1.4m lower than the previous 12 months. DCP RMS deferred revenue has remained the same during October at £4.5m. Receipts in October have increased to 36 from 23 in September. It is anticipated that the surge in DCP receipts arising from data exclusivity rule changes will reduce post 2016/17 although income is expected to be maintained through 16/17 and 17/18. Income could be adversely affected if the UK became a 'fast follower' after BREXIT.
DCP CMS (See DCP Measures below)	£9m	2%	30%	Green ●	Amber ●	1. CMS substitution - average fee charged 2. Rate of receipts 3. Value of deferred revenue	Amber ●	10%	Annual value is currently £0.1m higher than 15/16. DCP CMS deferred revenue has decreased by £0.1m during October. Receipts in October have decreased to 27 from 35 in September. Medium term risk remains at Amber as it is anticipated that the surge in DCP receipts arising from data exclusivity rule changes will reduce post 2016/17 although income is expected to be maintained through 16/17 and 17/18. Income could be adversely affected if the UK became a 'fast follower' after BREXIT.
EMA PL (excl inspections)	£12m	19%	22%	Amber ●	Red ●	1. The value of monthly earnings 2. The level of new contracts 3. Sterling/Euro exchange rate	Red ●	14%	Annual value is currently £1.8m higher than in 15/16. Bidding for scientific advice has temporarily reduced due to resource constraints. Income could be adversely affected if the UK became a 'fast follower' after BREXIT.
Other PL/PLP/PcL/CT	£15m	(2%)	(1%)	Green ●	Amber ●	1. The value of monthly earnings 2. The value of deferred revenue	Amber ●	17%	Annual value is currently £0.2m lower than in 2015/16. Income could be adversely affected if the UK became a 'fast follower' after BREXIT.
Other income	£9m			Green ●	Green ●		Green ●	11%	Income could be adversely affected if the UK became a 'fast follower' after BREXIT.
Regulatory Total	£107m							126%	
CPRD (Operational Income)	£9m	11%	17%	Green ●	Amber ●	Comparison against budget	Amber ●	137%	Unlikely to be affected by BREXIT. 16/17 performance at £5.3m is £0.9m higher to the equivalent period in 15/16.
CPRD Total	£9m							137%	
NIBSC (I&E)									
DH Funding (excl. Capital)	£10.2m	0%	n/a	Green ●	Red ●	DH 2016/17 Funding	Red ●	61%	DH have recently confirmed cash flat funding for 16/17 and indicated the same until 2020. A risk remains because of uncertainty on DH funding still exists from 2017/18 while the government continue with it's austerity measures. DH asking NIBSC to ensure that DH funding requirement is not greater than is necessary. Corrective action: Maintain pressure on DH.
Revenue funding	£2.3m	n/a	n/a						
Revenue funding for Corporate Dividend	£4.0m	n/a	n/a						
Depreciation	£5.5m	n/a	n/a						
Capital	£6m	n/a	n/a						
SubTotal	£22m	n/a	n/a						
NIBSC Standards	£8m	(2%)	19%	Green ●	Red ●	Comparison against budget and assumptions in sustainability model	Red ●	22%	Potential loss of influenza standards income (worth £3.9m in 2014/15) due to potential regulatory changes that could obviate the need for producers to use these standards. Due to the uncertainty created by BREXIT & potential for tariffs the medium & residual risk has changed to Red.
NIBSC Certification Fees	£4m	28%	28%	Amber ●	Red ●	Comparison against budget and assumptions in sustainability model	Red ●	12%	Annual value 14/15 is £1m higher than 13/14. Due to the uncertainty created by BREXIT the medium and residual risk has been changed to Red.
NIBSC Research Grants	£5m	0%	47%	Amber ●	Amber ●		Amber ●	14%	Due to the uncertainty created by BREXIT the medium & residual risk has changed to Amber. This is due to the potential loss of the EU Grant income which currently amounts to approximately £1m.
NIBSC Other	£4m	267%	610%	Green ●	Amber ●	Comparison against budget and assumptions in sustainability model	Amber ●	10%	
NIBSC Total	£43m							119%	
MHRA TOTAL	£159m							125%	

Item 11
Periodic Fee Measures:

