Medicines & Healthcare products
Regulatory Agency

Medicines and Healthcare products Regulatory Agency

Business Plan 2015-16

April 2015

CPRD NIBSC MHRA

This information is also available on the https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency website

Produced by Medicines and Healthcare products Regulatory Agency

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Chapter 1 – Introduction

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

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 and further development of CPRD and NIBSC. It highlights the key areas where we need to focus our efforts and, in keeping with our core aim to protect and improve the health of patients, none of these ambitions will compromise patient safety.

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.

As with previous annual Business Plans over this Corporate Plan period, this plan has been prepared in the context of significant challenges and opportunities:

- Both medicines and devices are global industries, with new producer countries and markets emerging all the time. Overall, there are fewer medicines being licensed, while there has been a dramatic increase in the development of new medical technologies and products including advanced therapies 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.
- The significant changes to the UK health and care system continue to bed down, with partnership and joined-up working across the system remaining critical to its success.
- Although the UK economy continues to show signs of recovery, money remains tight and the agency's financial position is getting more challenging. There will be continuing budgetary pressure across Whitehall and an expectation on us to support growth, the life sciences and innovation.
- 2015 will be an election year and – like all government departments and their agencies – we will need to ensure it delivers effectively the agendas of a new administration.

This Business Plan will support ongoing 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 regulatory centre.

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 most influential in the world. We will

[1] The 2013-18 Corporate Plan is available at www.gov.uk/government/publications/mhra-corporate-plan-2013-to-2018

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 Department of Health (DH) 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.

Some of our achievements over 2014-15

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 the following areas:

- Supporting safe innovation and UK growth
    - continued to support development of EU-level Adaptive Pathways scheme of work
    - launched the Early Access to Medicines Scheme (EAMS), which informs prescribers of promising unlicensed or off-label medicines that address unmet need
    - as part of above, introduced the Promising Innovative Medicine (PIM) designation
    - actively contributing to DH work on dementia and delivery of the UK's Five year Anti-Microbial Resistance (AMR) Strategy , as well as preparing for involvement in the Accelerated Access Review
    - strengthened our capability to support the development of advanced therapies and other innovative biopharmaceuticals
- Extending the scope and coverage of CPRD
- Contributing to the development of an improved, proactive approach to medicines and devices vigilance that uses innovative methodologies and technologies
    - completing and implementing pharmacovigilance proposals
    - development of Pharmacovigilance Risk Assessment Committee (PRAC) in the European Medicines Agency (EMA)
    - developed our formal response to Stephenson Review and appointed a new chair of the Devices Expert Advisory Committee (DEAC)
- Responding to recent report on NIBSC's scientific work following the External Scientific Review carried out by Sir Patrick Sissons and his expert colleagues
- 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.
    - Global supply chains – ICMRA, continued breakthroughs with China
- Taking forward work to define and develop our networks and relationships with healthcare professionals, patients and the public, and others in the health and care system (inc. NICE, the National Institute for Health and Care Excellence)

- Taking steps to ensure our financial sustainability, delivering the first year of a three year strategy to reduce headcount and become more efficient and cost-effective across our functions. We have supported our staff through these changes, helpful them to develop their careers and skills.

In addition, we had two significant milestones in 2014 with the British Pharmacopoeia celebrating 150 years of setting quality standards for medicines and medicinal products and the Yellow Card Scheme, our adverse reaction reporting system, celebrating its 50th anniversary. The Yellow Card Scheme now supports the reporting of all suspected problems or incidents to all healthcare products, not just suspected side effects to medicines.

Our focus for 2015-16

Over the next year our overall focus will include the following:

- Supporting the cross-Whitehall innovation and growth agenda – including playing a key part in the **Accelerated Access Review**[2] and continuing to progress and improve our **innovation** initiatives, including our **Early Access to Medicines Scheme.**
- Implementing a revised **medical devices funding** model that enables us to deliver our regulatory responsibilities at a financially sustainable level in the longer term.
- **Driving forward work on key EU negotiations and implementation** relating to clinical trials, falsified medicines and medical devices.
- **Continuing to grow CPRD** and increase uptake of its services, realising its significant public health and economic benefits as a unique data management tool.
- Building closer and strong **collaboration with the Department of Health and partners in the health and care system**, ensuring that we are working towards common goals around public health and innovation and growth.
- Progressing the agency's **efficiency programme**, including implementing the next year of our planned three year reduction in headcount across the agency.
- Being at the leading edge of **digital devices and technology** – including working with partners in the health and care system to promote the safe use of medical apps, exploring enhancements to our Yellow Card reporting mobile App, and using digital technologies across the agency to deliver cost-effective and smart services across the agency that put the user first
- Developing further our **excellence in science** – including implementing and evaluating the recommendations of the Stephenson review to improve our access to clinical advice and engagement with the clinical community, and developing the capabilities of NIBSC to ensure it remains a global leader in standardisation and control of biological medicines.
- Leading the further development of incident and **safety reporting** systems – including embedding Yellow Care reporting into National Health Service (NHS) and care

[2] Launched in November 2014, the Accelerated Access Review (formerly known as the Innovative Medicines and Medical Technology Review) will consider how to speed up access for NHS patients to cost-effective new diagnostics, medicines and devices. It will set out both short and long-term options for action by government departments and other relevant bodies (including the MHRA).

system to contribute to safe care and reducing avoidable harm, and maximising synergies between with CPRD our regulatory centre to strengthen vigilance work.

- Over the year we will monitor our performance against a number of performance targets and metrics (annexed to this plan). These mainly focus on aspects of our work that are most critical to the industries we regulate, and are designed to ensure we continue to meet our aspiration as a **world-class regulator that leads the way in best practice.**

Detail on how we will deliver these priorities is provided in chapter 3 below. This is over and above our ongoing core business, which is broadly set out in chapter 4.

Our strategic priorities for 2015/16 feed into all of the Department of Health's Goals and Priorities, in particular:

- **preventing people from dying prematurely** by improving mortality rates for the big killer diseases, to be the best in Europe through improving prevention, diagnosis and treatment and reducing health inequalities;
- **making a step change in the way technology and information is used** to enable more efficient and joined up working across the NHS and wider health and care system, improving quality of care and help people manage their own healthcare;
- improving **productivity** and long term **sustainability** and ensuring **value for money** for the taxpayer; and
- contributing to **economic growth**.

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 2015-16 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

Overview

The Medicines and Healthcare products Regulatory Agency operates as a Government Trading Fund. Agency operational funding is structured as follows:

- **Medicines regulation** is funded entirely from fees. In setting its fees the agency takes account of full cost recovery rules as set out in HM Treasury's Managing Public Money.

- **Devices regulation** is primarily funded through a service level agreement with the Department of Health.

- **NIBSC** derives approximately 60% of its revenue from fees charged for 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 the agency's centres – MHRA, NIBSC and CPRD - operates with segmented accounts which highlight their respective trading positions, bearing their appropriate share of corporate services costs. The key principle is that the three centres do not cross-subsidise each other.

