CET/16/060
As updated

Medicines and Healthcare Products Regulatory Agency

Budget 2016/17

Issue/Purpose: This report provides the CET and the Agency Board with the recommended 2016/17 budget.

Summary:

- 2016/17 is the fourth year in the current five year financial objective period that ends in March 2018. The agency will exceed its minimum required rate of return by approximately £60m (130%) by 2018.
- Over the remainder of the current 5 year financial objective period the regulatory centre will be close to breakeven, in line with the recommendation of the Triennial Review. Without corrective action it would go into deficit from 2017/18 given desired investments and the expected decline in income. The paper emphasises the importance of using the 2016/17 year to prepare robust plans.
- NIBSC continues to be in a financially sustainable position and has been steadily increasing its headcount towards 350 FTEs, recruiting the posts outlined from its first investment round and is now embarking on a second.
- The CPRD budget for 2016/17 has been set in line with the revised financial model and includes the assumptions made on volumes and price as set out previously (CET/15/280). CPRD's investment plans will be discussed with a sub group of the board early in 2016/17.
- The sensitivity analysis suggests that the income and cost budgets will be favourably exceeded for each centre, providing security alongside the flexibilities allowed by the trading fund regime, that the budgets can be approved.

Resource Implications See paper

Timings In preparation for the 2016/17 budget effective from 1 April 2016.

Action required by the Board

- To note and comment on the proposed budgets for the three centres for 2016/17.

Links Previous and associated CET and Board papers:

- CET-15-280 – Strategic Finance Update
- CET-15-129 – Strategic Fees and Cash

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Are there any sensitivity issues that would prevent this item being discussed by CET in the presence of staff observers? No

Which of the themes in the Corporate Plan does the paper support? All

Which Business Plan strategic activity does it support? All

CET Sponsor: Peter Commins – Chief Operating Officer

Budget 2016/17

1. Purpose

This report provides the CET and board with the recommended 2016/17 budgets. The paper also provides an update to the strategic financial position outlined in the report to the CET and board in January 2016 (CET/15/280) and sets the position for the 2017/18 Regulator fees' round.

The paper outlines the budgetary position for the Regulator (sections 4 and 5), the National Institute for Biological Standards and Control (NIBSC – section 6) and the Clinical Practice Research Datalink (CPRD – section 7). DH funding is outlined in section 8 and the budget for the whole Agency is summarised in section 9 with a sensitivity analysis (section 9.2).

There will be a financial strategy update for the Agency during 2016/17 along with updates in the regular monthly Finance and Procurement reports. This paper will be considered by the Agency Board in April in order to allow for the incorporation of any CET amendments.

2. Background

2016/17 is the fourth year in the current five year financial objective period that ends in March 2018. The agency will exceed its current required rate of return by approximately £60m (130%) by 2018 at which point the target return will be reset, potentially at a different level to the current 3.5%, and performance from that point onwards will be measured.

DH and the agency have agreed the priorities for 2016/17 and bilateral discussions have been held with all directors over several months to ensure that budgets are aligned with Business and Corporate Plan resource requirements.

An increase in Employer's national insurance contributions (£1.5m), taken with the government levy on employers to support apprenticeship training (£0.5m), means that centrally imposed cost increases will be £2m per annum, not including the significant additional cost of employing the target number of apprentices (2.3% of the workforce).

The Regulatory centre's budgets have been set in line with the multiple constraints of its statutory fees' regime, the recommendations of the Triennial Review, the DH letter of priorities for 2016/17 and the operational needs of the agency. Overall these translate into the following proposed objectives:

1. To have a reduced surplus as part of gradually aligning income and costs.
2. To support discussions with DH and the Treasury that further fee reductions in 2017/18 would not be sustainable, irrespective of any short term surplus during 2016/17.
3. To ensure transparency of the full cost of the proposed permanent establishment, a discipline that is especially important as recruitment gradually increases and is being undertaken alongside investments.

4. In line with CET and board discussions to continue to take the opportunity of the healthy financial position to invest in specific priorities and to support the best possible delivery of operational services.
5. To remain focussed on ensuring the agency's medium term stability and strategic development. The financial regime permits the agency to incur deficits provided that they are offset by surpluses within each 5 year period. The deliberate approach for the past ten years has been to *never* incur a deficit in *any* year because of the likely medium term, as opposed to immediate, consequences.

3. <u>Medium term implications of the 2016/17 budget</u>

The proposed budgets reflect the Accounting Officer's (AO) and directors' views of what is required in the short term to deliver services and meet Business and Corporate Plan priorities. As previously reported, whilst the agency does not have the immediate threat of government funding cuts, it is vital to see these annual budgets in the context of the period beyond 2016/17.

This section focusses on the Regulator because it is entering a more vulnerable strategic position given its high cost competitive position, its gradually declining income and its emerging IT investment proposals which are being developed to create a leaner, more customer focussed organisation. The agency's financial strength for the past ten years has meant that it has not had to focus on the short term pressures designed into the trading fund regime, of needing to make rapid adjustments to resources. The NIBSC and CPRD growth plans are consistent with those previously agreed.

The proposals in this paper reflect a full year increase in Regulator pay of £4.2m, to employ broadly the same number of staff as in 2013. The overall cost base of the Regulator will increase by £14m between 2015/16 and 2016/17, including £6m of IT investments still to be approved during the year. Whilst this is affordable from the next year's forecast income and expected costs, and consistent with the Triennial Review recommendation to balance income and cost, it does highlight the transitional nature of the coming year. The proposed budgets deliberately fund the full cost of the proposed permanent establishments and non-pay budgets in the interest of transparency, and resource the non-recurrent investment costs from secure positive variances in those budgets. The sensitivity analysis indicates that the overall position for the Regulator is secure for 2016/17.

The agency is currently developing an IT strategy that reconciles the emerging potential costs of investment with the Regulator's medium term sources of funding. The overall financial plan needs to incorporate the balance of the 2013 125 post reduction plan still to be achieved (£4.8m) and satisfy the challenge agreed at the AB/CET away day to as a minimum offset the additional running costs of the IT investment, through efficiencies enabled by those investments or achieved in other ways.

The agency needs to consider the level of resilience it wishes to establish for the period beyond 2018, for example, whether to create an underlying surplus to allow it to invest or respond to shocks without reliance on short term corrective measures. As explained in the strategic financial paper, given the agency's almost exclusively fixed costs for pay, accommodation and IT, any fall in activity would have an immediately destabilising effect.

It should also be noted that:

1. It is likely that DH will require an additional dividend to reflect the agency's financial strength, with any cash being paid over during April.
2. It is becoming increasingly likely that the agency will be required to relocate the Regulator from its current building before the end of its lease in 2021, hopefully to an accessible location elsewhere in London.

Update from the Corporate Executive Team discussion on 10 March 2016

1. CET noted that the income reduction projections were consistent with the fee reductions which are in place from April 2016. The broader picture summarised in Table 2 places the only material area of uncertainty, the level of reduction in DCP income in the period beyond 2016/17, in the context of the broader drivers of the Regulator's financial position.
2. CET agreed that preparation for the period beyond 2016/17 was a key priority given the inherent vulnerability of a trading fund once it approaches financial balance. CET agreed that there was not a secure basis at this point to consider a further medicines' fee reduction in 2017/18.
3. CET supported the suggestion to incorporate the existing headcount targets into the wider plans including the impact of the IT investments. The overriding objective was to establish the medium term resilience of the regulator.
4. The planned increase in the agency's pay costs was noted as consistent with short term operational delivery being the priority for the Regulator, and the growth plans in NIBSC and CPRD. The budgets were accepted as consistent with discussions at previous board and CET meetings that the agency should take advantage of the Regulator's current financial strength, for example, to mitigate the effect of holding vacancies in hard to fill posts by permitting "over-recruitment" in key operating areas. The budgets also reflect the deliberate encouragement of fixed term post investments in specific priorities, the pausing of the existing headcount savings' plans, and, the significant effect of central levies.
5. In recognition of the strategic priority of establishing the Regulator's medium term position it was agreed that CET needed to have visibility and oversight over the headcount changes in order to ensure that they were distributed in line with the latest priorities, and that plans needed to incorporate income generation as well as cost reduction.
6. CET noted the positive opportunity available to MHRA of having the breathing space to prepare robust plans during 2016/17.
7. The AO considered the proposals for the 2016/17 budgets taking into account operational delivery, the investment requirements, the Business and Corporate Plans and approved them following discussion at CET. It was agreed they would be presented to the board for comment.