2016-OB-30
Schedule 8

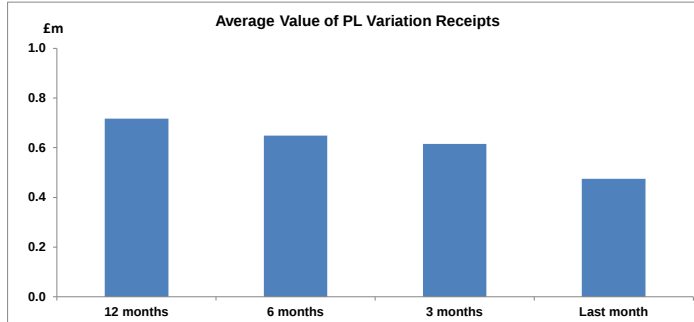
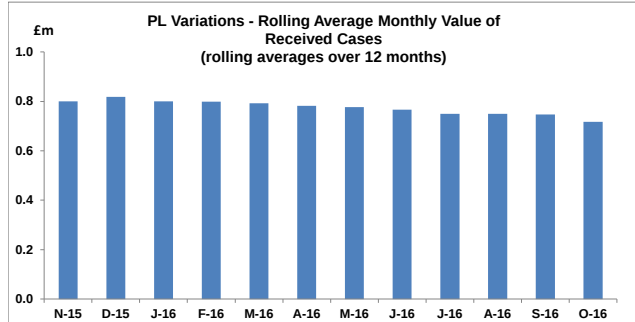
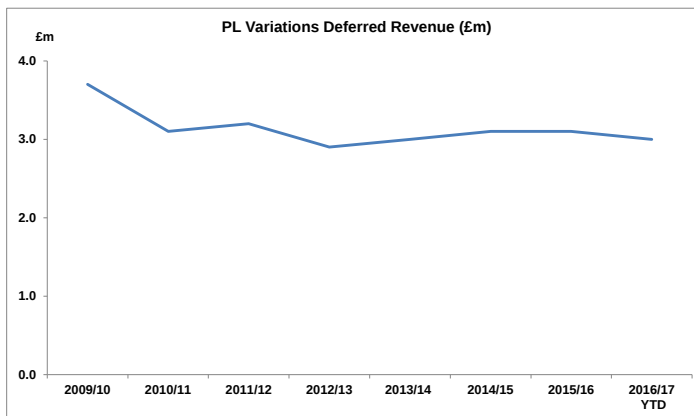
Periodic Fee Type (£'000s)	Fee 16/17	Billing (£'000s)		
		2015-16 (Billed)	2016-17 (Billed)	Difference
PL Prescription Only Medicine	2,428	30,187	30,386	199
PL Abridged Complex	9,710	6,828	6,292	(536)
PLPI Prescription Only Medicine	307	2,541	2,370	(171)
PL General Sales List	307	383	375	(8)
PL Pharmacy	307	395	383	(12)
PL New Active Substance Major	9,710	447	155	(292)
PL New Active Substance Additional Strength	6,554	90	13	(77)
PL New Active Substance Additional Dosage	6,554	41	0	(41)
PLPI Pharmacy	307	80	77	(3)
National Homeopathic Product	76	19	18	(1)
Herbal Remedy	76	28	27	(1)
PLPI General Sales List	307	1	1	0
PL No Status	307	1	1	0
Pcl Billing - Broken down into:				
ML Licences	468	431	398	(33)
WDL/WL Licences	Various	724	666	(58)
Total Billing		42,196	41,162	(1,034)

Number of Licences Billed		
2015-16	2016-17	Difference
11,928	12,515	587
758	648	(110)
8,113	7,719	(394)
1,230	1,221	(9)
1,238	1,246	8
18	16	(2)
17	2	(15)
5	-	(5)
213	252	39
505	472	(33)
352	351	(1)
5	2	(3)
2	3	1
883	851	(32)
2,345	2,394	49
27,612	27,692	80

Paid (£'000s)		
2015-16 Amount Received	2016-17 Forecast	Difference
18,681	17,526	(1,155)
6,776	6,292	(484)
2,501	2,333	(168)
391	375	(16)
398	383	(15)
155	155	0
13	13	0
31	0	(31)
79	76	(3)
19	18	(1)
28	27	(1)
1	1	0
1	1	0
405	374	(31)
681	626	(55)
30,160	28,200	(1,960)

PL Variation Measures:

Period	Average per month		Deferred Revenue
	Volume	Total Value £m	£m
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	1,488	0.79	3.10
2016/17 YTD	1,386	0.66	3.00
Last 12 months	1,432	0.72	n/a
Last 6 months	1,344	0.65	n/a
Last 3 months	1,220	0.61	n/a
Last month (Oct)	957	0.48	n/a



DCP Measures:

Period	Average per month		Deferred Revenue
	Volume	Total Value £m	£m
2009/10	95	2.01	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	69	1.40	10.3
2016/17 YTD	62	1.00	9.0
Last 6 months	59	1.17	n/a
Last 3 months	58	0.91	n/a
Last month (Oct)	63	1.02	n/a