As set out in the 2013-18 Corporate Plan the agency is 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 the 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. The agency will 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 services. This will entail adjustments to the regulatory function, including continuing the process to reduce the number of posts by 125 over three years, tightening non-pay budgets and seeking other efficiencies (for example in our accommodation costs, which will be circa £3m lower in 2015/16 following the contraction of the agency's headquarters from three floors to two when added to previously implemented property rationalisation).

Funding for devices regulation is at half the level of that in 2003 in real terms; 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. Following review of the basis of the funding of devices activities the agency intends implementing a revised devices funding model.

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

Breakdown of financial plans

The agency works to a five-year financial objective period which began on 1 April 2013. The financial objective is set out in the HM Treasury minute dated 24 February 2014 and is to achieve, averaged over the five year period as a whole, a return of at least 3.5% in the form of a surplus on ordinary activities before interest payable and dividends expressed as a percentage of average capital employed.

For 2015/16 this will require the following funding to be made available by the Department of Health:

- Devices regulation - £8.1m plus £1m for investment in further efficiencies (as provisionally discussed between DH/MHRA Finance)

- CPRD - A continued commitment to the investments required as set out in the CPRD business case

- NIBSC: as discussed between DH/MHRA Finance the provisional requirements are as follows:

£m	
12.5	Revenue funding – the same cash as 2014/15
4.0	The estimated dividend that NIBSC will have to generate as part of the trading fund.
5.5	The estimated value of the cost of holding NIBSC's assets.
6.0	NIBSC capital programme for 2015/16
28.0	£m TOTAL

Procurement

The agency's procurement policy is to use Crown Commercial Service framework agreements where it is possible and appropriate. This is backed up by the use of other available framework agreements and in house tenders. Gateways to access to these are controlled by a suite of business case Standard Operating Procedures to comply with the Efficiency and Reform Group / Cabinet Office controls procedures.

Our procurement team has a Small Medium Sized Enterprise Action Plan in place to encourage smaller businesses to tender for contracts with government departments and their agencies. To assist with this initiative, our procurement team maintains a contract register and a procurement pipeline to assist planning and informing the market of potential upcoming projects.

The procurement pipeline is published on the "Contracts Finder" portal found at: https://online.contractsfinder.businesslink.gov.uk

Chapter 3 – Key strategic activities for 2015-16

This chapter sets out the strategic priorities for 2015-16 – summarised further below – that will progress delivery of our 2013-18 Corporate Plan.

It is divided into sections based on the structure of the Corporate Plan.

Within each, we set out the key activities for Year 3, which form part of a wider portfolio of work the agency intends to deliver over the five year period.

1. Vision and scope of our role

- Make an effective contribution into major forward-thinking strategic exercises for the EU and international networks for medicines and devices, including the European Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) Strategy for 2015-20 and ongoing work on sustainability of EU network
- Continue to strengthen collaboration with partners across the health and social care network, including joined-up preparedness for public health emergencies
- Build scientific strength in biologics to meet future needs and support new medicines development

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

- Ensure the agency makes a full contribution to the cross-Whitehall growth and innovation agenda – both through maximising existing initiatives and identifying further initiatives where possible.
- Ensure effective and efficient implementation of EU legislation (inc. for Clinical Trials and Devices) in line with agency and wider DH objectives
- Continue to grow and increase uptake of CPRD services, in particular its clinical trial offering
- Continue to ensure safe access to a range of products for self-medication (inc. E-Cigarettes)

3. Strengthening surveillance

- Implement and evaluate the recommendations of the Stephenson review, including ensuring sufficient and appropriate level of clinical input to management of devices and establishing the Devices Expert Advisory committee (DEAC)
- Strengthen vigilance work, working with partners and developing new models – inc. linking with CPRD and NIBSC (increasing breadth of product testing experience)
- Lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system, working with UK healthcare bodies to ensure safety measures for medicines and devices contribute to safe care and reducing avoidable harm

4. Safe products and secure supply in globalised industries

- Continue to collaborate with international agencies to improve and harmonise global regulatory standards – including working with Indian regulators and stakeholders to ensure a secure supply of medicines, progressing the International Coalition of Medicines Regulatory Authorities (ICMRA) Good Manufacturing Practice (GMP) project and EU/US Food and Drug Administration (FDA) Mutual Reliance Initiative; developing International Standards/Reference materials; and selectively engage with the International Medical Devices Regulators Forum (IMDRF) in collaboration with European partners
- Continue to promote the safe purchase of medicines/ devices through the provision of accurate information, including developing a strategic threat assessment to the medical products supply chain

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

- Operate at a financially sustainable level, meeting our financial targets, including implementing a revised devices funding model
- Continue our Regulatory Excellence Programme to ensure our regulatory work is managed and proportionate, and that we are able to respond robustly to any further de-regulatory drive
- Develop agency wide Information Technology (IT) strategy that fully aligns with Cabinet Office and EU IT direction and allows the agency to maximise its organisational efficiency and support business needs.
- Continue to strengthen our internal leadership and management capability, alongside recruiting and developing people with the right skills to deliver our objectives
- Further develop the reputation of the agency with external stakeholders

1. Vision and scope of our work

This section sets out the overarching strategy which will guide our work over 2015-16 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 as a high performing organisation that makes a significant contribution to UK public health.

As well as maintaining 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 seek to support safe innovation in all the work we do.

We will continue to maximise synergies across the three centres within our organisation to ensure we remain abreast and part of scientific development. We also plan to build on the relationships we've developed with other organisations in the new health and care system and wider EU and international networks to enable better partnership working.

Our strategic priorities for 2015-16:

- **Make an effective contribution into major forward-thinking strategic exercises for the EU and international networks for medicines and devices, including the European Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) Strategy for 2015-20 and ongoing work on sustainability of EU network**
- **Continue to strengthen collaboration with partners across the health and social care network, including joined-up preparedness for public health emergencies**
- **Build scientific strength in biologics to meet future needs and support new medicines development**

It is important to highlight that, in addition to these three priority areas, we see increasing support to innovation to be a fundamental aspect of all the work we do across the agency. Our key priorities and activities for 2015-16 are set out in Theme 2 'Bringing innovation and new products speedily and safely to patients' which follows further below.

Make an effective contribution to next year's key strategic exercises for EU and international networks

As part of the increasingly global environment and networked EU system in which we operate, it is imperative that we make an effective contribution into major forward-thinking strategic exercises for the EU and international networks for both medicines and devices.

In particular, we will wish to ensure MHRA is a leading contributor to the development of an HMA/EMA Strategy for the period 2015 – 2020 and associated workplans, taking into account the network's sustainability in the future. We will also actively contribute to the HMA/EMA data gathering exercise, as an input into the revision of EMA fees – ensuring appropriate remuneration for the work of national competent authorities.

By continuing to chair the Competent Authorities Medical Devices (CAMD) Executive, we seek to enhance collaboration between European member states and the European Commission in developing and managing the EU medical devices regulatory system. Likewise, through continuing to play a lead role in the IMDRF alongside other international medical device regulators, we seek to build on the Global Harmonization Task Force on Medical Devices (GHTF) to accelerate international medical device regulatory harmonization and convergence.

