Medicines and Healthcare Products Regulatory Agency

Medicines and Healthcare Products Regulatory Agency Business Plan 2014-15

CPRD NIBSC MHRA

Contents

Chapter 1 – Introduction

This is the second annual Business Plan to deliver the 2013-18 Corporate Plan[1] of the Medicines and Healthcare Products Regulatory Agency.

This plan has been prepared in the context of some significant challenges and opportunities. Our mission is clear: we enhance and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research. We are a global leader in regulation, biological standards, and the provision of data for public health research, with a strong reputation and excellent track record. But we are also in working in a changing business environment:

- Both medicines and devices are global industries, with new producer countries and markets emerging all the time. There are fewer medicines being licensed, while there has been a dramatic increase in the development of new medical technologies and products including biological and biosimilar medicines.
- The European regulatory model is evolving. For medicines, we have seen changing work patterns and a continuing shift from national to EU licensing. For devices, new EU legislation is being developed and there is huge growth in healthcare products.
- Expectations from patients and the public are changing in line with general shifts in society, aided by the power of social media. Where at one time the view of the regulator was widely accepted, it is now often subject to challenge and greater transparency is expected.
- There have been radical changes in the UK health and care system, with new organisations and an increased emphasis on partnership and joined-up working.
- Although there are signs that the UK economy is coming out of recession, money remains tight, and our financial position is getting more challenging. There will be continuing budgetary pressure across Government and an expectation on us to support growth, the life sciences and innovation.

Our 2013-18 Corporate Plan sets out how we are going to develop and change our business, based on a foundation of effective regulation of medicines and medical devices. It highlights the key areas where we need to focus our efforts. We need to do further work to take some areas forward.

Every year we produce an annual Business Plan which sets out in detail how we intend to progress the corporate plan over the year. This is supported by divisional and centre plans, which link to individual staff objectives.

Some of our achievements over 2013-14

While the purpose of this document is to outline the key activities the Agency will be engaged in during the forthcoming year, it is important to recognise the achievements of the past year, which will be recorded in our Annual Report. Of note during this period we have made good progress in delivering our strategy. For medicines we successfully led a joint action project (SCOPE) to raise standards of pharmacovigilance across the EU, and we played a key role in revising and simplifying EU rules on clinical trials. We also continued to support Government work on Life Sciences, including launching the new Early Access to Medicines Scheme and playing a key role in the development of the European Medicines Agency's adaptive licensing pilot project. On devices, we led an EU initiative to reconfigure member state collaboration and cooperation with the EU Commission.

The National Institute for Biological Standards and Control (NIBSC) made a significant step in establishing an Advanced Therapies Division, which will draw together existing NIBSC work on cell

[1] The 2013-18 Corporate Plan is available at www.mhra.gov.uk.

and gene therapies, supplemented by additional investment. Our intention is for this division to become a major international hub for scientific expertise in cell and gene therapies, identifying and meeting needs for standardisation within the field, ensuring an internal capability to analyse and test cell and gene therapy products in the event of incidents and emergencies. We have also continued to grow the Clinical Practice Research Datalink (CPRD), including formally launching our Trailviz tool and making available to the research community a service to link up to 14 national NHS datasets.

Our priorities for 2014-15

Over the next year our overall priorities will be as follows:

- Supporting safe innovation and UK growth – leading and contributing to EU and global initiatives, strengthening our science base and making our regulation more supportive of innovation.
- As an EU leader, contributing to the development of an improved, proactive approach to medicines and devices vigilance that uses innovative methodologies and technologies.
- Ensuring the safety of products and supply in global industries – extending the reach of our services and reference materials; acting to avoid shortages and reduce the risk of illegal supply; and collaborating to improve global quality and resilience.
- Developing new products and services, and promoting them to existing and potential customers.
- Defining and developing our networks and relationships with healthcare professionals, patients and the public, and others in the health and care system.
- Achieving financial sustainability; becoming more efficient; supporting our staff through change and helping them to develop their careers and skills; and improving our business intelligence.

Detail on how we will deliver these priorities is provided in chapter 3 below.

A changing organisation

This Business Plan will support changes in our organisation over the coming years. We will be reducing the size of the regulatory and corporate divisions, in line with our changing business. We will also be growing the businesses of NIBSC and CPRD, and maximising the benefits they can bring to our third, regulatory centre, the MHRA.

Our public health mission will remain at the core of what we do. We will continue to be one of the best regulators in Europe and one of the largest in the world. We will collaborate increasingly with other EU and international regulators. This will maintain our leadership role in Europe and internationally, while enabling us to be more efficient and responsive.

We will develop new products and services and look for new income streams, while maintaining our focus on public health and science-based, impartial decision making. We will continue to develop and deliver Government policy on medicines and devices regulation as effectively as possible.

Internally, it will be important for us to become more efficient and to work more flexibly across the organisation, sharing skills, knowledge and expertise. This plan is produced in the context of the Agency's budget, and the need to streamline parts of the business.

Structure of this plan

The remainder of this plan is structured as follows:

Chapter 2	Overview of the financial context in which we are operating
Chapter 3	Our key strategic activities over 2014-15 to progress delivery of our

	2013-18 Corporate Plan
Chapter 4	Overview of our ongoing core business – including notable work in addition to our strategic activities in chapter 3
Annex A	Targets relating to our core business – particularly chosen to reflect aspects of our business where the industries we regulate have a choice about whether to use the UK regulator or another EU regulator
Annex B	Metrics relating to our core business – to be monitored over time to develop our understanding of our performance
Annex C	A table collating the strategic activities set out in chapter 3

Chapter 2 – Financial context

We operate as a Government Trading Fund. Our funding is structured as follows:

- We derive all of our income for our medicines regulation from fees. In setting our fees we take account of full cost recovery rules as set out in HM Treasury's Managing Public Money.
- We derive most of our income for devices regulation through a service level agreement with the Department of Health.
- We derive approximately 60% of NIBSC's revenue from fees we charge for our services, including the sale of biological standards, and from research funding. The Department of Health provides the remaining 40% to finance its important public health functions.
- CPRD is operated as a joint venture with the Department of Health's National Institute for Health Research with a 50:50 investment contribution.

Each of our centres operates with segmented accounts which highlight their respective trading positions, bearing their appropriate share of corporate services. The key principle is that the three centres do not cross-subsidise each other.

As set out in our 2013-18 Corporate Plan, we are operating in a financially challenging context. The regulatory environment has become more competitive and increasingly global. Changing work patterns and a more networked EU system, which includes changes to the pharmacovigilance model, with fees being set by Europe, has resulted in a reduction in regulatory income.