4. Regulator Strategic Update

The changes since the 2013 efficiency plan was agreed are:

- The 3rd floor at 151 BPR has been relinquished;
- Regulator non-pay cost control has absorbed the effect of inflation since 2013.
- A plan has been agreed to gradually align medicines' income and costs through lower fees. The CET agreed in June 2015 (Strategic Fees – CET/15/129), in the interests of stability and risk mitigation, to align fees and costs over two years. HMT is expecting the regulator to be in balance in 2016/17. A decision on 2017/18 fees will need to be made by June 2016 and at present there is not a secure basis for further cuts.
- There is still not government support for the implementation of devices' fees. If approved it would take some time to stabilise given the absence of a secure charging base. Risk mitigation measures have been agreed with DH to ease that transition, including DH's agreement to meet the cost of regulation until a new regime is implemented.

4.1. Fees, Assumptions and Operational Transformation

Once all one-off costs are removed, the regulator is set to make an underlying surplus in 2015/16, consistent with the forecast in the June 2015 fees' paper, and with the underlying surplus achieved in 2014/15.

Table 1 – Latest Assumptions

June 2015	Latest
Decentralised Procedure income would reduce from £16.5m to £10m per annum over two years	DCP income will remain at c£16m per annum through 2016/17 and 2017/18. 2018/19 and beyond is more uncertain, with a reduction to £10m being consistent with previous planning assumptions and current information.
Periodic Fee income would reduce from £32.4m in 2014/15 to £26m per annum over three years	Periodic fee income has reduced by £2.5m in 2015/16 and is set to reduce to £26m by 2018/19. This can be predicted with relative confidence because the volumes and age of existing marketing authorisations is known and the forecast allows for increased fees from new MAs.
Pay costs would reduce by a net £6m per annum. The Regulator would complete its 125 headcount reductions but this would be partially offset by pay awards and would then have to find other efficiencies because the fall in activity demanded it	Favourable variances in 2014/15 and 2015/16 have allowed the Regulator to pause its headcount reduction plan. The agency remains the highest cost member state across the top six providers for DCP applications.

June 2015	Latest
There would be a saving of c£3m per annum through relinquishing the 3rd floor at 151 BPR. A return to market rents with no rent free period would erode the annual saving when the rent review happens in September 2016.	The £3m saving has been accomplished; the 2016 rent review is yet to happen but the assumption remains the same with an increase in rent expected of £3m per annum. Wherever the agency is located it is assumed that it will pay a similar market rent to BPR.
Depreciation would reduce by £1m per annum by 2017/18 by capping the capital expenditure programme or efficiencies to that value would be found if investment was allowed above the cap	This has been superseded by the emerging operational transformation plan.
No changes in other volumes of fee earning activity	EMA fees for Pharmacovigilance work look set to be c£1m per annum, and increases in other activities such as clinical trials and variations of £1m per annum. There may be increases in EMA PL activity as more products use the centralised route to enter the market, with a likely decrease in national fees, the significance being that the agency has no control over the former.

The April 2016 fee reduction will save the medicines' industry £5.6m per annum with the impact on MHRA income recognition being approximately £3.5m in 2016/17 and with the full year effect being reflected in 2017/18 as deferred revenue is earned at the lower fee levels.

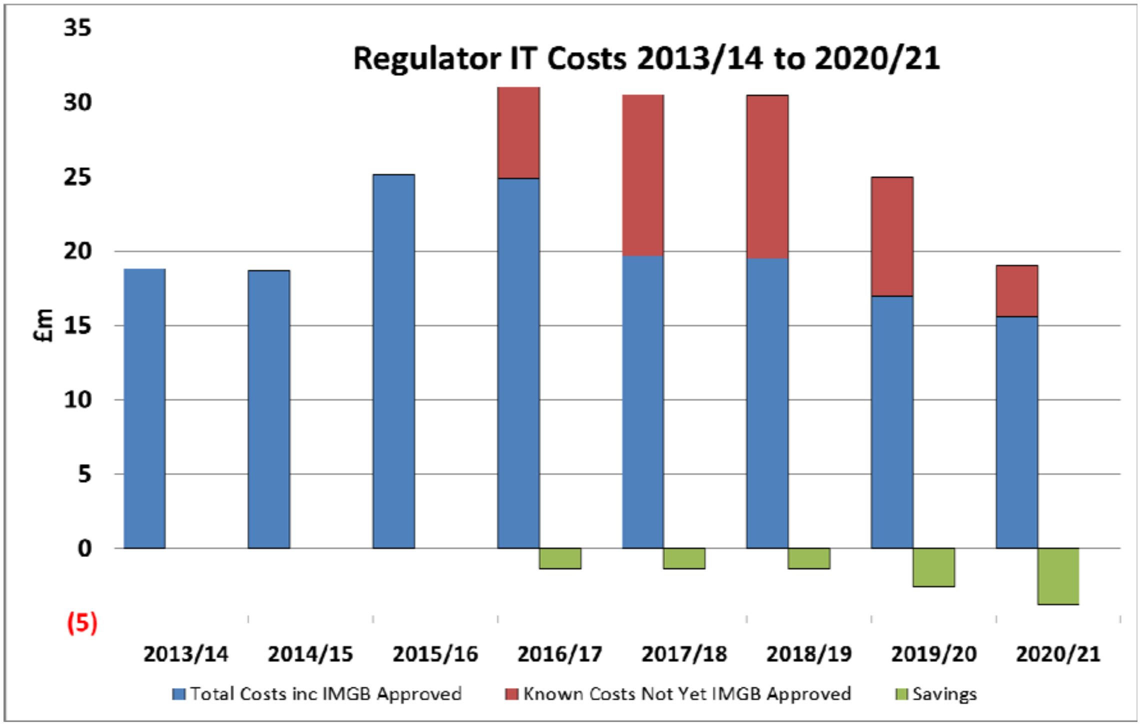
The January 2016 strategic finance paper (CET/15/280) identified the starting position for the operational transformation programme showing the impact on the Regulator's income and expenditure position.

The depreciation impact of the current assumed programme has been included below and in the budgets for 2016/17.

This outline plan is under development awaiting the objectives which will govern the approval of individual business cases. The CET held an organisational development day on 22nd March 2016 to start identifying the operational requirements from the IT investments. The summary of the CET discussion is included in the Digital, Information Management, Technology - Quarterly Update paper on the agenda of this meeting (MHRA 2016-OB-13).

The overall IT cost will increase during the years of investment and it is clear that the agency needs to identify savings and new income from across its activities in order to make a positive return on the investment. A summary of the costs identified to date is as follows (figure 1), prior to development of a plan which addresses the overall efficiency challenge.

Figure 1



Source: G:\Finance\2015-2016\Management Accounts\IT Cost Comparison 2013 to 2020 - Strategy V2.xlsx (Chart 4)

Figure 1 shows that total regulator IT expenditure was below £20m in 2013/14 and 2014/15. This has increased in 2015/16 as part of exiting the Accenture contract and investing in the immediately critical areas such as the corporate HR and Finance systems, the development of a Business Intelligence solution and the delivery of robust information and records management. The first projects have received IMGB approval and commenced expenditure, as reflected in the monthly budget reports. To date IMGB approvals total £20.2m for capital and one-off revenue expenditure with a further £10.3m for operation for the life of the projects.

Savings identified to date reflect the movement away from the Agency's contracts with Accenture. The area above the £20m level occupied by the blue and red bars represents the Agency's additional IT investment and forms part of the broader financial outlook.

This potential programme of investment from now on is only affordable if the agency meets the constraint that offsetting revenue savings will be identified in the ensuing business cases and then delivered, whether from IT enabled investment or elsewhere.

If the above emerging investment assumptions are integrated with the broader financial outlook beyond 2018 the position taking the most important variables is as summarised in table 2.

Table 2

Main Movement from 2015/16

£m	Five Year Financial Objective Period							
	Current			Next				
	15/16	16/17	17/18	18/19	19/20	20/21	21/22	22/23
Changes - all relative to 2015/16								
Volume Changes								
Periodic Fees		(1.1)	(3.8)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)
DCP		0.0	0.0	(3.0)	(4.0)	(5.0)	(6.0)	(6.5)
Fees								
April 2016 fee reduction		(3.5)	(5.6)	(5.6)	(5.6)	(5.6)	(5.6)	(5.6)
April 2017 - to be decided								
Pressures								
BPR Accommodation		(1.8)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Pay Awards		(0.8)	(1.5)	(2.3)	(3.0)	(3.8)	(4.5)	(5.3)
Pay On Costs (ERNIC, Pension)		(1.1)	(1.1)	(1.1)	(1.1)	(1.1)	(1.1)	(1.1)
Apprentice Scheme Surcharge		(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
Underlying Surplus / (Deficit)	**21.0**	**12.5**	**5.7**	**0.7**	**(1.0)**	**(2.8)**	**(4.5)**	**(5.8)**
Operational Transformation								
IMGB Approved	(10.4)	(5.0)	(1.0)	(0.8)	1.7	3.1	3.1	3.1
Not yet submitted for IMGB approval		(6.0)	(10.7)	(10.9)	(8.0)	(3.4)		
Assumed yet to be identified IT projects					(2.7)	(5.7)	(5.7)	(5.7)
Additional Income	0.2	0.5	0.4	0.4	0.4	0.4	0.4	0.4
Exceptional items								
Periodic Fee Refunds	(2.2)							
Reclassification of BI Phase 1 as Preparatory Analysis (subject to agreement in accounts)	(2.4)							
BPR Asset Re-lifing	(1.0)							
Corporate Reserve		(0.5)						
Forecast Surplus / (Deficit)	**5.2**	**1.5**	**(5.6)**	**(10.6)**	**(9.6)**	**(8.4)**	**(6.7)**	**(8.0)**

Source 1: G:\Finance\Mgt Accts General\Business Analysis\Strategy\2016 Fees Paper\Forecast v0.1 160121.xlsx – v0.2

Source 2: G:\Finance\Mgt Accts General\Business Analysis\Strategy\2016 Fees Paper\Budget 2016-17 workings rh.xlsx (new table 3)

5. Regulator 2016/17

5.1. Regulator Income

Changes to the key assumptions around income have been agreed with Divisions.