More generally, we willingly support the work of key EU committees and working groups, for instance through taking a leading role in the development of a co-ordinated assessment of Active Substance Master Files (ASMFs) – used for multiple marketing authorisation applications (MAAs) and/or marketing authorisation variations in one or more Member States – so as to reduce duplication of work, inefficient use of assessor resources, and inconsistent decisions being made on the same data.

Specific activities in 2015-16 will include the following:

1A. Licensing / VRMM / IE&S to ensure that MHRA is a leading contributor to procedural work in the EU regulatory network, including:

- ensuring that we remain within the upper quartile in our contributions to Rapp/co-rapp appointments for the various EU committees, scientific advice appointments and the preferred RMS for DCP work in cases where the UK is involved.
- significant involvement at EU level at the Good Manufacturing, Pharmacovigilance and Good Clinical Practice Working Groups

1B Devices to continue to chair CAMD Executive to maximise collaboration between Member States to improve market surveillance and vigilance as a key mechanism in enhancing product safety.

1C Devices to review and revise roles and responsibilities of all European working groups to ensure clarity of purpose and duplication of activities by end quarter two.

1D Devices to continue to lead for Europe on medical device single audit program (MDSAP) under the IMDRF programme and clarify European position on implementation of elements of MDSAP in the EU by end quarter three.

1E Licensing to take a leading role in the development of co-ordinated clinical trial assessment in Europe for multiple member state CTs. Develop a UK assessment template in preparation for implementation of the Regulation and promote for adoption by European colleagues and to liaise with the HRA on how to coordinate the ethics aspect of Part 1 assessment by end quarter one.

Strengthen collaboration with partners, including joined-up preparedness for public health emergencies

Building on the work we commenced this past financial year, we will continue to pursue further collaboration and partnership with other organisations in the health and care system, healthcare professionals, patients and the public as well as the UK and global academic life science base.

During 2014-15, the agency played a key role supporting the UK's response to the recent outbreak of the Ebola virus in West Africa through working with wider government departments and industry to expedite a series of safety trials of potential vaccines to combat the virus.

Ebola is one example of a public health emergency where – due to the high level of public protection – issues need to be addressed quickly, working across the health and social care network. As well as working together to agree and prioritise what needs to be done, when, and by whom, it is also essential that we effectively communicate this information to healthcare professionals, patients, and the wider public audience.

The agency will be looking to build on the lessons learned from its involvement in cross-Whitehall work on Ebola in planning for any future incidents of this nature. Likewise, we will ensure the MHRA continues to be a leading contributor to the international and national pandemic preparation, through development of candidate vaccine strains and associated reference materials in association with WHO, and through regulatory support activities in conjunction with the EMA, the Department of Health and Public Health England's immunisation policy and pandemic programme board.

Specific activities in 2015-16 will include the following:

1F Policy to implement strengthened arrangements for responding to health incidents through structured engagement with key partners in the Health & Social Care Network – with collaboration mechanisms with priority partners in place by end quarter three.

1G Policy and wider agency to actively contribute to cross-Whitehall work on ebola about future clinical trials of vaccines and other activities, which includes:

- deploying first production runs of trials from the start of 2015;
- preparing for wider and subsequent waves of trials, including other vaccines as they develop and prepare for all options up to mass vaccination, if necessary / practically possible and scientifically justified; and
- developing thinking on the use of convalescent plasma and a range of treatments

1H NIBSC to develop and supply reference for standardising ebola serological analysis and virus detection to enable internationally harmonised assays by end quarter four.

Building scientific strength in biologics

Through maintaining NIBSC's capability and position as a global leader in biologics, we seek to build scientific strength in in this area to meet future needs and support new medicines development. This includes ensuring we maintain our ability to respond swiftly and effectively to biologics-related public health challenges.

Following the external review of NIBSC's scientific direction, carried out by an independent panel chaired by Professor Sir Patrick Sissons between October 2013 and February 2014, we have been progressing our detailed response to the 19 recommendations made, including the formation of a new Scientific Advisory Committee.

In addition, our cross-agency Horizon Scanning Working Group continues to help us prepare for future scientific needs through systematically identifying and evaluating novel products, alongside assessing trends in technology and applications. This includes developing a plan for further development of our Horizon Scanning capability.

Specific activities in 2015-16 will include the following:

1I NIBSC to introduce new NIBSC/Academia biologics fellowship scheme by end quarter two.

1J NIBSC to establish regular strategic links with two major research funding organisations by end quarter three.

1K NIBSC to complete a further two MOUs with academic centres by end quarter four.

1L Agency to prepare for future scientific needs by completion of 2015 Horizon Scanning exercise by end quarter three.

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

We continue to support and champion safe innovation and make a large contribution to the cross-Whitehall growth and innovation agenda, which includes supporting delivery of the 2011 Strategy for UK Life Sciences.

We maintain a breadth of experience and capability in this area, including our international hub of expertise in advanced therapies, biotechnology and drug/device combinations, as well as the CPRD which enables a unique breadth of observational research and associated outputs that serve to improve and safeguard public health.

We work 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.

Our strategic priorities for 2015-16:

- **Ensure the agency makes a full contribution to the cross-Whitehall growth and innovation agenda – both through maximising existing initiatives and identifying further initiatives where possible.**
- **Ensure effective and efficient implementation of EU legislation (inc. for Clinical Trials and Devices) in line with agency and wider DH objectives**
- **Continue to grow and increase uptake of CPRD services, in particular its clinical trial offering**
- **Continue to ensure safe access to a range of products for self-medication (inc. E-Cigarettes)**

Making a full contribution to the cross-Whitehall growth and innovation agenda

Ensuring the agency makes a full contribution to the cross-Whitehall growth and innovation agenda – through taking on a leadership role in maximising existing initiatives and identifying further initiatives where possible – is at the core of what we do.

Engaging in the Accelerated Access Review is an absolute priority for this year as it will help set the direction for any new administration that comes into power after the General Election in May 2015. Consequently, it will be important for the agency to play a key role in that and actively engage in a number of relevant agendas - working with NICE, NHSE, and other key partners.

Further developing the EAMS, including implementing the Promising Innovative Medicine (PIM) designation as a first step – when data from early stages in a clinical development indicates that the medicinal product is likely to demonstrate significant benefit for patients in life-threatening or seriously debilitating conditions – is a priority for us.

Continuing to promote Adaptive Pathways (formerly Adaptive Licensing) – through ongoing discussions with the European Medicines Agency (EMA) on the adaptive pathways approach and other national and international stakeholders to improve timely access for patients to new medicines – is also key, as is early engagement with organisations involved in Advanced Manufacturing.

Last year saw the creation of the industry-chaired Medicines Manufacturing Industry Partnership (MMIP) under the Ministerial Industry Strategy Group (MISG). This builds on

the work on advanced manufacture in the Prime Minister's Life Sciences strategy. The agency is committed to supporting the regulatory work stream of this, through publishing case studies on interaction with MHRA and wider strategic engagement.