The trading fund model supporting our regulatory centre is designed to be responsive to growth and contractions of business, while ensuring that we are always resourced to discharge our responsibilities as a leading global regulator. We shall continue to maintain a sustainable balance of cost and funding, being flexible and implementing efficiencies in order to remain responsive and cost-effective in the delivery of our services. This will entail adjustments to our regulatory function, including taking the first steps in a process to reduce the number of posts over the next three years, tightening non-pay budgets and seeking other efficiencies (for example in our accommodation costs).

Funding for devices regulation is at half the level of that in 2003; and while a number of efficiency measures have been taken, this is against a backdrop of adverse incident reporting increasing by over 50% since 2009. A review of the basis of the funding of devices activities is underway, with a move to a model which levies fees for market surveillance under consideration.

For NIBSC, the primary objective is to continue to grow and invest to remain the global leader in biological medicines, and to maintain our global leadership position in biological standardisation.

CPRD will work to progress the activities in its business case, seeking to establish a secure e-health research data service offering unparalleled access to real world health data and supporting all types of data research and clinical trials. This will enable CPRD to achieve its public health and growth objectives as a world-class link into the unique healthcare datasets of the NHS.

Chapter 3 – Key strategic activities for 2014-15

This chapter sets out key activities in 2014-15 that will progress delivery of our 2013-18 Corporate Plan. It is divided into sections based on the structure of the Corporate Plan. The activities are intended to deliver the following objectives for the year.

1. Vision and scope of our role

- Build our capability and maintain our leading position in all regulatory areas, biologics and CPRD services, fully exploiting the synergies across the whole organisation and prioritising activities with the greatest impact and highest value.
- Define our role with other organisations in the new health and care system, healthcare professionals and the UK and global academic life science base, working together to build a common sense of purpose.
- Define our role with patients and the public.

2. Bringing innovation and new products speedily and safely to patients

- Lead and contribute to major innovation initiatives at national, EU and global levels, coming to an agreed and publicised role and position on UK PLC's offering to life sciences.
- Keep abreast of scientific developments and their implications for our work, defining those areas in which we want to be market leader and developing the required expertise.
- Develop the services and extend the reach of CPRD for the provision of data services for research purposes and vigilance as per the published plan and business case.
- Actively engage with the EU in working towards coordinated oversight mechanisms for devices and the sharing of information and resources.

3. Strengthening surveillance

- As one of the leaders in the EU, contribute to the development of an efficient, proactive approach to medicines and devices vigilance that utilises innovative methodology and technologies to improve safety reporting and communications.
- Working with and influencing organisations across the health and care sector, ensure that the systems for reporting adverse incidents are relevant and accessible to UK patients, public and health professionals

4. Safe products and secure supply in globalised industries

- Collaborate with other regulators to achieve a convergence of standards and practice, and make better use of global inspection audit and resources.
- Ensure the quality of medicinal products on the market and act to avoid shortages.
- Tackle the increasing risk of the illegal supply of medicines and devices.
- Develop biological standards to underpin manufacturing consistency and dosing accuracy of biologics.

5. Achieving excellence – a well-run, efficient and effective organisation

- Operate at a financially sustainable level, meeting our financial targets.
- Identify and implement revised or new processes to improve efficiency whilst meeting the needs of our customers.
- Ensure we recruit, retain and develop people with the right skills to deliver our objectives.
- Put in place appropriate mechanisms to monitor and measure progress against our objectives.

1. Vision and scope of our work

Our objectives:

- **Build our capability and maintain our leading position in all regulatory areas, biologics and CPRD services, fully exploiting the synergies across the whole organisation and prioritising activities with the greatest impact and highest value.**
- **Define our role with other organisations in the new health and care system, healthcare professionals and the UK and global academic life science base, working together to build a common sense of purpose.**
- **Define our role with patients and the public.**

This section sets out the overarching strategy which will guide our work over 2014-15 and to which the activities in the following four sections of this chapter will contribute. It also sets out some further, specific activities with the aim of building our capability and further developing our relationship with stakeholders.

Our overarching strategy

We are, and will continue to be, a high performing organisation that makes a significant contribution to UK public health. We will maintain our ability to function in all regulatory areas, having regulatory responsibility for all medicines and devices on the UK market and playing a leading role in the development of the regulatory framework for these products.

We face financial constraints created by an increasingly active global environment, changing work patterns and increased networking and competition in the EU system, and ongoing austerity within the UK. In response, we will become more effective at operating our business model. We will prioritise our activities and focus resources on the core activities that we must undertake, and the other activities that have the greatest impact or highest value. We will also identify non-value added work that we should stop doing, and continue to improve our productivity and increase our efficiency across the organisation, simplifying processes where possible.

The increasingly global environment and networked EU system in which we operate demands that we focus on the work we must do and on other work with the greatest impact and highest value, with effort proportionate to risk and need. In doing this, we must respond to the challenges and opportunities we face, including:

- maintaining NIBSC's capability and position as a global leader in biologics – ensuring we maintain our ability to respond swiftly and effectively to biologics public health challenges
- fully developing and marketing our CPRD service, realising both its public health and economic benefits as a unique data management tool
- being recognised for our role supporting safe innovation, working with industry to identify opportunities – both within, and through adjusting, the regulatory framework – to enable innovative products to reach the market earlier while maintaining appropriate safeguards
- fully exploiting synergies across the organisation, in particular between our three centres – for example, exploring how CPRD services can strengthen our vigilance work and how NIBSC expertise can inform our regulation of drug/device combinations
- remaining abreast and part of scientific development – making best use of the wide-ranging expertise within the agency and continuing to build external networks with key stakeholders
- building a clear network of responsibilities with mechanisms to ensure consistent delivery of supervision and services across the EU – continuing to lead work to increase the efficiency and effectiveness of the network, through avoiding duplication of activities and costs and minimising regulatory burdens.

Building our capability

While we are working towards avoiding duplication of activities and costs, and minimising regulatory burdens, it is important that we maintain our capability across all regulatory areas and continue to be a thought leader in Europe and globally. As part of this, we will need to make the best use of the abilities, capabilities and knowledge across the organisation – in particular, ensuring that CPRD's services are developed further and that NIBSC continues to be a world leader in biologics. Specific activities in 2014-15 will include the following:

1A. Progress the NIBSC integration project and ensure cross-agency access to key relevant information as identified in NIBSC merger project by quarter two.
1B. Review and make decision on a business case for establishing an in vitro diagnostic reference lab (IVD) at NIBSC as envisaged in the recast IVD Directive by quarter three.
1C. Take forward cross-agency group work on data transparency, carrying out a survey by quarter one on the types of data held by the agency and current practice on retention and release.
1D. Re-establish our NIBSC Scientific Advisory Committee by quarter two.
1E. Hold first NIBSC divisional Quinquennial Review by quarter four.
1F. Delivery of the activities and expenditure in year three of CPRD's published plan and business case
1G. Strengthen the CPRD-NIHR relationship to more fully integrate the clinical trial offering both at a service and IT software level, recruiting a project manager in quarter one.
1H. Work with the Farr Institute (four centres) throughout 2014-15 to increase the volume of both observational and interventional research, particularly using linked datasets, used by them and their partner universities.
1I. Throughout 2014-15 CPRD, in conjunction with MHRA and NICE, to offer additional input to joint scientific advisory meetings as to how data, as available from CPRD, can enable studies of a more real world nature for both HTA and regulatory safety/effectiveness purposes.