The main changes from the current budget (2015/16) to next year has resulted in a net increase in budgeted regulator income of c£3.3m (3%) – table 3:

Table 3

Regulator Income Budget	£m	£m
Volume changes		
Product Licensing (mainly DCP, variations, Labels & leaflets, EMA)	2.6	
EMA Pharmacovigilance Fees	0.4	
Inspections - filling vacancies	0.4	
Devices - lower volumes of CFS	(0.2)	
Devices - Notified Bodies and EU project	0.3	
Periodic Fees - setting the budget in line with expectations	2.2	
BPCRS	0.2	
Conferences [TBC]	0.4	
E-cigarette notifications	0.5	
Sub-Total - Volume Changes		6.8
Fee Changes		
Licensing	(1.7)	
Clinical Trials	(0.3)	
Periodic Fees	(1.5)	
BPCRS	TBC	
Sub-Total - Fee Changes		(3.5)
Funding Changes		
DH Funding (Devices)	0.0	
DH Funding (NIBSC share of corporate costs)	0.0	
Sub-Total - Funding Changes		0.0
TOTAL CHANGE TO EXISTING REGULATOR		**3.3**

- Product Licensing income (inclusive of EMA) has been increased by £2.6m more accurately reflecting performance in 2015/16 and knowledge of the molecules coming off data exclusivity in 2016/17 that should generate decentralised procedure applications.
- EMA Pharmacovigilance fees came into force on 1 August 2014 with the first fees being received in December 2014. Fee activity volumes are still hard to predict with certainty but the 2015/16 budget of £0.6m looks set to be exceeded by £0.4m. The budget for 2016/17 has been increased in line with 2015/16 performance and current expectations of volumes.
- Periodic fees income has been set in line with the assumptions in tables 1 and 3 increasing the budget by £2.2m to £29.7m. There will be a drop in receipts due to the aging of marketing authorisations, and economies in the generic

and parallel import pharmaceutical sectors, but this expected reduction has been pushed out further, from 2016/17 to 2018/19, to allow for the change in data exclusivity rules.

- Inspectorate have developed their income budget based on staff numbers that are below full complement; but recruitment strategies and workforce planning are beginning to have an impact with more accredited inspectors expected to be in post during 2016/17.
- DH funding for Devices and NIBSC 2016/17 has been indicated to the agency as the same cash as 2015/16, and an assumption that the non-cash funding of the cost of capital and dividend continues for NIBSC.
- British Pharmacopoeia Chemical Reference Substance sales have grown by over 50% since 2007/08. The growth has been consolidated into the income budgets. The review into BPCRS prices will recommend a simplified pricing structure that will have an impact on overall income that offsets the volume increase budgeted in 2016/17 reducing the current over recovery of full costs.
- The volumes of e-cigarette notifications are very uncertain and so have been conservatively budgeted at £0.5m.

5.2. Regulator Pay

The 2016/17 budgets account for over-recruitment in the operating divisions to allow for staff turnover, with several additional fixed term posts already approved.

The cost of the Regulator pay bill was £52m in 2013/14 and is set to be the same in 2015/16. By the end of 2015/16 the Regulator will have removed 30 permanent posts out of the original 125 target, but has had to pay for pension increases, pay awards, a temporary increase in the permanent establishment of IMD and an increased number of fixed term posts over the same period.

5.2.1. Communications

Fixed term posts have been agreed for the following:

- Digital Transformation Programme – 1 G7, 2 SEOs
- WHO fake medicines programme – 1 G6
- Devices CAMD – 1 G7
- CPRD programmes – 2 FTEs
- NIBSC programmes – 1 FTE
- E-cigarettes – 1 SEO
- Events Manager – 1 HEO

Additionally there has been identified one additional post but is not yet agreed:

- EU Presidency – 1 HEO

5.2.2. Finance and Procurement

The implementation of the Oracle Finance system and integration of NIBSC finances into one system for the whole Agency is planned to be completed by the end of 2016.

The Division will deliver savings as part of undertaking the NIBSC transactions currently provided by Public Health England. The agency will save £0.3m per annum from the SLA with PHE and incur additional costs of c£0.2m.

5.2.3. Policy

Policy Division utilise resources provided through the fast stream system to deliver work on behalf of the Agency. These staff have been filling 2 fixed term posts which will need to continue into 2016/17.

5.2.4. Human Resources (HR)

The HR staffing requirement has been reviewed in order to ensure it is capable of delivering to a larger agency with differing needs across the centres and a workforce that is on several different sets of terms and conditions.

The staff complement at 19.8 permanent established posts and 4 fixed terms posts is higher than the target that was set as part of the 125 FTE reduction plan, but there is a plan to remove the fixed term posts associated with the HR Oracle project once the new system is implemented.

5.2.5. Information Management Division

The IMD IT permanent staff establishment is 43 FTEs, an increase on the headcount target of 12, with a commitment to reduce that to 39 and to offset the overall increase with savings in IPU.

5.2.6. Licensing

It has been agreed that the division can over recruit by 10 assessors plus 2 support staff, on the understanding that when volumes of work decrease the Division will manage the workforce back down through turnover. In addition the income budget for decentralised procedures is being increased in line with assumptions. Recruitment can be on a permanent basis but the posts will be funded on a fixed term basis and kept under review through the normal monthly meetings. The additional resource will enable the division to:

- Absorb the work associated with the latest activity volumes and assumptions over the next 2 years;
- Maintain the agency's position with the EMA in terms of rapporteurships and scientific advice;
- Ensure the agency is ready for the EMA's PRIME (Priority Medicine) scheme where we will be 'hand-holding' companies prior to their application (we will earn scientific advice income during this).

5.2.7. Vigilance and Risk Management of Medicines (VRMM)

Five fixed term posts for 12 months have been previously agreed to deal with the Renewals backlog. A further fixed term post will be added to these, so that six posts are present in 2016/17. These should generate over £0.2m of non-recurrent income.

A further fixed term post has been agreed to be extended throughout 2016/17 in order to cover maternity leave.

5.2.8. Inspections, Enforcement & Standards (IE&S)

The current fixed term posts will continue into 2016/17. In addition the following fixed term posts have been agreed:

- 1 SEO and 1 HEO for 2 years (1 SEO and 1 EO) will be recruited to do the work that was previously done by the more expensive use of C13 Associates.
- 1 EO for 18 months to be administrator for the MHRA Enforcement evidence store. This role is current carried out by a temporary resource.
- 2 posts (H/SEO) for 1 year for the Fakeshare project funded by the Italian competent authority. The funding (less than £0.1m) for the two posts and other costs associated with the project has already been received and need to be spent by August 2016 when the project is due to end.
- 1 G7 for 2 years to deal with more complicated work in the Defective Medicines Reporting Centre and Inspection Action Group and to enable succession planning.
- 1 G6 for six months to work on the tender for the British Pharmacopoeia publishing contract. The Division is looking to get a fast-streamer.

There will be a continuing programme of investment in equipment at the MHRA and BP laboratories operated at LGC in Teddington and also the investment in the herbals laboratory based at South Mimms (total £0.4m).

5.2.9. Devices

It was agreed during the 2014/15 budget round that the Devices requirement to reduce by 9 posts as part of the Regulator's headcount reductions would be deferred subject to a review in light of DH funding and implementation of a new fee regime. The case for flexibility remains and so all of the Devices post reductions continue to be deferred until the outcome of the new fee system is known.

Once the impacts of the new fee charging regime are known the sustainability of the Devices financial position, including the corporate allocations, can be considered further. In the meantime, the Director of Devices is implementing the divisional reorganisation but is committed to remain within current agreed headcount limits.

- Increased volumes of work on notified bodies' inspections require additional resource (1 FTE potentially increasing to 2).
- Fixed term posts (1 FTE at HEO for 12 months) are required for the EU Health Programme funded by EU grant of £0.7m of which the MHRA will receive £0.2m.
- 2 SEO fixed term posts may be required to backfill for staff diverted onto IT projects in line with approved business cases.