The MHRA Innovation Office will continue to help organisations that are developing innovative medicines, medical devices or using novel manufacturing processes navigate the regulatory processes so they can develop their products or technologies. Over 130 enquires have been received so far

MHRA has helped companies move forward with innovative health plans by providing regulatory advice early on in the process. We will continue to publish case studies on the gov.uk website to illustrate the work we are doing in this area. Through having further developed our Innovation Office as a "one stop shop", we will be able to direct less experienced innovators to the most appropriate expertise as efficiently as possible.

We will engage with key academics and take an active involvement in initiatives to further the development of stratified and personalised medicine through the provision of scientific advice and a centralised application process. We will also support and promote key meetings contributing to pharmacogenomics and companion diagnostic development through the Pharmacogenomics Working Party discussions as well as UK-PSM network and Innovate UK (TSB) initiatives. We are actively engaged in discussions on harmonisation of practices across the globe to enhance stratified medicine through development of international guidelines.

The agency wants to ensure it is at the heart of the emerging national and global debate on the use of genomics for disease diagnosis to ensure that best practice is developed in line with regulatory, scientific and commercial expectations. The agency has set up an internal genomics forum to take this work forward and engage with other partners.

As well as seeking to embed our staff in key EU committees, we will take part in international initiatives like MIT's NEW Drug Development ParadIGmS (NEWDIGS) program, which is focused on enhancing the capacity of the global biomedical innovation system to reliably and sustainably deliver new, better, affordable therapeutics to the right patients faster, the first project of which is focused on the evolution of global pharmaceutical regulation.

We will also continue to contribute to other DH priorities, for example through ensuring MHRA contributes to regulatory discussions on dementia and antimicrobial resistance (AMR) through attendance at DH steering groups and identifies any activities where we can contribute to these areas. We will support DH proposals for digital health and care priorities, particularly with respect to workstream 5 of the National Information Board, which is focused on initiatives to support innovation and growth in healthcare. In addition, through the various initiatives set out in this section, we will support drug development and research into rare diseases in line with 'The UK Strategy for Rare Diseases' published by DH in November 2013.

In line with the 'Working to reduce the use of animals in scientific research' delivery plan, which was published in February 2014, we are committed to a reduction in animal testing. NIBSC is an international leader in developing alternatives to Replace, Reduce and Refine animal testing (the 3Rs) and over the past ten years, the European Pharmacopeia (Eur Ph) has adopted nine new tests developed by NIBSC that have reduced the numbers of animals used in medicines testing labs by tens of thousands. In addition, MHRA Toxicologists are continuing to have dialogue with counterparts from China's FDA to discuss a number of initiatives that have the ultimate aim to reduce animal testing, and both centres (MHRA and NIBSC) are working closely with NC3Rs.

Specific activities in 2015-16 will include the following:

2A Policy / agency to contribute to the Innovative Medicines and Medical Technologies Review led by the Office for Life Sciences helping to maximise existing initiatives and to identify further initiatives where possible.

2B NIBSC to develop and deliver in collaboration with UK Bio Industry Association (BIA) a strategy to improve links with small and medium-sized enterprises (SMEs) for provision of technical advice on innovative biologics development by end quarter four.

2C NIBSC to develop strategy for provision of reference materials to support development of Precision Medicines by end quarter two.

2D Licensing to contribute to an interim report on the Innovation Office by end quarter one.

2E Licensing to contribute to evaluation of the scheme one year on by end quarter three.

2F Licensing / Devices / NIBSC / IE&S to encourage harmonisation of classification decisions and regulation of innovative combination medicine/medical device products by continued participation in EU Innovation Office network and preparation of reflection paper on borderline/combination products (for EU Innovation Office network meeting in quarter one.

2G Licensing/ VRMM to review and amend processes, including effectiveness of risk management plans, based on experience from early applications and as EAMS relationship with NICE and NHSE evolves by end quarter four.

2H Licensing to further develop and promote joint MHRA/ NICE scientific advice as well as other MHRA support mechanisms and licensing flexibilities by end quarter four.

2I Devices to continue to promote the safe use of medical apps working with NHSE digital, HSCIC, NICE and other medical/professional colleges/bodies with Quarterly report on progress from quarter two.

2J Devices to issue updated guidance for medical apps developers, healthcare clinicians and others to educate on what is required to maximise safety and regulatory compliance by end quarter two.

2K Devices to review and evaluate resource operational and strategic requirements for this fast developing area by end quarter four.

Ensuring effective and efficient implementation of EU legislation

As the European regulatory model continues to evolve, we will carry on progressing UK objectives in the negotiation and implementation of EU legislation in line with agency and wider DH objectives.

In particular, we will seek to conclude negotiations on devices legislation where our concern is to strengthen the innovation friendly approaches within EU regulation. We are

also preparing for possible legislation relating to a new initiative on clinical evaluation in devices.

Having concluded a significant block of pharmaceutical based regulation, we want to implement the Falsified Medicines Directive and Clinical Trials Regulation in a timely and proportionate manner.

We will also continue efforts for increased collaboration between MHRA and the Health Research Authority through developing national legislation supporting the implementation of the CTR that addresses the needs of both MHRA and HRA and the development of a UK specific IT system allowing MHRA and HRA to work together on the assessment of CTAs under the CTR.

Specific activities in 2015-16 will include the following:

2L Policy / Devices to continue to press for closure of the negotiation of the revision of the devices legislation ensuring final provisions are proportionate, unambiguous and implementable by end quarter four.

2M Policy / Devices to continue preparations for implementation of the revised legislation, anticipating key changes where possible (for instance on joint audits of notified bodies and transparency) and working with stakeholders to deliver a smooth and effective transition.

2N IE&S / Policy / NIBSC / Licensing to ensure the proposed revision to the Advanced Therapies Medicinal Products (ATMP) regulation results in a more enabling proportionate legislation in line with Regenerative Medicines Expert Group (RMEG) report by end quarter four.

Continuing to grow and increase uptake of CPRD services

During 2015/16, CPRD will continue to grow and increase uptake of CPRD services, in particular its interventional research activities.

Our aim is to fully develop and market our CPRD service, realising both its public health and economic benefits as a unique data management tool. More generally, the agency seeks to improve the UK's data offering working with other stakeholders including the MISG.

Growing the CPRD customer base for academics and in the commercial sector both here in the UK, Europe and internationally is an ongoing aim.

Specific activities ongoing or completed by Q4 2015-16 will include the following:

2O CPRD to build effective working relationships with key partners to effectively complement our capabilities. Collaborative working exercises undertaken and/or MoUs signed with key partners, including Health and Social Care Information Centre (HSCIC), Farr, National Health Service England (NHSE), Genomics England, National Institute of Health and Research (NIHR), Clinical Research Network (CRN), and Academic Health Scientific Networks (AHSN).

2P Promote CPRD among stakeholders and industry to widen the range of use of CPRD, which may be measured through numbers of unique clients, numbers of observational studies undertaken, numbers of clinical trials in which CPRD services are provided.