Interacting with stakeholders

The health and care landscape has changed significantly in the last few years. We work with many health and care stakeholders to help protect and improve public health, and will seek to better define our role working with other key organisations, healthcare professionals, and the UK and global academic life science base. Though clarifying roles and responsibilities and prioritising partnership working, we will aim to maximise efficiencies, clarify responsibilities and ensure a joined-up, strategic approach to public health issues.

We will also seek to define the profile and relationship we should have with patients and the public, taking account of their expectations of what we should be doing and ensuring they are involved in decision making where appropriate and beneficial. This is particularly important given the recommendations of recent reviews into public health issues – including the report into the Mid Staffordshire NHS Foundation Trust Public Inquiry, the Earl Howe review of the MHRA and the Department of Health regarding Poly Implant Prothèse (PIP) breast implants, and the Stephenson review into access for clinical advice for devices.

Specific activities to take forward in 2014-15 will include the following:

1J. Review and implement appropriate elements of the Stephenson Review into access for clinical advice for devices – responding to the report, including establishing an architecture and core processes and appointing a new advisory body, by quarter four.
1K. Establish cross-agency groups and project plans to define and develop key strategic relationships with:
    a. other organisations in the health and care system by quarter two
    b. healthcare professionals (including responding to the Stephenson Review) by quarter four

c. patients and the public by quarter two
d. the UK and global academic life science base by quarter two.

2. Bringing innovation and new products speedily and safely to patients

Our objectives:

- **Lead and contribute to major innovation initiatives at national, EU and global levels, coming to an agreed and publicised role and position on UK PLC's offering to life sciences.**
- **Keep abreast of scientific developments and their implications for our work, defining those areas in which we want to be market leader and developing the required expertise.**
- **Develop the services and extend the reach of CPRD for the provision of data services for research purposes as per the published plan and business case.**
- **Actively engage with the EU in working towards coordinated oversight mechanisms for devices and the sharing of information and resources.**

We support and champion safe innovation and make a large contribution to the Government growth and Life Science initiatives. We will build on a breadth of experience and capability in this area. This includes our international hub of expertise in advanced therapies, biotechnology and drug/device combinations, and the CPRD database, which is a database of choice for health research data.

We have contributed to the delivery of the Prime Minister's 2011 Strategy for UK Life Sciences. In particular, we have played a key role in the Expert Group on innovation in the regulation of healthcare[2] and in March 2014 launched the Early Access to Medicines Scheme, which will inform prescribers on promising unlicensed or off-label medicines that address unmet need. We will continue to progress our work in this area.

Strengthening our support to innovation

We will continue to support and encourage safe innovation wherever possible, leading innovation initiatives at the UK, EU and global level in 2014-15 and beyond. In collaboration with other bodies, we will help to develop an agreed role and position in the UK's offering to life sciences. We will publicise our role and highlight the innovation initiatives available to industry, encouraging industry to take advantage of them. In our work within the EU, we will continue to pursue our aim of creating a proportionate regulatory framework and ensure Europe is attractive for product development.

We will also draw together our work in key innovative areas where there are likely to be rapid scientific advances, including personalised medicine, genomics and other advanced therapies – to ensure that we are prepared for the regulation of products of the future; are clear what industry and others need from us, and what we are able to deliver; and that we have a strategy to address the growing demand and challenges in these areas. In addition, we will fully contribute to important Government priority public health areas such as dementia and anti-microbial resistance.

For devices, we will actively engage with the EU in working towards coordinated joint audits of notified bodies and a greater sharing of information, aiming to enhance both the speed and quality of responses to public health threats, and to leverage costs across the EU as a whole. We will continue to play a leading role in influencing EU negotiations on the revised medical devices Regulation and will re-designate UK notified bodies as per the 2013 implementing legislation. We will continue to push for better coordination of the work of EU member states and the EU Commission following the recommendations of the inter-authority task force chaired by the UK in 2013-14. This covers both operational effectiveness and strategic development of the system.

[2] The Expert Group brought together government, regulators, the NHS, industry and the academic and third sector communities. The report of the Expert Group was published in October 2013 and made recommendations on a range of issues relating to the regulatory environment which we and wider Government are taking forward. It is available on our website: mhra.gov.uk.

We will work with others to promote and develop scientific advice and concepts. For example, we will look to further promote joint MHRA/NICE scientific advice (as well as other MHRA support mechanisms and licensing flexibilities) to stakeholders, including through our website and at stakeholder meetings. We will convene a one day roundtable discussion on Physiologically-Based Pharmacokinetic modelling (PBPK) involving representatives from the MHRA, industry, other competent authorities and experts in this area.

Specific activities for 2014-15 will include the following:

2A. Effective implementation of the EU Clinical Trials Regulation – including consulting on new domestic legislation for clinical trials by quarter one; and continuing efforts for increased collaboration between MHRA and the Health Research Authority, ensuring that the IT systems for this collaboration are in place when the Regulation comes into force mid-2016.
2B. Establish a national platform on reclassification as a pilot and identify metrics to measure the outputs from this initiative by quarter one.
2C. Develop a clear strategy and work plans for the new NIBSC division for Advanced Therapies by quarter one.

Developing CPRD

The number and type of offerings from CPRD's services have increased over the past year, and CPRD is seen as the leader in the provision of data services for research purposes. CPRD will continue to progress its business case for year three, extending its reach into new areas in 2014-15. The health data environment is currently evolving, and CPRD needs to collaborate with, and rely on, the Health and Social Care Information Centre (HSCIC) in expanding its data coverage and linkages, therefore delivery of some CPRD services. We will also need to work with the HSCIC and other partners – including Public Heath England and NHS England – to ensure that the CPRD research message is understood and works alongside a broader over-arching message about the value and security of health data.

Specific activities for 2014-15 will include the following:

2D. Formally launching CPRD's clinical trial offering in quarter two, and throughout the year moving more of its products that are currently in development from beta testing to full deployment.
2E. As the population cover of primary care data increases, extending CPRD's existing data services (Risk Management Tracking of new medications) and launching new services (Pregnancy and Children Trackers). And working to develop a service related to Promising Innovative Medicines and how exposure and outcomes data on early use will be made available from CPRD.
2F. Throughout 2014-15 CPRD will continue working with our Devices division and the Health and Social Care Information Centre to get coded device exposure data added to the standard HES reporting data. This will enable greater analysis of devices safety and effectiveness to be undertaken.