5.2.10. Directorate

Sir Kent Woods' appointment as Chair of the EMA Management Board has now finished releasing 0.25 FTE from the Directorate budget.

5.2.11. Fixed Term Appointments Summary

The 2015/16 budget included 35 fixed term appointments during the year at a total cost of £1.5m. For 2016/17 this has increased to 62.3 fixed term appointments at a cost of £2.8m.

5.3. Regulator Pay Summary

Table 4 below shows the estimated impact of the above on the Regulator pay budget. The final budget will include a refined pay costing based on actual salaries, and the figures in table 4 may be subject to alteration as finer details on the exact timings and grades of new fixed term posts and over recruitment in Licensing become available.

The Regulator's share of the apprentice scheme surcharge will be c£0.3m while the increase in employer's national insurance contribution will be c£1.1m.

Table 4

Regulator	£m	£m
Regulator Pay Budget 2015/16		**54.0**
Devices changes	0.2	
Net increase in cost of fixed term posts	1.3	
Over recruitment in Licensing (to offset turnover)	0.5	
Pay Award (1%) from August 2016	0.8	
Increase in Employers NI contribution	1.1	
Apprentice Scheme Surcharge	0.3	
Pay Costing Refinements	0.0	
		4.2
Regulator Issued Pay Budget 2016/17		**58.2**

Table 5 (below) sets out the Regulator's and corporate divisions' budgeted position in terms of permanent and fixed term posts for the 2016/17 budget which will be delegated as control totals following approval.

Table 5

Regulator Staff	Perm. Est. 2016/17	Fixed Term Posts 2016/17
Operate		
Licensing	240.9	12.0
VRMM	120.3	7.0
IE&S	185.5	14.3
Devices	95.0	1.0
Operate Sub-Total	**641.7**	**34.3**
Corporate		
Communications	35.0	11.0
Finance & Procurement	31.2	2.0
Facilities & Estates	7.0	0.0
Policy	19.9	2.0
Human Resources	19.8	4.0
Directorate	6.9	0.0
IMD (excl IPU)	43.0	6.0
IMD - IPU	64.8	3.0
Corporate Sub-Total	**227.6**	**28.0**
TOTAL	**869.3**	**62.3**
Total Regulator	**871.3**	**62.3**

Source: G:\Finance\2015-2016\Management Accounts\FTE monitoring v3.xlsx

5.4. Regulator Non - Pay

The regulator has saved £3m in 2015/16 from releasing the 3rd floor at 151 BPR with rates and service charges for 151 BPR set to increase by £0.2m (3%) in 2016/17. It is assumed that the rent review in September 2016 will be based on current market rents.

IT operate services and other IMD non-pay budgets were frozen at 2013/14 recurrent levels for 2014/15 and for 2015/16 before a decision was taken to implement a transformation of key services. The operational IM non-pay budget for 2016/17 will include the savings from exiting the Accenture IO contract (c£1m per annum) but that will be more than offset by increases from: the additional scope requested from the IO replacement service providers (c£0.3m); Software and Licences (c£1.5m), Networks (c£0.5m) and SIAM (Service integration and management[1], "Managing providers in an efficient way", linked to the move away from Accenture) (c£0.8m), a net increase to the operational IM budget of c£2.1m.

As in 2015/16 specific business cases for IT investment that focus on timetabled, realisable benefits of proposed changes will come to the IMGB. In the meantime a budget will be held in Corporate for those projects already approved by IMGB that will run into 2016/17 and also for those that are in the portfolio for 2016/17 but have not yet been approved by IMGB. This budget will be issued to IMD as and when milestones are reached or when projects are approved by IMGB.

The corporate budget also includes £0.5m for the costs of the first year of the three year joint falsified medicines and medical devices campaign that is subject to cabinet office approval. There is an expectation for divisions to absorb other reactive pressures through prioritisation.

The net increase in issued divisional non-pay budgets is £4.1m (12%) compared to 2015/16 (table 6).

Table 6

Regulator	£m	£m
Regulator Non Pay Budget 2015/16		**34.1**
IM Operational Budget net change	2.1	
Accommodation 151 BPR	1.8	
Other divisional net changes	0.7	
Depreciation	(0.5)	
		4.1
Regulator Non Pay Issued Budgets 2016/17		**38.2**
Corporate Budget - not issued		
IMGB approved projects budget	5.0	
IMGB portfolio - Corporate budget	6.0	
Corporate Reserve - FMD and Devices campaign	0.5	
Regulator Non Pay Corporate Budget 2016/17		**11.5**
Regulator Non Pay Budget 2016/17		**49.7**

5.5. <u>Overall Effect of Changes in Regulatory Income and Expenditure</u>

Table 7 sets out the Regulator draft budget for 2016/17 and compares it to the 2015/16 budget.

[1] https://www.gov.uk/service-manual/technology/service-integration.html

Table 7

Regulator Budget Comparison

£m	2015/16 Budget	2016/17 Issued Budgets	2016/17 Projection	2016/17 Corporate Projection
Income	97.2	100.5	+4.5	105.0
Pay	54.0	58.2	-4.5	53.7
Non Pay (Issued budgets)	34.1	38.2	-3.5	34.7
Dividend	3.5	5.0	+0.0	5.0
Surplus /(deficit)	5.6	(0.9)	+12.5	11.6
Net Corporate Reallocation	1.2	1.4	+0.0	1.4
Surplus	6.8	0.5	+12.5	13.0
Operational Transformation				11.0
Corporate reserve				0.5
Retained Surplus				1.5

A sensitivity analysis on the 2016/17 Regulator budget is included in section 8.2 but table 7 also details how the issued budget compares to the 2016/17 projection shown in table 2.

The 2016/17 income budgets have factored in increases in DCP, European Medicines Agency (EMA) income and periodic fee income, and reflect the impact of the fee reductions.

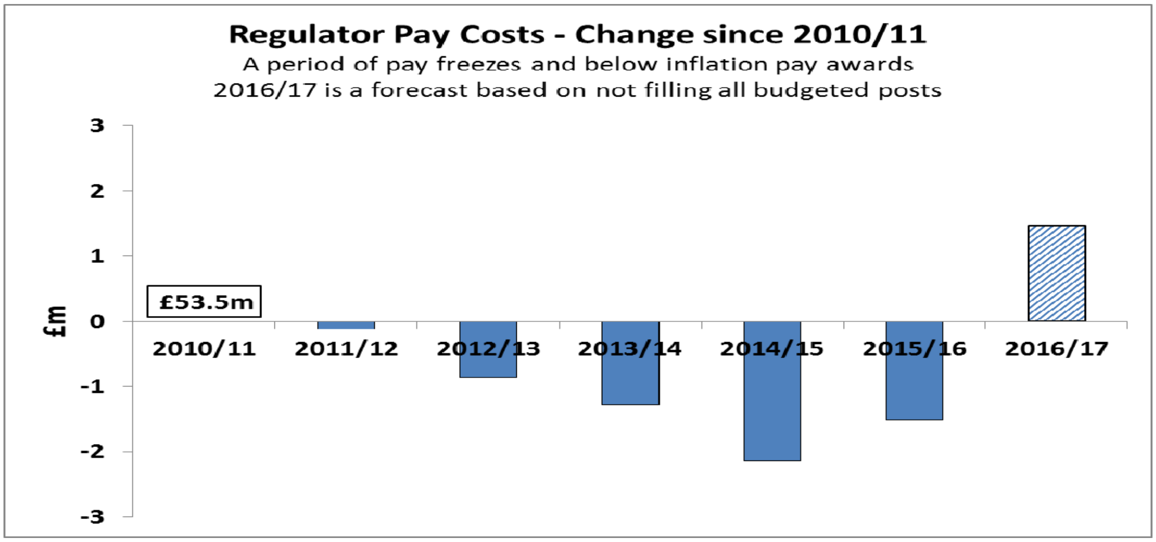
For 2016/17 the Regulator budget will consist of the issued budgets and the expected variance to those budgets will be included in Corporate along with the £11.5m of reserves for operational transformation and other reactive needs. During 2016/17 issued budgets will be tightened further in preparation for the 2017/18 budget round.

Table 8 and Figure 2 summarise the changes in the regulator's pay costs from 2013.