2Q Roll out CPRD data tools to aid patient recruitment and data capture for the delivery of clinical trials and interventional studies.

2R CPRD to continue to work towards access to a wider range of additional linked datasets based on criteria such as customer demand, public health benefit and previous negotiations with data custodians with a target of adding a further two datasets linked to primary care data by the end of 2015/16.

Continuing to ensure safe access to a range of products for self-medication

Leading and enabling access to a wide range of medicines in the self-care arena – supported by sound regulatory decisions that are informed by a broad range of stakeholder engagement – is an important area of work for us.

As part of our efforts to ensure the public may safely access products, like e-cigarettes, these must be promoted responsibly and accompanied by accessible and empowering patient information.

Specific activities in 2015-16 will include the following:

2S VRMM to hold three meetings of the UK Platform for reclassification of non-prescription medicines in order to ensure sound regulatory decisions are made with maximum stakeholder engagement and to reach a common approach by stakeholders to supporting patient and consumer access to non-prescription medicines by end quarter four.

3. Strengthening surveillance

The agency has a key role to play in the development of EU and global networked vigilance for medicines and devices. This includes working to enhance patient care and safety in relation to the use of medicines, devices and combination products.

Our strategic priorities for 2015-16:

- **Implement and evaluate the recommendations of the Stephenson review, including ensuring sufficient and appropriate level of clinical input to management of devices and establishing the Devices Expert Advisory committee (DEAC)**
- **Strengthen vigilance work, working with partners and developing new models – inc. linking with CPRD and NIBSC (increasing breadth of product testing experience)**
- **Lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system, working with UK healthcare bodies to ensure safety measures for medicines and devices contribute to safe care and reducing avoidable harm**

Implementing and evaluating the recommendations of the Stephenson review, inc. establishing the Devices Expert Advisory committee (DEAC)

Following the independent report by Professor Terence Stephenson that makes recommendations about how MHRA can improve its access to clinical advice and engagement with the clinical community in relation to medical devices, we will continue to implement and evaluate these findings.

This includes establishing the Devices Expert Advisory Committee (DEAC) which will be responsible for providing independent, expert input and advice on a wide range of aspects relating to medical advice to help ensure safe use and management of medical devices and provide a link to professional bodies.

Specific activities in 2015-16 will include the following:

3A Implementation and evaluation of Stephenson report actions to ensure sufficient and appropriate level of clinical input for safe management of devices through building systematic and collaborative relationships with leading clinical institutions and developing a sustainable database of accredited clinical expertise which would be available by end quarter two.

3B Devices Expert Advisory Committee formal response to Stephenson report by end quarter one.

3C As part of implementation of Stephenson report, continue forming the Devices Expert Advisory Committee (DEAC) - ensuring appropriate representation as a gateway to expert clinical advice for MHRA - to reinforce and build new links across the clinical community in UK healthcare. (First meeting expected by end quarter two.

Strengthening vigilance work

We plan to work with partners and develop new models to strengthen vigilance work. This includes linking with CPRD and NIBSC to increase the breadth of the product testing experience.

For instance, we will work with work with NHS and other stakeholders to put medicines and devices safety information as an indicator of safe care, including delivering against the action plan for Sign up to Safety to demonstrate how MHRA contributes to the campaign objectives of reducing avoidable harm and saving lives.

Vaccine safety will remain a public health priority. We will build upon strategies to integrate Yellow Card and CPRD analysis into a strengthened, routine model of vaccine vigilance and risk management, and we will continue to work within the EU Network to promote evidence-based decision-making on vaccine safety. Alongside, this, we plan to establishing the Ebola vaccine lot release procedures.

Through the MHRA-NIBSC VISION Network, we will seek to link laboratory-based research and analysis into Yellow Card and epidemiological analyses.

Specific activities in 2015-16 will include the following:

3D Devices working with Portsmouth Hospitals to implement agreed pilot programme to incorporate implant bar codes (Unique Device Identifiers) into existing hospital patient electronic record systems and to store the information locally by end quarter two.

3E Devices working with CPRD and HSCIC to develop national information standards for the incorporation of UDI information (device and production identifiers) into suitably anonymised central records (HES, care data or other) as required in SCCI Statement of Need (SoN) - SCCI2025 by end quarter four.

3F NIBSC to implement strategy to increase efficiency and resilience of testing capability by end quarter four.

3G NIBSC to extend range of products under test by end quarter four.

3H Complete an initial project within the MHRA's Vigilance and Risk Management of Medicines (VRMM) division to refine and further develop internal systems and methods for pharmacovigilance of vaccines, with oversight from the VISION Network by end quarter one.

Leading the further development of incident reporting systems

One of our key aims for next year is to lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system. This will involve working with UK healthcare bodies to ensure safety measures for medicines and devices contribute to safe care and reducing avoidable harm.

We continue to work with NHS England to improve volume and quality of medical device reporting through engagement of the Medical Device Safety Officers (MDSO) and NHS England safety first network.

Through the WEB-RADR (Recognising Adverse Drug Reactions) project, we are seeking to implement a pilot Adverse Drug Reporting (ADR) mobile application, which would allow

patients and healthcare professionals to report suspected adverse drug reactions to national EU regulators, alongside investigating the potential for publicly available social media data to help identify drug safety issues.

We are also continuing to lead the SCOPE project, which seeks to strengthen collaboration for operating pharmacovigilance systems across Europe and, in turn, helps to safeguard public health across the EU as a whole.

Specific activities in 2015-16 will include the following:

3I VRMM to lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system and champion reporting as an indicator of safe care with NHS and ALB stakeholders by end quarter four.

3J VRMM to lead the SCOPE Joint Action for pharmacovigilance according to agreed milestones including, holding a forum for SCOPE stakeholders to provide update on progress and deliverables by end quarter three.

3K VRMM to evaluate the Yellow Card mobile App delivered by the WEB-RADR project based upon feedback on the prototype launched at the end of 2014/15, conduct a survey and deliver enhancements based on user feedback by end quarter four.

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

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.

Our strategic priorities for 2015-16:

- **Continue to collaborate with international agencies to improve and harmonise global regulatory standards – including working with Indian regulators and stakeholders to ensure a secure supply of medicines, progressing the ICMRA/GMP project and EU/US FDA Mutual Reliance Initiative; developing International Standards/Reference materials; and selectively engage with IMDRF in collaboration with European partners**
- **Continue to promote the safe purchase of medicines/ devices through the provision of accurate information, including developing a strategic threat assessment to the medical products supply chain**

Continuing to collaborate with international agencies to improve and harmonise global regulatory standards

We will continue to collaborate with international agencies to improve and harmonise global regulatory standards.

This includes working with Indian regulators and stakeholders to ensure a secure supply of medicines; progressing the ICMRA GMP project and EU/US FDA Mutual Reliance Initiative to enable reliance on other trusted global regulators' inspections; and further developing International Standards/Reference materials.

Specific activities in 2015-16 will include the following:

4A Shared leadership of first ever European Joint Action for device compliance and enforcement activity, which includes taking a lead role in a critical training and inspection pilot for future cross-EU joint actions in market surveillance from quarter one.