3. Strengthening surveillance

Our objectives:

- **As one of the leaders in the EU, contribute to the development of an efficient, proactive approach to medicines and devices vigilance that utilises innovative methodology and technologies to improve safety reporting and communications**
- **Working with and influencing organisations across the health and care sector, ensure that the systems for reporting adverse incidents are relevant and accessible to UK patients, public and health professionals**

We have a key role to play in the development of EU and global networked vigilance for medicines and devices, working to enhance patient care and safety in relation to the use of medicines, devices and combination products. New legislation that came into force in July 2012 marked a significant change towards a more networked approach to pharmacovigilance (vigilance of medicines) across the EU. It introduced new EU-wide procedures to assess safety issues and new tasks for the EMA, and aimed to reduce the burden on industry by adopting a more networked approach. We have since played a leading role in influencing the new EU fees system to support these processes.

We are now coordinating a three year EU-wide pharmacovigilance project to help member states meet the requirements of the new pharmacovigilance legislation. This joint action project was launched in late 2013 and is called 'Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE). In addition, we are leading the Innovative Medicines Initiative funded WEB RADR project to leverage new technologies for pharmacovigilance. Building on recent strategies for proactive pharmacovigilance of new national immunisation campaigns, we are also working on a project to make optimal use of CPRD data, alongside Yellow Card data, to support near real-time, life-cycle vigilance and risk evaluation for major new vaccines. We will develop our capabilities in this area and work with other EU regulators to achieve a more proactive vigilance approach, making use of CPRD's expertise and available technology.

On devices, we are championing several related EU projects with regulators and industry to improve the consistency, breadth and transparency of vigilance data reported on devices placed on the market within the EU. The most notable of these concerns the accelerated development of a European vigilance reporting module.

Specific activities for 2014-15 include the following:

3A. Ensure the SCOPE project is operating within budget and timelines, delivering a promotional SCOPE leaflet and launching a project website by quarter one.

3B. Lead the WEB RADR project:
   a. successfully completing contract negotiations by quarter two
   b. developing a prototype app for ADR reporting for use by UK patients and healthcare professionals by the end of quarter four

3C. Complete the review of simplification of medicines and devices reporting by quarter one, and implement as necessary developments to the Yellow Card website by quarter three.

3D. Establish a cross-agency group and develop a project plan by quarter one to explore synergies between CPRD and pharmacovigilance reporting.

3E. Continue to champion the accelerated development of an EU devices vigilance portal ahead of the implementation of revised regulations:
   a. By quarter two, forming a task force with representatives from competent authorities, industry and notified bodies; and researching all funding options, including EU Joint Action funding.
   b. By quarter four, reaching a common position within the task force on the IT architecture and design of the vigilance portal.

4. Safe medicines and devices and secure supply in globalised industries

Our objectives:

- **Collaborate with other regulators to achieve a convergence of standards and practice, and make better use of global inspection audit and resources.**
- **Ensure the quality of medicinal products on the market and act to avoid shortages.**
- **Tackle the increasing risk of the illegal supply of medicines and devices.**
- **Develop biological standards to underpin manufacturing consistency and dosing accuracy of biologics.**

The medicines and devices industries are becoming increasingly globalised. This has created more complex threats to secure supply and quality, requiring more partnership working with regulators outside the UK and reinforcing the need for a risk-based approach to regulation.

Harmonising regulation and standards to improve global quality and resilience

We will collaborate actively with international regulators to effectively deploy inspection resource proportionately, based upon risk. Our aim is to enable individual country regulators to make regulatory decisions through risk assessment by the use of shared information and mutual reliance of inspection findings between global agencies. To achieve this, there will need to be a convergence of key standards, with practical arrangements in place and a clear role for us in the inspections network. Activities in 2014-15 to achieve this will include the following:

4A. Agree a Memorandum of Understanding (MoU) with India by quarter three and agreements with individual states by quarter four.
4B. Agree a renewal of the MoU with China by quarter two.

Ensuring quality and secure supply

We have an important role in increasing the quality and securing the supply of medicinal products on the market. The annual British Pharmacopoeia publication of authoritative standards, the international biological standards work of NIBSC and pharmacopoeial harmonisation activities with others are three such ways that we fulfil this role. To help secure the supply of medicinal products, we work with the Department of Health to ensure that there is no overdependence on vulnerable sources and that there are plans in place to deal with any risk of shortages in the supply chain. We will continue to support the development of harmonised global audit standards for devices via active participation in selective International Medical Devices Regulatory Forum (IMDRF) initiatives, particularly the Medical Devices Single Audit Programme (MDSAP).

It will be key for us to engage with other regulators from countries supplying medicinal products and their components – including through agency-led training events, forming work sharing programmes and accepting regulatory outcomes from trusted partners. There is always a risk that illegal medicinal products get on to the market, but we work hard to reduce this risk, seeking a more secure supply chain and more public awareness of the risk of illegal sources of supply.

Specific activities in 2014-15 towards this end will include the following:

4C. Publicise and make available to stakeholders the revised Enforcement strategy by quarter two.
4D. Implement the Falsified Medicines Directive (including concluding the safety features part in the most balanced way possible) by quarter four.

4E. Continue support for the increasing role of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), including preparing to take the role as Chair in 2016-17 and to undertake the PIC/s annual seminar and training event in 2016.
4F. Contribute to the work of the International Coalition of Medicines Regulatory Agencies (ICMRA), including leading a project on inspections and developing a working framework in Good Manufacturing Practice – aiming to maximise benefits from joint inspection programmes and acceptance of other regulators' outcomes. This will be undertaken throughout 2014-15 with benefits being realised in 2015-16.

Extending the reach of our services and reference materials to improve global quality and resilience

January 2014 marked the 150th birthday of the British Pharmacopoeia, our authoritative collection of medicinal standards. We will undertake a year-long programme of events and activities to celebrate this important publication, which continues to be a successful business and play a significant role in ensuring the quality of medicines in the UK and internationally.

In 2014-15, NIBSC will be aiming to meet the international demand for existing biological standards, maintaining its position as the dominant supplier of international standards. NIBSC will also be developing biological standards to underpin manufacturing consistency and dosing accuracy of biologics. In 2014-15, this will include the following:

4G. Complete six key international standardisation projects (Hib PRP; Hepatitis B S antigen; Lupus anticoagulant; Hepatitis C (detection); anti-malaria antibody; Factor Xia) by quarter three.
4H. Raise the profile of scientific expertise and reach of services/reference materials through improved visibility and marketing, launching an improved website by quarter three.
4I. Develop a revised strategy for the prioritisation, establishment, Quality Assurance compliance and supply of NIBSC diagnostic standards by quarter four.