Table 8 Change in budgeted pay costs

Regulator Staff Costs	**£m**	**£m**
Original Plan for 2016/17 (before pay awards)		**46.0**
Remainder of posts from original headcount reduction plan (95 FTEs)	4.8	
Rebased HR and temporary increase in IMD IT perm est.	1.0	
Cumulative Impact of pay awards and grade inflation	2.7	
Pension increases (effective from 2014/15)	0.4	
Increase in Fixed Term Positions	1.0	
Over Recruitment in Licensing	0.5	
Devices posts	0.5	
Increase in Employers National Insurance contribution	1.1	
Apprentice Scheme Surcharge	0.3	
Total		**12.2**
Issued Budgets 2016/17		**58.2**

Figure 2 Change in actual and forecast pay costs



Source: G:\Finance\2016-2017\Budget 2016-17\Board Papers\Regulator Pay Costs.xlsx

In 2011/12 the agency reduced its headcount by 50 posts with savings starting in 2012/13. CET agreed to the 125 headcount reductions in 2013/14 with the early savings impact being experienced in 2014/15. Since then the headcount reductions have been paused and more fixed term posts have been implemented to deal with activity as well as increases from pay awards and pensions. This is in line with CET and Board discussions that the healthy financial position allowed for targeted investments and maintaining operational delivery.

Pay budgets have been underspent in 2015/16 by c£2m (c5%). The pay budgets for 2016/17 continue the budget discipline of assuming all posts will be filled which gives some leeway for underspending and being able to react flexibly to pressures, but ensures transparency over the costs of a full establishment.

Non-pay budgets still allow scope within divisional and corporate budgets to respond to pressures that arise during the year. If one-off revenue expenditure for IT projects (£6m) is removed from 2015/16 performance non-pay budgets would have been underspent in by c£3m (c8%) in 2015/16. As with 2015/16 scope remains to respond to pressures or to allow investments with realisable benefits.

6. NIBSC

6.1. Strategic Update

6.1.1. Background

In preparing for merger it was highlighted that there is a risk to allowing expenditure to increase on a recurrent basis given the threat of DH funding reductions. The sustainability model was developed to promote growth in NIBSC trading income to:

- allow investment where there are assurances of tangible benefits to be realised in terms of growing future financial independence from DH funds or that the investment on public health grounds alone is on a non-recurrent basis;
- make the centre more resilient to cuts in future DH funding, although cuts will continue to be resisted;
- adhere to a key principle of setting a 5 year plan that is in recurrent balance.

6.1.2. Pricing Strategy

The NIBSC SMT has the remit to adjust its pricing strategy if market conditions require, and for 2014/15 and 2015/16 decided to implement a 10% price increase for WHO International Standards (WHO IS) rather than the 21% that was included in the model for each of those years. The plan is to continue WHO IS price increases at the lower rate of 10% per annum in the medium term. The rationale for the percentage adjustments is that:

- The European Directorate for the Quality of Medicines and Healthcare (EDQM) has not increased the price of its standards since before the merger. NIBSC international standards prices are now significantly higher, resulting in both a reputational and market risk from perceived overpricing
- Larger step increases could be perceived as an abuse of NIBSC's position in sales of WHO International Standards. Standards fees are politically sensitive – manufacturers generally provide the raw materials, often highly valuable, free of charge on the understanding that NIBSC is carrying out a public service and WHO is particularly concerned to ensure that International Standards established under its auspices are widely and equitably available.
- NIBSC's financial performance has been strong, despite a £1.4m DH funding cut and the pressure of a £1m increase in employer's pension contributions as a result of a compulsory move to the Civil Service Pension Scheme, giving NIBSC the ability to attain its pricing strategy over a longer timeframe.

6.1.3. Investment

NIBSC has been steadily increasing its headcount towards 350 FTEs, recruiting the posts outlined from its first investment round and is now embarking on a second. The second round of investments has been previously agreed and was detailed in the CET Strategic Finance paper (CET/15/280).

All of the investments are either for a finite period of time or could be switched off relatively easily. They have been incorporated into the financial model and are sustainable.

6.2. Key Risks

6.2.1. DH Funding

The DH has indicated its agreement to flat revenue funding for NIBSC for 2016/17 and as a planning assumption to 2019/20.

The agency also receives cash funding for capital requirements to continually invest in the site at South Mimms (and also receives non-cash funding for the resulting depreciation charges). The capital funding each year since merger has been between £6-8m (with 2015/16 yet to be confirmed), but is at risk if fiscal belts are tightened or more resources are diverted to the Harlow project.

The provision of capital funding and the non-cash element to cover the depreciation impact on the income and expenditure account from those investments was agreed pre-merger and remains a strategic strength.

The plan to centralise all property within the control of the Government Property Unit and impose a capital charge (a proxy for rent) at the market value of freehold sites would impact NIBSC if it led to the current capital charge neutralisation being terminated (other public sector organisations already pay capital charges mainly based on existing use value) The timing and exact impact is not yet clear, but assuming a 3.5% capital charge, a rate consistent with *Managing Public Money*, this would create a c£3m liability for NIBSC, an 8% increase in the NIBSC cost base. This change would require a transitional arrangement for NIBSC.

6.2.2. Flu Standards income

2015/16 has been a lucrative year in terms of the sales of flu standards as NIBSC stepped in to provide c£1m of flu standards into US markets after the failure of the Center for Biologics Evaluation and Research CBER (part of the FDA) to provide any. This should be a one-off, CBER is expected to deliver in 2016, and there is limited opportunity to commercially exploit our enhanced reputation in the US market because CBER normally provides flu standards in the US for free. Some US firms, who normally totally rely on CBER, may now diversify their exposure to risk by regularly purchasing some quantities of flu standards from NIBSC.

The longer term risk is the potential development of a new assay that would obviate the need for flu standards. If it were to happen, the likely timescale would be about 5 years from now and would result in the loss of £4-5m per annum.

6.2.3. Control Testing

Income from control testing is worth c£5m per annum and is not under the same sort of threat or volatility as flu standards. NIBSC's aim is to maintain its existing, and continue attracting new, product control work in a competitive European market in line with its goal to maintain competence across the spectrum of biological medicines. There are a number of factors which create a challenging environment for NIBSC, the most important of which is probably the almost complete lack of UK-based production of vaccines.

Opportunities for new product testing business are also limited - most new biological medicines are not subject to batch release, there is little appetite in the community for extending the scheme, there is an increasing move toward combination vaccines, reducing the overall number of products in use, manufactured batch sizes are increasing and, although some companies have asked for the release of each packing lot, European requirements specify that only the final filling lot is tested. NIBSC nevertheless engages closely with manufacturers and has been successful in winning testing for innovative products that do require control testing. One such example is for Bexsero, the new meningitis B vaccine, but others are in the pipeline, such as Mosquirix and Fluenz.

6.2.4. EU Seventh Framework Programme (FP7)

NIBSC has completed several pieces of work granted under the EU's FP7 programme, as part of the former HPA and since merger, and will complete all of current FP7 grants by the end of 2017/18. A recent EU audit of completed projects both at PHE and NIBSC has led to a recommendation that the method of apportioning overheads should be changed, both retrospectively and for current open programmes. The recommendation has not yet been accepted by the European Court of Auditors but NIBSC is exposed to a negative correction of £1m in 2015/16 and a further £0.5m in its plans across 2016/17 and 2017/18.

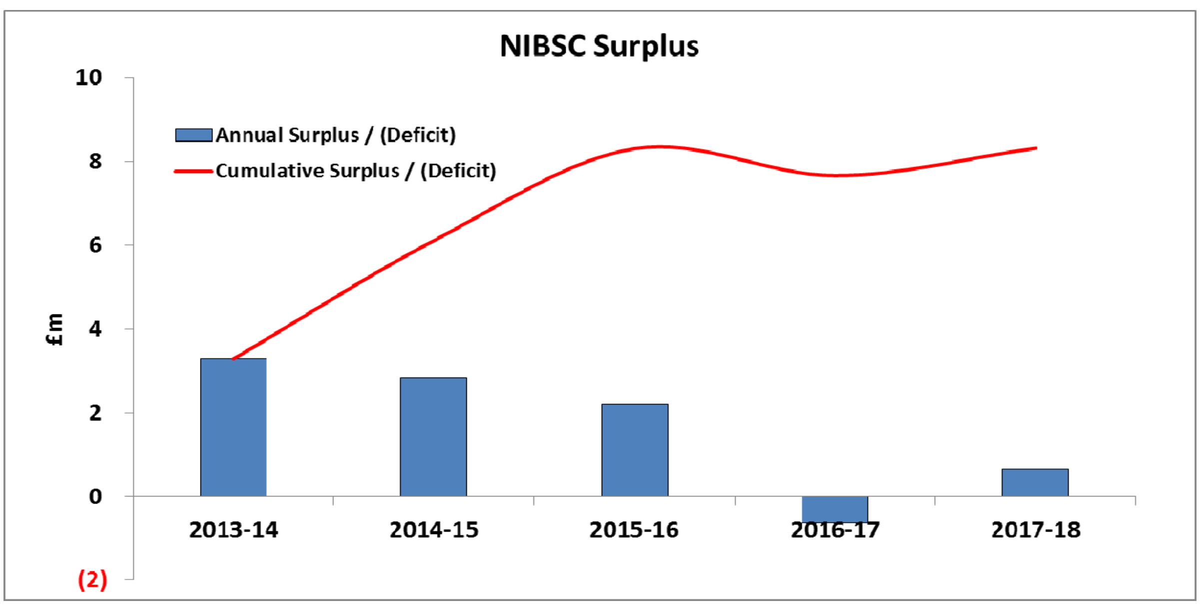
This is only a short term exposure; FP7 has now been replaced with a new programme, Horizon 2020, where NIBSC can take fresh decisions based on more consistent overhead allocation rules.