4B IE&S to develop a wider strategy for the MHRA's Inspection, Enforcement and Standards (IE&S) division's involvement in China, USA & India international policy making use of interactions via symposia/ training, including workstreams relating to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) by end quarter two.

4C IE&S role in International Coalition of Medicines Regulatory Agencies (ICMRA) GMP project to establish a working framework by end quarter two.

4D IE&S to enable utilisation of other Inspectorates outcomes in national Risk Based Inspection programmes by end quarter four.

4E IE&S initiatives with DH and others to avoid overdependence on vulnerable sources through continuing to collaborate with EMA and other stakeholders to mitigate risks of medicines shortages ongoing quarter one to quarter four.

4F Enforcement to participate in, influence and develop international strategies and initiatives both unilaterally and collaboratively that support enforcement activity ongoing quarter one to quarter four.

4G British Pharmacopeia (BP) to contribute to and participate in Pharmacopoeial Harmonisation activities to strive to achieve high quality standards across the global landscape.

4H BP collaborative initiatives to promote development of international partnerships (to include work with China, USA, India and Europe including making use of interactions via symposia, meetings & conferences) ongoing quarter one to four.

4I Policy / IE&S role in the implementation of Falsified Medicines Directive logo for distance selling over the internet in 2015.

4J Policy / IE&S role in Falsified Medicines Directive overseeing implementation of safety/security features in medicines which include anti tampering and 2D barcoding of listed products following enactment of the delegated act by end quarter three – then ongoing implementation to 2019.

4K NIBSC completion of planned 2015/16 work programme to support the clinical safety and efficacy of biopharmaceuticals through developing WHO International Measurement Standards by end quarter three.

4L NIBSC provision of vaccine candidate strains and potency reagents to support timely supply of influenza vaccines for both Northern and Southern Hemispheres by end quarter four.

Continuing to promote the safe purchase of medicines / devices through the provision of accurate information

We will continue to promote the safe purchase of medicines/ devices through the provision of accurate information, including developing a strategic threat assessment to the medical products supply chain. We will also enhance the safe and effective use of adrenaline auto injector devices through contributing to and implementing the findings of the Committee for Medicinal Products for Human Use (CHMP) review.

Specific activities in 2015-16 will include the following:

4M IE&S / Comms to develop a strategic threat assessment that identifies existing and emerging threats by end quarter one.

4N IE&S / Comms to complete a control strategy that details activities to address the identified threats by end quarter two.

4O Comms to develop and deliver supporting plan for patient facing campaign on counterfeit medicines and medical devices by end quarter two.

4P Licensing, collaborating with Devices Division and Notified Bodies, to address the need for guidance both within the agency and for Industry and Notified Bodies in the area of drug-device combination products by end quarter four.

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

As per previous years, 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.

Our strategic priorities for 2015-16:

- **Operate at a financially sustainable level, meeting our financial targets, including implementing a revised devices funding model**
- **Continue our Regulatory Excellence Programme to ensure our regulatory work is managed and proportionate, and that we are able to respond robustly to any further de-regulatory drive**
- **Develop agency wide IT strategy that fully aligns with Cabinet Office and EU IT direction and allows the agency to maximise its organisational efficiency and support business needs.**
- **Continue to strengthen our internal leadership and management capability, alongside recruiting and developing people with the right skills to deliver our objectives**
- **Further develop the reputation of the agency with external stakeholders**

Operating at a financially sustainable level, including implementing revised devices funding model

The agency will continue to meet our financial targets next year. Implementing a revised devices funding model will be key to us delivering our regulatory responsibilities in relation to devices at a financially sustainable level in the longer term.

Specific activities in 2015-16 will include the following:

5A Deliver a funding scheme that allows the MHRA to recover its anticipated costs of device regulation in 2016/17 through a new periodic fee, adjustments to existing fees and minor central funding through gaining Ministerial agreement to fees proposal and launching formal consultation in quarter two.

5B Deliver the agency budget for 2015-16 and achieve the third year of the Corporate Plan's financial strategy by end quarter four.

5C Increase external income of NIBSC. Implement new pricing and marketing strategies for standardisation and control in line with 5 year financial model by end quarter four.

Delivering undertakings we have made on regulation and preparing for a new administration

We will continue to manage our Regulatory Excellence Programme with the overall aim of ensuring our regulatory work is managed and proportionate. In particular, we will ensure we have delivered our deregulatory commitments wherever possible in the run up to the

General Election in May and be able to contribute effectively to any further de-regulatory initiatives from a new Government.

Specific activities in 2015-16 will include the following:

5D Policy to continue effective delivery of our Regulatory Excellence Programme, including quarterly collaboration with industry through our Medicines Liaison Group, to ensure a managed and proportionate approach to regulation.

Developing agency wide IT strategy that fully aligns with Cabinet Office and EU IT direction

The Information Management Division has commenced a three year implementation plan that will transform the way people access MHRA information. We will use digital technologies to deliver services that put the user first, and give them the smartest and most cost-effective services possible. We will create an environment for our people to flourish and will collaborate with all our stakeholders to deliver solutions quickly and safely.

We will enable this transformation by adopting cloud based services where we can, developing a system wide view of information and their supporting processes, and .to build and develop partnerships to support the wider change. We will adapt our delivery model to take on more control in house, and to break up our larger contracts through use of the frameworks. Critically, we will govern the Information and Data we receive and produce, to ensure accurate data is delivered in a timely manner to the right people with a controlled and well managed storage policy. In particular, we will:

- improve information management compliance through producing a coherent approach to records management across the agency;
- implement a new HR service technology and upgrade the existing Finance technology; and
- improve threat assessment and governance regimes to ensure the confidentiality, integrity and availability of personal and other data is assured.

Specific activities in 2015-16 will include the following:

5E IT strategy and IMD Operating model to set the direction to guide our investment and move to a different delivery model with multiple suppliers sourced through the Digital framework by end quarter two.

5F IMD Business Services & Corporate and compliance to agree Business Service Roadmap identifying savings from the Application Management Contract and initiate some early projects on this roadmap such as Devices and Business Intelligence by end quarter one.

5G IMD Business Services & Corporate and compliance to improve agency Information Management Compliance to produce a coherent approach to records management across the agency by end quarter three.

5H IMD Business Services & Corporate and compliance to implement a new HR and Finance Services technology by end quarter three.

5I IMD Business Services & Corporate and compliance to agree corporate casework solution and initiate the project by end quarter three.

5J IMD to agree Infrastructure Outsourcing (IO) contract roadmap and transition plan to new suppliers and complete the transition to these suppliers by end quarter four.

Continuing to strengthen our internal leadership and augment our workforce

We will continue to strengthen our internal leadership and management capability alongside recruiting and developing people with the right skills to deliver our objectives.

Specific activities in 2015-16 will include the following:

5K HR to implement MHRA talent management and succession strategy in line with the wider Civil Service framework for business critical, leadership and technical roles by end quarter one.