5. Achieving excellence – a well-run, efficient and effective organisation

Our objectives:

- **Operate at a financially sustainable level, meeting our financial targets.**
- **Identify and implement revised or new processes to improve efficiency whilst meeting the needs of our customers.**
- **Ensure we recruit, retain and develop people with the right skills to deliver our objectives.**

Being a well-run, efficient and effective organisation is essential to the delivery of an excellent service in a competitive environment, and the minimisation of costs and fees charged. We need to be financially sustainable and have the right design, culture and shape (including skills, competencies, knowledge, experience and systems) to deliver our strategy. In 2014-15 and beyond, we will seek to maximise our efficiency and minimise the burdens we create, with our customers in mind.

Pursuing excellence in our regulation and customer service

We have already taken steps through the Red Tape Challenge process, with input from stakeholders, to identify and put in place changes in the way we work. Our Regulatory Excellence Programme will continue to bring together and progress further opportunities to minimise burdens. For example, we are currently piloting a simplification of the way we handle variation applications; once this work is completed, a training workshop will be developed for industry.

We are also looking to increase the usability, usefulness and affordability of our RamaXL service, a subscription service providing organisations with direct access to real-time information on their own products and non-confidential information on all other products authorised in the UK. In 2014-15, we will work further with industry to help scope this project and explore options, such as possibly developing a self-service portal.

We will also begin to roll out a new business intelligence tool within the agency from April 2014, aiming to improve how we operate and our service to customers. As this project progresses, we expect to see:

- improved management decisions and better insights into risk
- better external facing information provided to customers
- more time spent using information rather than gathering data
- more rapid reporting leading to more accurate data reporting
- utilisation of data to give better intelligence to compare our performance with that of other Member States.

We are driving down our costs in a number of ways, notably through reviewing our IT strategy and the use of IT suppliers to exploit cost savings and synergies between ourselves and other Civil Service departments.

Specific activities in 2014-15 will include the following:

5A. Deliver the agency's Budget for 2014-15, reducing costs through various measures such as restructuring and infrastructure resourcing, and achieving the first year of our 2013-18 Corporate Plan's financial strategy.
5B. Agree an agency marketing and business development plan by quarter two.
5C. Progress our Regulatory Excellence Programme to ensure that the regulatory policy and negotiation work of the agency is delivered.

5D. Agree a project plan by quarter two to deliver the IT system changes required for moving to human resources and finance shared services by April 2015.
5E. Establish plans by quarter two to manage the transition for, and the risks of, moving to a new IT supplier in December 2014.
5F. Develop a revised restructuring and redeployment approach by quarter one.
5G. Assist staff to understand the opportunities for development and progression within and outside of the agency, identifying the key skills required by quarter three.
5H. Develop career paths to map onto the Civil Service grading system by quarter four scientific, technical and professional skills to support standardisation and control work.

Supporting our staff

Our staff are our most important resource, and manpower planning will be a key focus for us over the next year and beyond. We will take forward initiatives to build a strong employer brand and an engaging working environment, attracting talent and motivating staff to remain working for us. Our management and leadership capability will be developed in order to build the performance of all areas in the agency. Specifically in 2014-15 we will undertake the following activities:

5I. Develop a programme to increase management and leadership capability across the organisation by quarter two, linking to areas highlighted in the Civil Service people survey.
5J. Implement an approved strategic recruitment approach to attract, select, recruit and retain staff within Civil Service constraints for specialist areas and senior roles – ongoing, but to deliver benefits by quarter three.
5K. Develop an employer brand campaign to support the recruitment and retention approach, agreed by quarter three.
5L. Undertake a major review of all HR data, systems, processes and activity within the agency and of that held by payroll and the MyCSP pension administrator by quarter one, implementing all recommendations by quarter four.
5M. Develop a new HR delivery model and programme of work to support shared services from April 2015.

Chapter 4 – Core Business

This chapter sets out core business activities of note to be undertaken by our three centres and our corporate divisions, in addition to the strategic activities earlier in this plan.

MHRA Regulatory Centre

Our MHRA regulatory centre delivers our regulatory responsibilities in relation to medicines, devices, blood quality and the British Pharmacopoeia. It comprises four divisions: Licensing; Vigilance and Risk Management of Medicines (VRMM); Inspection, Enforcement & Standards (IE&S); and Devices. These divisions will continue their core regulatory work of assessing applications, monitoring products in the market place and responding to issues as they arise, conducting inspections, taking enforcement action as necessary, overseeing notified bodies, developing monographs and guidance, and contributing to the European and global regulatory network.

2014-15 activities of note in addition to strategic work in the business plan

We will further improve our medicines licensing service to our customers through our process improvement initiatives and through significantly developing our regulatory guidelines. We will also implement the new EU Clinical Trials Regulation, which will replace the Clinical Trials Directive 2001/20/EC. The Regulation aims to increase the attractiveness of the EU for conducting clinical trials on medicines by reducing administrative and regulatory burdens, increasing the clarity of the law and increasing harmonisation across the EU. We will further support the Government's innovation and life sciences agenda through contributing to the Government's regenerative medicines initiative.

With the aim of increasing collaboration on enforcement across the EU, we will provide sole secretariat support to two meetings of the Heads of Medicines Agencies (HMA) Working Group of Enforcement Officers (WGEO). This will involve the 28 EU member states, some EEA countries, a selection of international observers and representatives from several Customs organisations. The group will pursue greater sharing of knowledge, skills and experience regarding enforcement activity in support of legislation relating to medicines crime.

We will also develop a portal for stakeholders to submit wholesale dealer applications and applications for the manufacture, importation and distribution of active pharmaceutical ingredients following the implementation of the Falsified Medicines Directive. As part of the 'digital by default' agenda, we will aim to move by the end of the year to only accepting electronic applications.

We will also undertake a variety of important initiatives in relation to pharmacovigilance. We will develop a national strategy for various models of access following the success of the EU stakeholder platform on access. We will also begin work on a UK stakeholder engagement exercise to move the agenda forward in relation to wider access to medicines, developing a pilot stakeholder event covering two therapeutic areas. We will work collaboratively with external stakeholders to deliver medicines information which meets the needs of all patients and healthcare professionals to enable delivery of the wider medicines optimisation strategy. We will start developing a strategy to ensure that the voice of patients informs regulatory decision-making in relation to safety issues, and will contribute to the Department of Health's Children and Young People's Health Outcomes Strategy to promote the safer use of paediatric medicines

For devices, we will work to ensure a sustainable funding model for devices. This will entail completing a legal review of a planned fee generation regime; developing a detailed implementation plan; completing consultation with industry; and confirming and agreeing a programme for implementation with the Department of Health, HM Treasury and the Department for Business

Innovation and Skills. Alongside this we will redesign the organisation of our Devices division to respond to current pressures and ensure leadership and management continuity. This will include completing the development of career pathway models for core roles, and focusing on our middle tier of managers as a first step in enhancing management development.