6.3. Financial Summary

The financial impact of both investment rounds, the updated pricing strategy, and the likely correction of the EU FP7 grants, have been incorporated into the financial model along with latest cost assumptions (figure 3).

A deficit would be planned for 2016/17 but this would only happen if all posts were filled which has not been the experience in the first three years of the current five year financial objective period.

Figure 3



Source:

6.4. <u>NIBSC 2016/17 Budget</u>

The financial sustainability model, originally developed as part of the merger preparations from 2013/14, has been updated and continues to adhere to the key principle of setting a 5 year plan that is in recurrent balance.

If all posts were filled from 1 April 2016 the plan for 2016/17 would be a deficit of £0.5m but there is little expectation of that happening – please see Table 9 below. Again, this approach has been adopted in order to maintain transparency over the full cost of the permanent establishment.

During the first half of 2016/17 NIBSC will look to refresh its five year financial model to take it into the next five year financial objective period starting April 2018. As part of that the investments that were agreed in 2014 will be reviewed.

Table 9

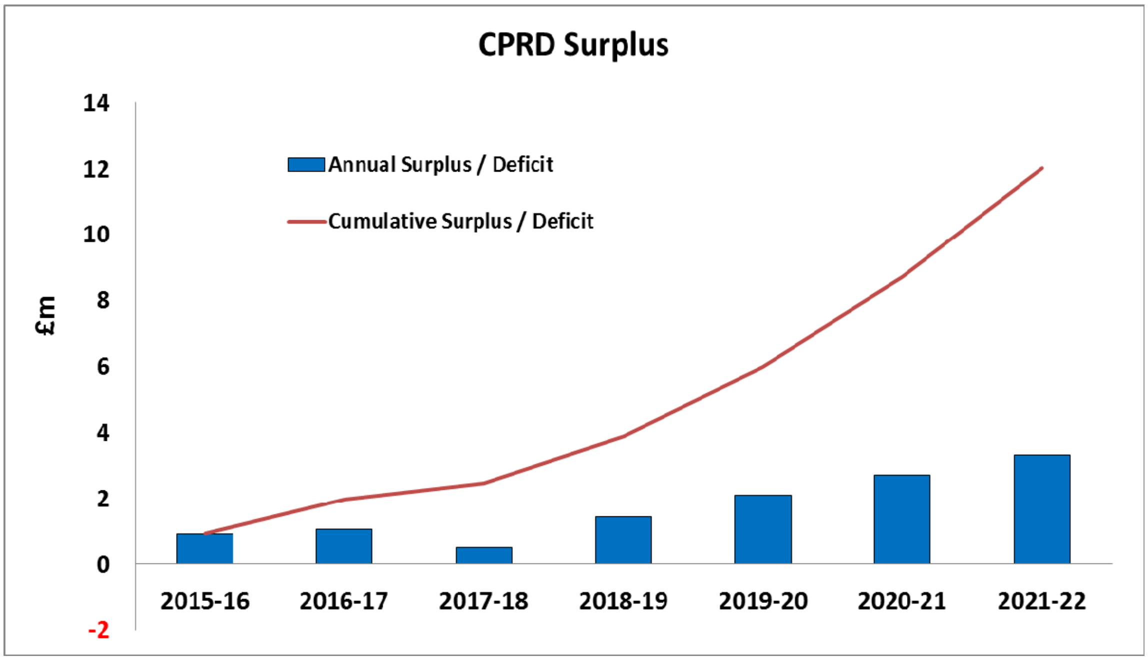
		NIBSC	
£m	**Budget 2015/16**	Forecast 2015/16	**Budget 2016/17**
Income			
Operating Income	21.5	21.6	22.6
DH Funding - revenue	10.2	10.2	10.2
DH Funding for NIBSC depreciation	5.5	5.5	5.5
DH Funding for NIBSC dividend	4.0	4.0	4.0
Total Income	**41.2**	**41.3**	**42.3**
Expenditure			
Pay	20.3	18.6	20.6
Non Pay	17.3	16.0	18.2
Total Expenditure	**37.6**	**34.6**	**38.8**
Operating Surplus / (deficit)	**3.6**	**6.7**	**3.5**
Dividend Payment	4.0	4.0	4.0
Surplus / (deficit)	**-0.4**	**2.7**	**-0.5**
Capital Expenditure	8.4	4.6	6.0

7. CPRD

7.1. Strategic Update

CPRD's strategic plan is as previously agreed (CET/15/254 and CET/15/280) with the financial model revised to: better reflect the positive income performance in 2015/16; the restructure of the Division being accounted for in full from part-way through 2016/17; and, depreciation arising from the new IT platform included from part-way through 2017/18 (figure 4).

Figure 4

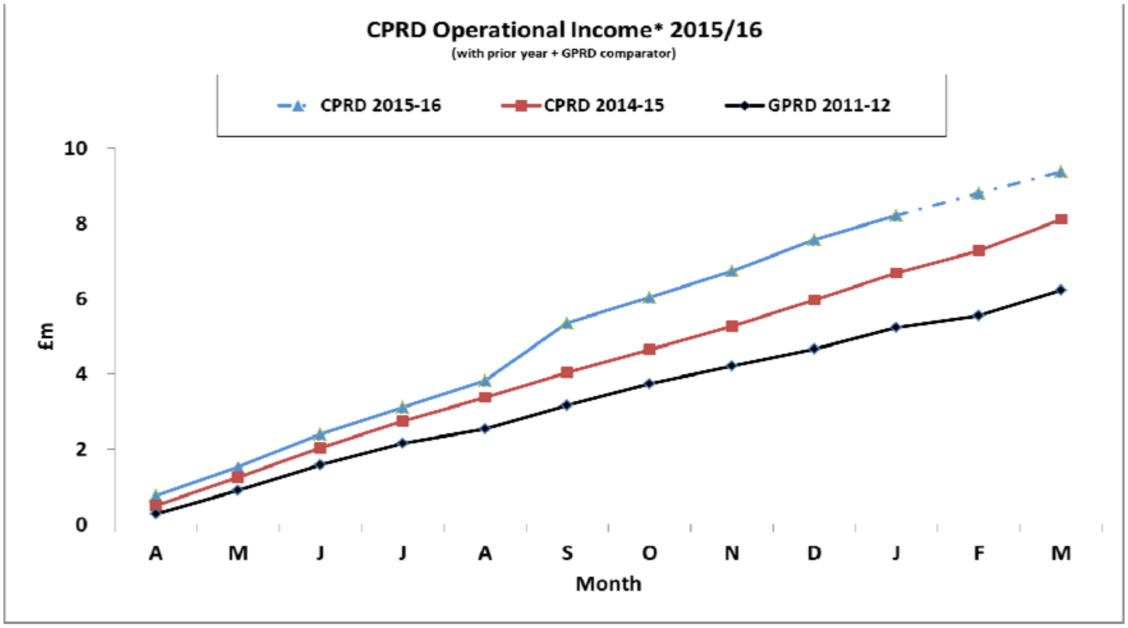


Source: G:\Finance\Mgt Accts General\RCP\Pricing Review\CPRD Pricing model V2.xlsx

Plans will be reviewed each year to ensure they are as ambitious as possible given the likely positive response to the DECIDE trial, the increasingly rich data becoming available and the planned increase in GP practice recruitment during 2016/17.

CPRD has made progress in terms of business and income growth since its inception in 2012/13 with income forecast to be c55% higher in 2015/16 than in the last year of GPRD (2011/12) (figure 5).