5L HR to implement an approved strategic recruitment approach to attract, select, recruit and retain staff within Civil Service constraints for specialist areas and senior roles (including use of social media and flexible contract options to fill business critical roles) by end quarter two.

5M HR to identify 'career pathways' framework (which sets out clusters of related roles and possible options for career progression) to enhance and develop career development opportunities by end quarter three.

Further develop the reputation of the agency with external stakeholders

We plan to further develop the reputation of the agency with external stakeholders. This will include identifying training needs and providing appropriate, focussed workshops to allow stakeholders to gain maximum benefit from interactions with Licensing Division.

In addition, we will consider the future and further development of the Central Alerting System (CAS) – working with DH and other partners – to ensure it supports effective communication with healthcare professionals.

Specific activities in 2015-16 will include the following:

5N Comms to complete customer insight research for Licensing and British Pharmacopoeia (BP) as part of the agency Marketing Strategy by end quarter one.

5O Customer services to support improved customer services functions and consistency across the agency by developing a cross agency customer service plan by end quarter two.

5P Comms to implement employer brand campaign to build the Agency's reputation as a desirable place to work and support our recruitment and retention approach by end quarter three.

5Q Comms to build our reputation for patient safety through collaborative working with healthcare professionals and others in the health and social care system by promoting integrated reporting and developing professional networks to promote patient safety by end quarter four.

5R Comms to further develop the Patient Consultative Forum and hold at least three stakeholder meetings over the course of 2015/16 to gain feedback and input into specific topics by end quarter four.

5S NIBSC to implement agreed corporate and divisional academic stakeholder interaction plan(s) by end quarter four.

5T Licensing to arrange appropriate seminars and training events for interested parties on Clinical Trial Regulations, applications for generic products, Parallel Import issues and other LD initiatives including CCC variations and drug/device combination products from quarter one.

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.

2015-16 activities of note in addition to strategic work in the business plan

Licensing

Licensing division will continue their regulatory work of assessing new and variation submissions for all chemical and biological products within high level targets to ensure we remain a leading contributor to European procedures. In addition, purely national, herbal, homeopathic, parallel import applications and Notified Body consultations on devices incorporating ancillary medicinal substances will be assessed in line with published targets.

The division will provide a comprehensive regulatory and scientific advice service to stakeholders both within and outside of the UK, including national and European scientific advice, provision of a Regulatory Information Service, provision of a clinical trials helpline, responding to Freedom of Information requests, and publishing UK public assessment reports for new marketing authorisations and major non-safety variations of clinical importance. We will continue to be actively involved in and make a major contribution to EU Committees including CHMP and its working parties and other groups, CAT, COMP, HMPC, CMDh and its working groups, and to contribute to the work of EDQM.

The division will maintain, support and utilise a suitable independent expert advisory structure to ensure decisions are robust and to provide full and appropriate advice to the licensing authority. The division will ensure appropriately experienced staff are available and robust systems are in place for continued preparedness for responding to public health emergencies. Licensing division will continue close and effective collaboration with all other divisions in the agency particularly VRMM, IE&S and Devices. We will continue to support GMP, GCP, GDMP inspections. We will work with colleagues in the Department of Health to ensure safe supply of critical medicines in the event of potential shortages, providing input into risk reviews and expediting assessments as necessary.

Vigilance and Risk Management of Medicines

We will continue to undertake a variety of important initiatives in relation to pharmacovigilance. This includes managing the Yellow Card Scheme – our early warning system for the identification of previously unrecognised adverse reactions – by effectively capturing and analysing reported data from healthcare professionals, patients and the pharmaceutical industry and conducting more detailed reviews if necessary. In

some cases, this involves developing a regulatory position, consulting national and EU expert advisory groups and committees as appropriate. We also assess all data sources to monitor for changing benefit/risk balance of a medicine or vaccine and communicate the benefits and risk to healthcare professionals and patients through updated product information and other means.

In the forthcoming year we will focus on preparing our ADR IT system for the introduction of EU systems for Identification of Medicinal Products and E2B (R3) for exchange of case safety reports. We will also be reviewing our processes for safety variations and renewals so that product information can be updated more efficiently. Vaccine safety will remain a public health priority. We will build upon strategies to integrate Yellow Card and CPRD analysis into a strengthened, routine model of vaccine vigilance and risk management, and we will continue to work within the EU Network to promote evidence-based decision-making on vaccine safety. We will work with licensing division to deliver access to innovative and promising treatments where there is an unmet need through the Early Access to Medicines Scheme by ensuring plans are in place to identify and manage risks.

Another priority is improving access to medicines – both paediatric and self-medicines. On the former, we aim to increase the number of medicines licensed for use in children by assessing paediatric investigation plans and studies including children submitted under the European Paediatric Regulation. On the latter, we improve the choice of medicines available to patients for self-medication and reclassify medicines from prescription to pharmacy only or pharmacy to general sale where it is safe to do so. In 2015-16, we will embed the UK stakeholder platform work into routine operational activity as part of a wider stakeholder engagement which will enable access to a wide range of medicines supported by healthcare professionals and patients and deliver the broader Department of Health self-care agenda.

Inspection, Enforcement & Standards

In addition to continuing to meet its regulatory obligations and duties, the significant core work activities for the Inspection, Enforcement & Standards (IE&S) division for next year are set out below.

The British Pharmacopoeia will progress joint working with the Chinese Pharmacopoeia to promote and ensure the quality of reference standards and products. BP will also develop plans for the establishment of a Centre of Excellence at NIBSC for DNA barcoding, biologicals and herbal monographs and reference materials.

As part of a progression towards closer working, IE&S will work with the Veterinary Medicines Directorate within Defra in relevant internet related investigations and will include them in appropriate technical training & symposia. British Pharmacopoeia are also collaborating with the Veterinary Medicines Directorate to get the reference to British Pharmacopoeia (Veterinary) back into Veterinary legislation.

A recent restructure within the inspectorate will be embedded to promote cross GXP working including the implementation of new business heads to oversee strategy and innovation & risk, control and governance.

The inspectorate will continue to react quickly and effectively to any significant public health incidents that arise domestically and internationally.

Operation Pangea, the dedicated week of action on internet crime, will for the first time include medical devices following the recent merger of devices compliance with medicines enforcement which now sits within one enforcement regime. The enforcement

unit will also continue to collaborate internationally with counterparts, to progress investigations of crime relating to medical products where matters are outside of UK jurisdiction.

We will also develop and implement a divisional quality strategy that will describe the matrix of representatives that will work together and drive quality through all that IE&S do including moving towards the new ISO 2015 standard.

Finally, following the implementation of the existing licensing portal within IE&S this year, plans to extend the portal to include applications for manufacturing licences will be developed and progressed.

Devices

In addition to continuing to meet its regulatory obligations and duties for next year, the Devices division has some significant core work activities that are worth highlighting.

We will work to deliver good quality and timely single route medical devices reporting from large healthcare providers in partnership with NHS England, National Reporting and Learning System managers, Local Risk Management System providers and Medical Device Safety Officers. Where any compliance issues arise, we will work alongside our colleagues in IE&S on handling and resolving these.