We will continue to drive implementation of a new collaborative model for working with fellow member states and the European Commission on devices regulation. We will agree priority initiatives, establish milestones and drive implementation; and gain agreement on a plan for development of an EU market surveillance and vigilance portal ahead of implementation of new Devices legislation.

In the UK, we will contribute to the Department of Health's implementation of the recommendations of Sir Bruce Keogh's review into cosmetic interventions, including working with NHS England to improve adverse incident reporting in order to enhance medical device safety. We will also implement recommendations from the Stephenson Review into access to expert clinical advice. This will include mapping and prioritising engagement with clinical stakeholders; designing and establishing management processes for clinical expert groups; and reviewing and re-designing the configuration of the clinical team to address sustainability, robustness and optimal use of agency capability.

Developing adverse incident management for devices will also be key. We will re-design our organisation to further shift towards signal detection and focus resources on high-risk incidents. In order to support this process, we will develop supporting IT to reduce manual analysis and support process, including reporter communications. We will also initiate a stakeholder communications exercise to manage and shape expectations and understanding of risk-based adverse incident methodology.

Key changes to respond to financial challenges

The regulatory centre will need to make some reduction and redeployment in headcount to respond to an increasingly active global environment, changing work patterns, an increasingly networked and competitive EU system, and ongoing austerity with the UK. This will force efficiencies in our procedures. We will need to be more adaptable in delivering our responsibilities, and ensure that we have a flexible, skilled and experienced body of staff able to meet the demands we face. This will also create opportunities for us to work in more innovative and collaborative ways.

Clinical Practice Research Datalink (CPRD)

CPRD is the English NHS observational data and interventional research service, jointly funded by the agency and the Department of Health's National Institute for Health Research (NIHR). CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.

Throughout 2014-15, CPRD will be taking forward the activities for Year three identified in its business case, working collaboratively in a complex environment and promoting the value of using healthcare records for research purposes

2014-15 activities of note in addition to strategic work in the business plan

CPRD will, on a range of fronts, work to further increase the population cover of primary care data to the maximum achievable level. We will aim to recruit as many Primary Care practices as possible that are research ready (there are approximately 2000 of these) to join the CPRD system. This work is in conjunction with the activities outlined in chapter 3 and includes specific requirements related to National Institute for Health Research (NIHR) funding and the need for further collaboration between the NIHR and CPRD.

We will also formally launch our clinical trial offering by quarter 2, following up with continual introduction of software products to extend our offering and added value. In addition, we will further develop our business through introducing new data products, extended risk management tracking, pregnancy and children trackers, and more datasets for linkage.

Key changes to respond to financial challenges

Business development remains the focus for CPRD. As outlined above, GP practice recruitment will be a priority. Partnership with other health bodies will also be key. We will also work with the Health Quality Improvement Partnership in order to get full agreement to access audit datasets; and with NIHR to develop collaborative working with those that undertake the clinical work in clinical trials. We will also extend our work to pilot Pragmatic Trials to a system that can work across all GP IT systems, fully enabling such studies across a large population.

National Institute for Biological Standards and Control (NIBSC)

NIBSC is a global leader in the standardisation and control of biological medicines, and in supporting science and research and the regulation of medicines and devices, strengthening the support provided to the UK's medicines industry.

2014-15 activities of note in addition to strategic work in the business plan

We will continue the routine supply of pre-existing international standards and reference materials to customers (over 150,000 items were shipped to over 80 countries in 2013), and will replace international standards and reference materials where stocks are running low. As the UK's Official Medicines Control Laboratory, we will carry out Official Control of Batch Release Authority (OCABR) testing of medicines for the EU, and issue of Release Certificates required for marketing. We will also deliver a wide range of research activities, largely funded from external sources. Alongside this, we will continue to contribute to a wide range of policy making and advisory bodies, building on the 150 contributions we have made over the last four years.

Key changes to respond to financial challenges

NIBSC has had to deal with substantial organisational change over the past five years, and the uncertainty associated with this, along with significant cuts to its funding as part of the Health Protection Agency, required careful financial management. Staffing levels dropped by 10% during this period. External revenue generation has remained strong, however, helped greatly by increased demand for influenza vaccine standards; and this has put NIBSC in a position where it can begin to reinvest in key emerging areas of biological medicines, such as Advanced Therapies building on the UK Stem Cell Bank platform, and in succession planning for critical skills and leadership.

Corporate divisions

Our corporate divisions comprise Finance and Procurement, Human Resources, Information Management, Policy and Communications. They support the work of our three centres, playing a vital role in ensuring we can deliver our public health and Government responsibilities.

2014-15 activities of note in addition to strategic work in the business plan

The key activity for Finance and Procurement (working with HR) will be preparing for the move to the Cabinet Office's Independent Shared Service Centre 1 (ISSC1). This will involve changes to the way the agency handles all transactions in these areas, including purchasing goods and services, collecting income and reporting these activities to management. In doing this, the division will continue to ensure that the agency procurement pipeline is managed effectively, and that all procurement adheres to central Government policies. At the same time the division will be providing insight into the changes that are impacting on the agency's finances, including the changing market for our products and services, particularly the changing role of Europe in them.

Human Resources will focus on putting in place a people strategy to support the delivery of the people elements of the Corporate Plan, and to drive the people related activity taking place across the agency. In addition to the strategic projects that will be commenced in the current year such as workforce and succession planning, there is a strong focus on 'delivering the basics'. For example, the HR division will support the agency through its first year of the performance management process for all staff and has been focusing learning and development activity on building management capability, in anticipation of the additional management and leadership challenges that this will bring. With Finance and Procurement, the division will also work to support the transition to shared services for the transactional HR activity currently provided by the division.

In addition to the work on moving to HR and Finance shared services, the Business Intelligence project and our IT Infrastructure supplier, a key priority for Information Management will be the restructuring of our internal IT governance model. In a changing digital landscape, our role to manage and deliver IT services and solutions needs to become more flexible. There will be a new focus on how and where we procure IT services and how IT projects are managed, as well as a more rigorous approach to service management of our suppliers.