Figure 5

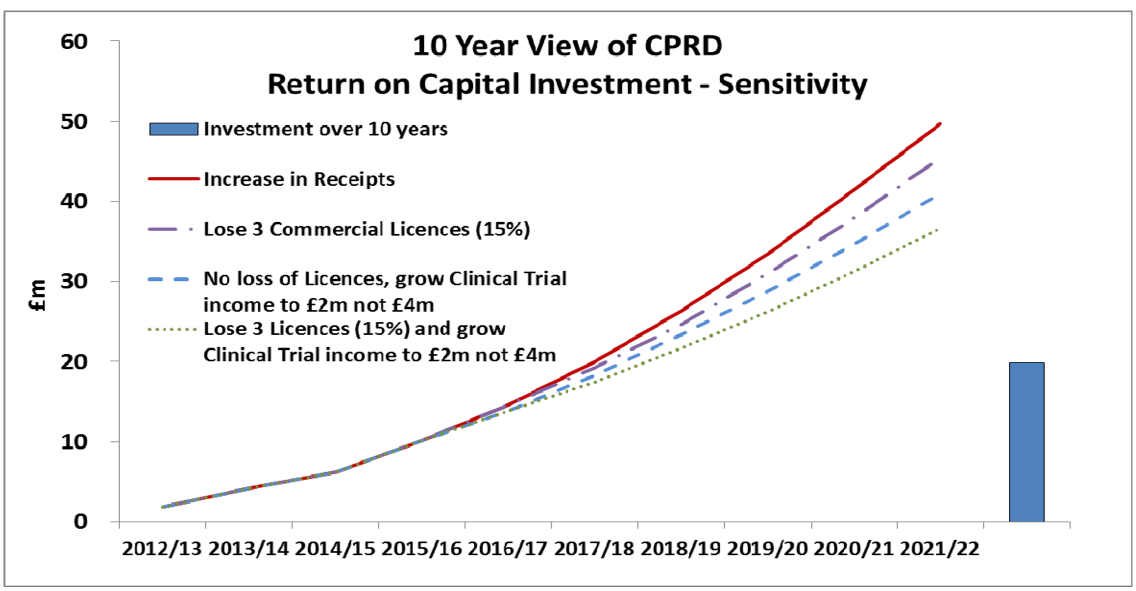


Source: G:\Finance\Mgt Accts General\RCP\Pricing Review\CPRD Pricing model V2.xlsx

The main CPRD capital investment of £7m across 2016/17 and 2017/18 will be subject to business cases which will be discussed with a sub-group of Agency Board NEDs at a formative stage and needs to be linked to growth in data, capabilities and new receipts.

The return on investment is an increase in receipts of £50m over 10 years compared to £20m of capital investment over the same time-frame. Even with pessimistic only sensitivity analysis, the return would still be positive (figure 6).

Figure 6



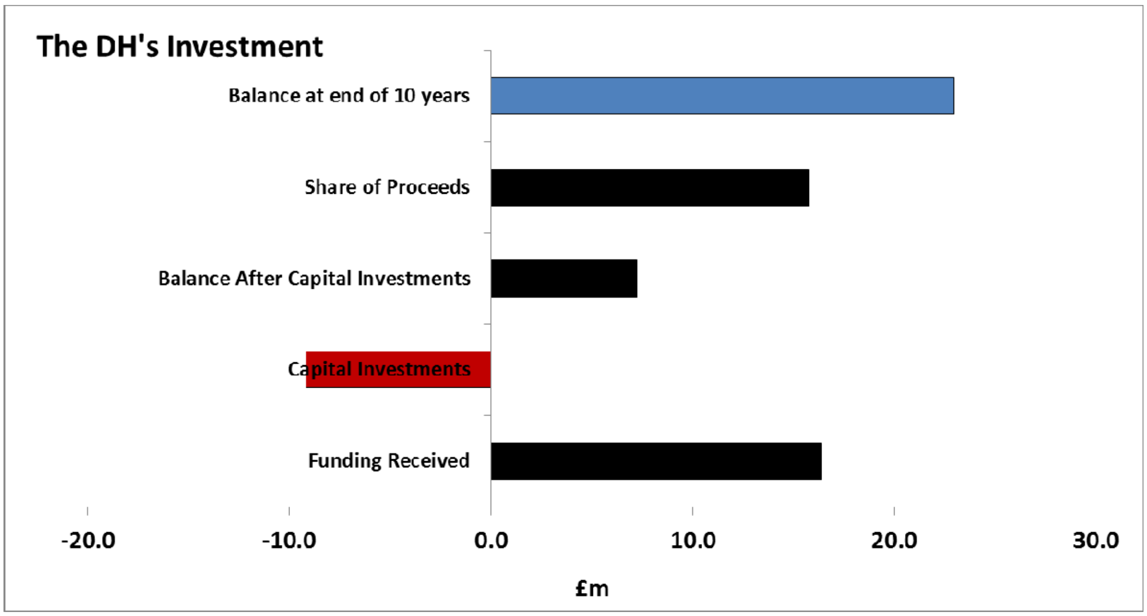
Source: G:\Finance\Mgt Accts General\RCP\Pricing Review\CPRD Pricing model V2.xlsx

7.1.1. Funding and Accounting

In terms of the financing of CPRD the position has not altered that MHRA could finance CPRD with its own resources but has greatly valued the joint nature of the initiative, which most importantly reflects the shared commitment to its success. MHRA currently holds £13m of unused DH cash funding out of the original plan of £30m with MHRA contributing the historic performance of GPRD at a surplus if £3m per annum for 10 years.

MHRA has received £16m of the DH contribution to date, £1m being additional to the original plan, leaving £15m more to be received. If one takes the most challenging view that only income receipts additional to historic GPRD income should pay for all of CPRD's investments and costs, the cash already given will be reinstated during the period of the original business case (2012 to 2022), the timescale depending on the pace of CPRD's growth (figure 7)

Figure 7



Source: G:\Finance\Mgt Accts General\RCP\Pricing Review\CPRD Pricing model V2.xlsx

DH is aware that MHRA does not need the cash and they have reiterated their commitment to funding CPRD as originally intended irrespective of the financial modelling because it remains for them a key strategic national research asset.

7.2. CPRD Budget 2016/17

The CPRD operational budget for 2016/17 has been set in line with the revised financial model (Table 10) and includes the assumptions made on volumes and price as set out previously (CET/15/280).

Table 10

	2012/13 Actual	2013/14 Actual	2014/15 Actual	2015/16 Forecast	2016/17 Budget
Income					
Observationals	7.8	8.2	8.0	8.7	9.0
Clinical Trials	0.0	0.0	0.0	1.0	1.5
Total Income	**7.8**	**8.2**	**8.0**	**9.7**	**10.5**
Expenditure					
Pay	2.3	2.6	3.0	2.7	4.2
Non Pay	2.3	2.4	3.5	4.8	4.0
Corporate	1.0	1.3	1.3	1.3	1.4
Total Expenditure	**5.6**	**6.4**	**7.9**	**8.8**	**9.6**
Surplus / (deficit)	**2.1**	**1.9**	**0.2**	**0.9**	**0.9**
Capital Expenditure	**1.2**	**2.7**	**3.5**	**2.2**	**4.0**

CPRD is budgeted to make a surplus of c£0.9m in 2016/17.

Income forecast at £10.5m represents growth of 8% compared to 2015/16 and 75% compared to the final year of GPRD, but is dependent on successfully completing the DECIDE pragmatic clinical trial and commencing work on preparing another trial of similar size. Recruitment of patients to the DECIDE trial is expected to take all of 2016 with the result that limited progress with delivery of the next trial is expected.

The increase in pay costs is for the restructure of CPRD, increasing the staff complement to 69.25 FTEs and is budgeted to be fully in place by the end of the first quarter.

The capital expenditure of £4m is part of the £7m across 2016/17 and 2017/18, and is subject to business cases that will detail the costs, timings, benefits and return on investment.

8. DH Funding 2016/17

For 2016/17 DH has indicated that they will be providing flat funding for Devices and NIBSC. Table 11 summarises the positions for 2015/16 and into 2016/17.

Table 11

			2015/16		2016/17
Area			**Current Funding (£m)**	**Forecast Outturn (£m)**	**Indicative**
Funding					
	Devices revenue	Cash	8.1	8.1	8.1
	NIBSC revenue	Cash	12.5	12.5	12.5
→	NIBSC Depreciation	Non cash	5.5	5.5	5.5
→	NIBSC Dividend	Non cash	4.0	4.0	4.0
	TOTAL		**30.1**	**30.1**	**30.1**
Capital Funding					
	NIBSC	Cash	6.0	6.0	*TBC*
	Devices	Cash	1.0	1.0	*TBC*
	TOTAL		**7.0**	**7.0**	**0.0**

→ NIBSC depreciation (non-cash) is forecast to be £5.5m in 2015/16 and dividend £4m. The agency has not received a DH funding letter confirming these values, but the principle of neutralising outturn values is well established.

DH has agreed to meet the cost of devices' regulation until a new regime is approved to commence.

NIBSC have absorbed the c£1m additional running cost resulting from staff being transferred into the Civil Service Pension Scheme as of 1 April 2015 and the £0.2m increase due to voluntary transfer to Civil Service Terms and Conditions without recourse to additional DH funding.

The agency previously stated it would want to include these items as part of the annual revenue negotiations with DH. However, DH finance's and NIBSC's ability to invest while maintaining a sustainable financial position means that any request for additional funding is likely to be denied. The DH financial position may also mean that there is more pressure on capital funding.

9. Whole Agency

9.1. Three Centre Agency - Summary

Table 12 below summarises the draft operating budgets for the 3 centres, the detail of which will be presented in the monthly reports to the CET and Board within the control totals in the following summary.