Policy will continue to help the agency to deliver its responsibilities for Government policy and to engage actively with wider Government objectives. This will include continuing to support growth and the life sciences, and ensuring a proportionate approach to regulation. Working with other parts of the Agency, we will progress UK objectives in the negotiation of EU legislation on devices regulation and pharmacovigilance fees, and ensure active management of any risks arising from implementation of EU legislation on clinical trials and Falsified Medicines Directive safety features. We will support and coordinate agency input into key strategic initiatives at an EU and international level – including the International Coalition of Medicines Regulatory Agencies (ICMRA), work on the operational and financial sustainability of the EU regulatory network, and seeking a funding regime for devices regulation. The agency will work in collaboration with the Department of Health on the Tobacco Products Directive and, together with the Department, will jointly support the review of herbal medicines chaired by the Deputy Chief Medical Officer.

In a UK context, we will help the agency define and develop its role and contribution in the new health and care system. We will also ensure, as the organisation's resources tighten, that the agency continues to offer a high quality services to Ministers and is effectively managed, with clarity about organisation and responsibilities across the corporate divisions and the rest of the agency.

Communications will focus on developing and implementing the updated agency communications and reputation strategy, and will take forward a number of strategic projects. These will include work

on promoting and marketing the agency's services and the breadth of its activities and expertise; and developing and implementing workstreams to improve the agency's engagement and communication with healthcare professionals, and our relationship with patients and the public. We will complete the transition to gov.uk for the regulatory website, redevelop the NIBSC website and develop our use of social media. We will support all areas of the agency by managing relationships with the media; engagement with stakeholders, patients and the public; employee and manager communications; and customer and information services. We will implement communications campaigns on enforcement, counterfeiting, and adverse incident reporting, and organise a range of high-profile events, exhibitions and speaker opportunities.

Key changes to respond to financial challenges

Like the divisions within the regulatory centre, the corporate divisions will need to make some reduction and redeployment in headcount to respond to a tightening financial context. Similarly, this will require increased efficiency, adaptability and flexibility in how they work, but will also create opportunities for innovation and collaboration.

Annex A – Performance targets

No.	Activities	2014-15 Targets
PM1	**Medicines licensing – validation of applications**	a) For Type IB/II variations, 97% of scientific validation process completed within 14 days of case creation
		b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation.
		c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt.
PM2	**Medicines licensing – assessment of applications**	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: 97% assessed within the designated time
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.
PM3	**Assessment of clinical trials and investigations**	a) The assessment of applications for clinical trials of medicines in the UK: 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials)
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less
PM4	**Capturing and analysing adverse event reports – making reports available, issuing alerts and acting on signals**	a) Maximum timescales between receipt of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% within 3 working days
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days
PM5	**Publication of UK assessment reports for new Marketing Authorisations**	Publish 98% of UK assessment reports for new Marketing Authorisations within 60 net calendar days of grant of new Authorisations
PM6	**Standards and control**	a) Biologics standards supply - 93% of all materials supplied within 6 working days
		b) Batch release activity – 99% of all requested OCABR and non-EU testing completed within agreed timelines: • 8 days for Plasma Pools

No.	Activities	2014-15 Targets
		• 10 days for Parenterals • 15 days for Haemostasis • 60 days for vaccines
PM7	**CPRD activity**	a) To enable 280 research studies in 2014/15.
		b) To double (8% to 16%) the population cover of primary care data within the CPRD system by the end of the financial year.
PM8	**Answering Freedom of Information requests, letters and Parliamentary Questions**	a) In working towards achieving 100% compliance, ensure that at least 92% of requests under the Freedom of Information Act are replied to within 20 working days.
		b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 80% of cases with less than 5% returned to MHRA by the Department for rewriting.
PM9	**Finance – income and expenditure position**	Achieve an income and expenditure surplus during 2014-15, and as a minimum, exceed a 3.5% per annum return on capital employed.

Annex B – Performance metrics

We will track the following metrics over the year as part of monitoring the performance of our business.

Work volumes

- Per cent of rapporteurships allocated to the UK

- Number of scientific advice rapporteurships

- Number of applications received:
  - UKRMS
  - UKCMS
  - National, Variations (IA, IB, II)
  - clinical trials of medicines
  - clinical investigation notifications for medical devices

- British Pharmacopoeia Chemical Reference Substances sales

- NIBSC
  - number papers and scientific papers authored
  - £ of externally awarded research grant/contract funding utilised/won during the year
  - number of standards established and shipped

- CPRD:
  - Number of contacts with and type of potential CPRD customers
  - Rate of delivery of datasets post approval of the research study by ISAC

Public health

- Number of alerts and safety reports issued:
  - Medical Device Alerts issued and the timescales.
  - (a) fatal and (b) serious UK adverse drug reaction reports issued.
  - Yellow card reports made by (a) healthcare professionals (b) the public

Capacity, efficiency and capability

- Numbers of inspections / UK & overseas for (a) GMP (b) GDP (c) GPvP (d) GCP and (e) GLP

- Critical inspection findings referred for regulatory action for (a) GMP (b) GDP (c) GPvP (d) GCP and (e) GLP

- Number of new investigations opened

- Year to date number of prosecution cases(including number of defendants)

- Conviction rate

- Number of administrative complaints

- Number of FOI requests and internal reviews

- Number of ICO investigations

- Number of customer service enquiries by phone and email and overall satisfaction with customer services

- Average time taken to process invoices

- HR metrics:
  - Staff in post
  - Staff turnover
  - Average number of days sick per member of staff
  - Average number and spread of learning and development days per member of staff
  - Time to fill critical vacancies
  - Number of posts reduced against annual target for the budgetary savings

Annex C – Collated strategic activities for 2014-15

No	Activity	Outputs
1 – Vision and scope of our work		
1A	NIBSC integration project	Progress the NIBSC integration project and ensure cross-agency access to key relevant information as identified in NIBSC merger project by quarter two.
1B	IVD Reference Laboratory	Review and make decision on business case for establishing IVD reference lab at NIBSC as envisaged in the recast IVD directive (carried forward from 2013/14) by quarter three.
1C	Data transparency	Carry out a survey and report to CET by quarter one on the types of data held by the agency and current practice on retention and release.
1D	NIBSC Scientific Advisory Committee	Re-establish NIBSC Scientific Advisory Committee by quarter two.
1E	NIBSC Quinquennial Review	Hold first NIBSC Divisional Quinquennial Review by quarter four.
1F	CPRD's plan and business case	Delivery of the activities and expenditure in year three of CPRD's published plan and business case.
1G	CPRD-NIHR relationship	Strengthen the CPRD-NIHR relationship to more fully integrate the Clinical Trial offering both at a service and IT software level, recruiting a project manager in quarter one.
1H	CPRD working with Farr Institute	Work with the Farr Institute (4 centres) throughout 2014-15 to increase the volume of both observational and interventional research, particularly using linked datasets, used by them and their partner universities.
1I	CPRD input in joint scientific advisory meetings	Throughout 2014-15 CPRD, in conjunction with MHRA and NICE, will offer additional input to joint scientific advisory meetings as to how data, as available from CPRD, can enable studies of a more real world nature for both HTA and regulatory safety/effectiveness purposes.
1J	Clinical advice for devices	Review and implement appropriate elements of the Stephenson Review into access for clinical advice for devices – responding to the report, including establishing an architecture and core processes by and appointing a new advisory body, by quarter four.
1K	Strategic relationships with others	Establish cross-agency groups and project plans to identify and define key strategic relationships we want to develop with: a. other organisations in the health and care system by quarter two b. healthcare professionals (including responding to the Stephenson Review) by quarter two c. patients and the public by quarter two d. the UK and global academic life science base by quarter two.

2 – Bringing innovation and new products speedily and safely to patients		
2A	Effective implementation of the EU Clinical Trials Regulation	Consulting on new domestic legislation for clinical trials by quarter one; and continuing efforts for increased collaboration between MHRA and the Health Research Authority, ensuring that the IT systems for this collaboration are in place when the Regulation comes into force mid-2016.
2B	Reclassification	Establish a national platform on reclassification as a pilot and identify metrics to measure the outputs from this initiative by quarter one.
2C	NIBSC Advanced Therapies Divisions	Develop a clear strategy and work plans for the new NIBSC division for Advanced Therapies by quarter one.
2D	Formally launching CPRD's clinical trial offering	Formally launching CPRD's clinical trial offering in quarter two, and throughout the year moving more of its products that are currently in development from beta testing to full deployment.
2E	Extending CPRD's existing data services	As the population cover of primary care data increases, extend CPRD's existing data services (Risk Management Tracking of new medications), launch new services (Pregnancy and Children Trackers), and develop a service related to Promising Innovative Medicines and how exposure and outcomes data on early use will be made available from CPRD.
2F	Adding coded device exposure data to standard HES reporting data	Throughout 2014-15, CPRD will continue working with our Devices division and the Health and Social Care information Centre to get coded device exposure data added to the standard HES reporting data. This will enable greater analysis of devices safety and effectiveness to be undertaken.
3 – Strengthening surveillance		
3A	SCOPE Joint Action	Ensure the SCOPE project is operating within budget and timelines, delivering a promotional SCOPE leaflet and launching a project website by quarter one.
3B	WEB RADR	Lead the WEB RADR project: a. Successfully completing contract negotiations by quarter two b. Developing a prototype app for ADR reporting for use by UK patients and healthcare professionals by the end of quarter four.
3C	Medicines and devices reporting	Complete the review of simplification of medicines and devices reporting by quarter one and implement as necessary developments to the Yellow Card website by quarter three.
3D	CPRD and pharmacovigilance reporting	Establish a cross-agency group and develop a project plan by quarter one to explore synergies between CPRD and pharmacovigilance reporting.
3E	EU devices vigilance portal	Continue to champion the accelerated development of an EU devices vigilance portal ahead of implementation of revised regulations: a. By quarter two, forming a task force with representatives from competent authorities, industry and notified

		bodies; and researching all funding options, including EU Joint Action funding. b. By quarter four, reaching a common position within the task force on the IT architecture and design of the vigilance portal.
4 – Safe products and secure supply in globalised industries		
4A	MoU with India	Agree a Memorandum of Understanding (MoU) with India by quarter three and agreements with individual states by quarter four.
4B	MoU with China	Agree a renewal of the MoU with China by quarter two.
4C	Enforcement Strategy	Publicise and make available to stakeholders the revised Enforcement strategy by quarter two.
4D	Falsified Medicines Directive	Implement the Falsified Medicines Directive (including concluding the safety features part in the most balanced way possible) by quarter four.
4E	Pharmaceutical Inspection Co-operation Scheme	Through the year, continuing to support the increasing role of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), including preparing to take the role as Chair in 2016/7 and to undertake the PIC/s annual seminar and training event in 2016.
4F	ICMRA	Contribute to the work of the International Coalition of Medicines Regulatory Agencies (ICMRA), including leading a project on inspections and developing a working framework in Good Manufacturing Practice – aiming to maximise benefits from joint inspection programmes and acceptance of other regulators' outcomes. This will be undertaken throughout 2014-15 with benefits being realised in 2015-16.
4G	International standardisation	Complete six key international standardisation projects (Hib PRP; Hepatitis B S antigen; Lupus anticoagulant; Hepatitis C (detection); anti-malaria antibody; Factor Xia) by quarter three.
4H	NIBSC services and references materials	Raise profile of scientific expertise and reach of services/reference materials through improved visibility and marketing, launching an improved website by quarter three.
4I	NIBSC diagnostic standards	Develop revised strategy for the prioritization, establishment, Quality Assurance compliance and supply of NIBSC diagnostic standards by quarter four.
5 – Achieving excellence – a well-run, efficient and effective organisation		
5A	Financial strategy and budget	Deliver the agency Budget for 2014-15, reducing costs through various measures such as from restructuring and infrastructure resourcing, and achieving the first year of the Corporate Plan's financial strategy.
5B	Marketing and business development plan	Agree an agency marketing and business development plan by quarter two.
5C	Regulatory Excellence programme	Progress our Regulatory Excellence Programme to ensure that the regulatory policy and negotiation work of the agency is delivered.

5D	Move to shared services	Agree a project plan by quarter two to deliver the IT systems changes required for moving to human resources and finance shared services by April 2015.
5E	Move to new IT supplier	Establish plans by quarter two to manage the transition for, and the risks of, moving to a new IT supplier in December 2014.
5F	Restructuring and redeployment	Develop a revised restructuring and redeployment approach by quarter one.
5G	Key skills	Assist staff to understand the opportunities for development and progression within and outside of the agency, identifying the key skills required by quarter three.
5H	Career paths	Develop career paths to map onto the Civil Service grading system by quarter four scientific, technical and professional skills to support standardisation and control work.
5I	Management and leadership capability	Develop a programme to increase management and leadership capability across the organisation by quarter two, linking to areas highlighted in the Civil Service people survey.
5J	Strategic recruitment approach	Implement an approved strategic recruitment approach to attract, select, recruit and retain staff within Civil Service constraints for specialist areas and senior roles – ongoing, but to deliver benefits by quarter three.
5K	Employer brand campaign	Develop an employer brand campaign to support the recruitment and retention approach, agreed by quarter three.
5L	HR data, systems and processes	Undertake a major review of all HR data, systems, processes and activity within the agency and of that held by payroll and MyCSP pension administrator by quarter one, implementing all recommendations by quarter four.
5M	HR shared services	Develop a new HR delivery model and programme of work to support shared services from April 2015.

Medicines and Healthcare Products Regulatory Agency

MHRA Business Plan 2014-2015

April 2014

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