Table 12

Agency Budgets 2016/17

£m	Regulator	NIBSC	CPRD
Income			
Operating Income	94.6	22.6	10.5
DH Funding - revenue	10.4	10.2	
DH Funding for NIBSC depreciation		5.5	
DH Funding for NIBSC dividend		4.0	
Total Income	**105.0**	**42.3**	**10.5**
Expenditure			
Pay	53.7	20.6	4.2
Non Pay	34.7	18.2	4.0
Net Reallocated costs	(1.4)		1.4
Corporate Budget	11.5		
Total Expenditure	**98.5**	**38.8**	**9.6**
Operating Surplus / (deficit)	**6.5**	**3.5**	**0.9**
Dividend Payment	5.0	4.0	0.0
Surplus / (deficit)	**1.5**	**(0.5)**	**0.9**
Capital Expenditure	**7.4**	**6.0**	**4.0**

The agency will continue to make capital investments in all three centres in 2016/17 to support its business and corporate plans. All capital investments are subject to business cases and appropriate governance. The capital budget for 2016/17 is £17.4m.

- MHRA – Investments will be: in the agency's digital technologies to deliver cost-effective and smart services for the benefit of the users of our services (£6m); to further Devices efficiencies and facilitate the move to a new funding regime (£1m); and, in the MHRA and BP laboratories to replace obsolete equipment (£0.4m).
- CPRD - £7m over two years (£4m in 2016/17) to invest in CPRD IT platforms that will improve the capabilities of the user environment enabling CPRD to enhance its service offerings enabling continued growth.
- NIBSC - £6m to continue investment in the facilities and equipment at the laboratory site in South Mimms.

9.2. Sensitivity Analysis

The sensitivity analysis (table 13) identifies the potential unfavourable and favourable impacts on the budgeted retained surplus/deficit of each of the three centres for 2016/17. On balance the analysis suggests that the income and cost budgets will be favourably exceeded for each centre, providing security alongside the flexibilities allowed by the trading fund regime, that the budgets can be approved.

The largest income streams for the Regulator are from Product Licensing and Periodic Fees. The largest cost in both the Regulator and NIBSC is pay, and the area where there is likely to be the largest variance from plan is CPRD, particularly the level of income. For the Regulator the sensitivity is in addition to the column "Corporate Projection" in Table 7 and for CPRD and NIBSC the columns "2016/17 Budget" in Tables 9 and 10 respectively.

Table 13

2016/17 Budget - Sensitivity Analysis

	Regulator		NIBSC		CPRD	
	Unfavourable	Favourable	Unfavourable	Favourable	Unfavourable	Favourable
Budgeted Retained Surplus /(Deficit)	**+£1.5m**		**-£0.5m**		**+£0.9m**	
Income (I)						
Regulator - Product Licensing	-£0.5m	+£0.5m				
Regulator - Periodic Fees	-£0.5m	+£0.5m				
Regulator - e-cigarettes	+£0.0m	+£0.5m				
CPRD - Clinical Trials					-£0.5m	+£0.0m
CPRD - Observationals					-£0.3m	+£0.5m
NIBSC - Trading			-£1.0m	+£1.5m		
DH Funding NIBSC			+£0.0m	+£0.0m		
DH Funding Devices	+£0.0m	+£0.0m				
Expenditure (E)						
Pay	-£1.0m	+£1.0m	+£0.5m	+£1.0m	+£0.0m	+£0.5m
Non Pay - Outturn Performance	-£1.0m	+£4.0m	+£0.2m	+£0.3m	-£1.0m	+£0.5m
Potential Range Surplus / (deficit)	**-£1.5m**	**+£8.0m**	**-£0.8m**	**+£2.3m**	**-£0.9m**	**+£2.4m**
Range as a % of total budgets	**5%**		**4%**		**17%**	

9.2.1. Regulator – Product Licensing (PL) including EMA

The issued income budget, in volume terms, for Product Licensing and EMA has been set £3m (6%) higher than in 2015/16 reflecting the higher level of DCP volumes anticipated and the higher volume of EMA PV work. The outlook for DCP receipts and other PL income streams includes an unfavourable reduction in volumes of £0.5m that reflects a possibility of a decline in volumes. The favourable view is that receipt volumes will be boosted with larger occasional spikes in DCP receipts and that the impact of the fee reduction is not felt until later in the year than profiled.

9.2.2. Regulator – Periodic Fees

The budget for 2016/17 has been set £2.2m higher than in 2015/16, matching the budget to the assumptions set out in table 3. The range reflects the experience of changes in the volumes of marketed medicines and the potential to continue to tightly control the collection of income.

9.2.3. Regulator – e-cigarette notifications

The budget for e-cigarette notifications has been set conservatively low due to the uncertainty of volume information. The favourable view is based on higher volumes that may require correction to fees in following years.

9.2.4. CPRD – Clinical Trials

The budget for CPRD Clinical Trials is based on the November 2015 strategy, a volume of trials worth £1.5m. The unfavourable view is that no new large contracts are signed in 2016/17 reducing income by £0.5m.

9.2.5. CPRD – Observationals

An income budget for observationals of £9m has been set in line with the November 2015 strategy. The unfavourable view is that income stays at 2015/16 levels, while the favourable view is that growth continues at the same rate as seen in 2015/16

9.2.6. NIBSC - Trading

The NIBSC flu standards budget incorporates a pessimistic view of sales which could increase by as much as £1m against budget. But flu standard sales are volatile so an unfavourable view of a £0.5m reduction against budget is shown. Certification fee income could fluctuate by c£0.5m either way against budget depending on continued use of NIBSC as an Official Medicines Control Laboratory (OMCL). Research grant income could reduce by up to £1m depending on whether there are any delays to existing projects, but that would be offset by cost deferrals.

9.2.7. DH Funding NIBSC and Devices

The Agency has not yet received formal notification of DH funding levels for 2016/17. The unfavourable view is for a 10% cut to revenue funding either at the start of the financial year, or part way through, although this is considered unlikely given DH's verbal agreement.

9.2.8. Pay

Pay budgets have been set based on posts being filled for the full year in NIBSC and CPRD, the favourable view reflects posts not being filled for the full year. In the Regulator, the budget at a corporate level takes into consideration posts not being filled for the full year so the sensitivity analysis reflects a smaller variance to budget in relative terms.

9.2.9. Non-Pay – Outturn Performance

Within the Regulator non-pay expenditure budgets there is still scope for under-spending and this is reflected in the favourable view, along with an underspend due to timing differences in operational transformation equivalent to half of the cost of projects that are yet to be approved by IMGB (£3m). There is the potential for more expenditure on operational transformation than the £11m allocated in the corporate budget, but this is considered unlikely as the agency's ability to deliver this level of change would be the limiting factor.

It is unlikely that NIBSC will overspend on non-pay, but there is a reasonable likelihood of an underspend.

CPRD remains the area where there is a high degree of variability expected in non-pay expenditure, in relative terms and this is reflected in the analysis.

9.3. Responsibilities of the Agency's Chief Executive as Accounting Officer

As the Agency is a Trading Fund, HM Treasury (HMT) appoints the Chief Executive of the Agency as Accounting Officer (AO).

The Chief Executive as AO is personally responsible for safeguarding the public funds for which he or she has charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of the Agency.

Expenditure authorisation limits are delegated each year by the AO to individual directors and their nominated staff. These delegated limits are kept under at least annual review to remain appropriate to the scope of responsibilities within each post. Once the budgets are approved by the AO, the regulatory, NIBSC and CPRD centres each manage their revenue and capital budgets with the Information Management Governance Board approving all IT investments. The AO approves all individual commitments with a value greater than £1m.

Assurance to the AO is also provided by the board. An example is that the next phase of CPRD's investment programme will be examined by a group of NEDs whilst the plans are at a formative stage, early in 2016/17, following a successful meeting during 2015/16 which examined the plans already in place.

In addition the AO has to comply with the following central government controls.

1 – Advertising and communications

Internal agency approval – spend over £5k

Cabinet Office Approval – spend over £100k

2 - Strategic supplier management

Cabinet Office Approval – spend over £5m

3a – Technology Controls

DH Approval – spend over £100k

Cabinet Office Approval – spend over £5m

3b – Digital

DH Approval – all spend

Cabinet Office Approval – all spend

4 – Consultancy

Internal agency approval – all spend

Cabinet Office Approval – any contract over 9 months, any contract over £20k, any procurement related spend.

5 – Property and Facilities Management

Cabinet office Approval – in effect all spend

6 – Commercial Models

Cabinet office controls – spend over £5m

7 – Redundancy

Cabinet Office Approval – all spend

8a – Recruitment

Internal agency approval – all spend

8b – Temporary Staff and Professional Services

Internal agency approval – all spend

DH approval – any spend over £200k total or where the daily rate exceeds £900 / day.

9 – Learning and Development

CSL approval – all generic L&D not on the CSL portal

CSL approval All business specific / profession specific L&D over £10k (aggregated over 3 years)

10. Recommendation

The Agency Board is asked to note and comment on the proposed budgets for the three centres for 2016/17.