We will also continue working with NHS Blood and Transplant (NHSBT) and Serious Hazards of Transfusion (SHOT) on the development of a single reporting and learning system for adverse blood reactions and events. Improving the devices adverse incident management/ blood adverse incident system is a priority for us and should enable a more risk aligned process for reporting.

In addition, we will monitor the introduction of the certificates of free sale fee regime and work with manufacturers on a voluntary pilot UK vigilance transparency scheme to provide feedback to reporters on all incidents reported in a number of areas.

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 2015-16, CPRD will be taking forward the activities for year four identified in its business case, working collaboratively in a complex environment and promoting the value of using healthcare records for research purposes

2015-16 activities of note in addition to strategic work in the business plan

CPRD has a structured programme of practice recruitment which is talking effect in increasing the volume of data available for research. Traditionally the research data resource has come from practices using the Vision GP practice system. We are now actively collecting data from a substantial number of EMIS practices, and we will continue to grow this data source during the year. We also have negotiations in hand to collect data from the third major GP system, TPP. There are a range of activities involving partner organisation including Clinical Research Networks, the RCGP and NHS England which will increase the population cover of CPRD.

During 2015-16 we will use our clinical trial products to offer services to organisations undertaking medium to large clinical trials. Development of our software tools will continue, with deployment of the full range of tools by the end of the year. These tools will improve the efficiency of clinical trials and help improve the progress of products to market.

Key partnership development

A key feature of the implementation of CPRD services is the building and development of partnerships. Key partnerships include the Health and Social Care Information Centre (HSCIC), the Farr Institute, NHS England (NHSE), Genomics England, National Institute of Health and Research (NIHR), Clinical Research Network (CRN), and Academic Health Scientific Networks (AHSN). Maintaining an effective relationship with these partner organisations is fundamental to securing CPRD role as the NHS research service.

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.

2015-16 activities of note in addition to strategic work in the business plan

We will continue to build our standardisation programme through development of new and replacement WHO international standards and reference materials to meet the demands of existing and new biological medicines. Over 150,000 items were shipped to over 80 countries in 2013 and we anticipate that this will grow significantly in the coming year. We will also lead a programme to refresh global strategy for development of international physical measurement standards for biologics in collaboration with WHO, recognising the rapidly changing needs of the field, and the important of standards to underpin innovation. Key areas of focus for 2015 will be standards to support biosimilar medicines, advanced therapies (gene therapeutics and regenerative medicines) and the use of genomic tools for diagnosis of disease. We will also strengthen our scientific and business links with international standards organisations, such the international pharmacopeias, in order to increase the reach and public health impact of the standards we develop (in particular NIFDC in Beijing, USP in Washington and EDQM in Strasbourg).

We will fulfil our responsibilities as the UK's Official Medicines Control Laboratory, carrying out Official Control of Batch Release Authority (OCABR) testing of manufactured biological medicines and blood plasma pools according to stringent quality requirements and timelines, and authorising batches for release on to the European market. We will also work with manufacturers to develop new capacity for testing medicines in line with anticipated demand. As the requirements of EU In Vitro Diagnostics Directive become clear, we will explore further the possibility of becoming an EU Reference Laboratory for IVDs.

We will maintain a broad-based relevant regulatory science research programme, using the Regulatory Science Research Unit (RSRU) programme as a platform to attract additional external support for work relevant to our standardisation and control mission. Our aim will be to achieve the deliverables for 2015 agreed as part of the 5 year RSRU funding programme and to increase the annual research income we have available to support important research from its current figure of ~£3.5m per annum.

We will implement the remaining elements of our agreed investment plan, building resilience into our scientific team through succession planning in key areas of our existing biologics capability, and recruiting expert staff in new areas of importance (for example bioinformatics, cancer gene therapy, biologics structure analysis). This will take account of input from our newly established Science Advisory Committee. We will also carry out the next in our series of planned external quinquennial reviews of Scientific Divisions. Finally we will continue our contribution to a wide range of national and international policy making and advisory bodies relating to biological medicines, with the aim of ensuring that decisions are based as securely as possible on scientific evidence.

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 corporate responsibilities.

2015-16 activities of note in addition to strategic work in the business plan

Finance and Procurement

Finance and Procurement will continue to lead on the preparation of the agency's statutory accounts, the management of risk and provision of financial controls; the coordination of the internal audit plan for the agency and ensuring compliance with all HM Treasury, Department of Health, National Audit Office and Accounting Standards requirements and guidelines. The division will maintain the timely payment of supplier invoices and employee's expenses. Alongside this they deliver effective and efficient credit control, cash management and the allocation of sales receipts.

Additionally, the team will continue to provide a management accounting, financial planning and business analysis service to the agency which enables managers at all levels to understand the financial position of the areas under their control. They will continue to provide insight to the Chief Executive, Corporate Executive Team and Agency Board, thereby adding value to decision making and strategic planning across the agency. They will also continue to take the lead in achieving the best value for money from the agency's purchasing requirements by providing: expert advice; competitively sourcing requirements; and, making sure appropriate contracts are put in place to mitigate risk. The division also maintains close relations with the Department of Health, its ALBs and Cabinet Office functions to maintain compliance with legislation and any Government policy.

Human Resources

Human Resources (HR) will plan and implement a number of significant operational projects to support the agency in the achievements of its objectives. This will include the re-commissioning of occupational health services through a new occupational health provider, implementation of a new HR system and providing strategic support to planned organisational change programmes and projects.

In addition, there is a planned approach to work and engage with the wider civil service, Department of Health / ALB to share learning and good practice and pool resources where necessary. With the overall aim of continuous improvement for the HR function in providing an effective and efficient HR service.

Given the importance of equality and human rights, we will continue to ensure the agency fulfils its obligations under The Equality Act 2010 (Specific Duties) Regulations 2011. This includes having employment policies and training in place to eliminate discrimination and advance equality of opportunities whilst fostering good employee relationships.

Information Management

In addition to the essential work of moving our IT infrastructure supplier and IT strategy delivery including moving HR and Finance onto more stable platforms following a Department of Health decision not to proceed with Shared services at this time, the key activities that IT will be concentrating on this year are to build an effective, efficient and

focused team and enhance its governance procedures. This will enable a flexible and more proactive approach to managing the service provided by our IT suppliers, deliver efficiency and timely IT projects and effective engagement with the our key stakeholders to ensure that we meet and deliver to their needs. Emphasis will be on delivering quality products setting 'digital-by default' as our standard, also continuing to work and influence in the European arena to ensure suitable integration with and delivery of effective products for our internal and external stakeholders. Our Information Processing Unit (IPU) will continue to work with IT IMD to develop and improve their business processes and will work with IT IMD to develop and improve their IT solutions.

The agency will also ensure compliance with HMG information and protective security standards as set out in the Security Policy Framework and the 10 Steps to Cyber Security. We will do this by having the necessary roles, governance, systems, checks and training in place.

Policy:

Policy will continue to help the agency to deliver its responsibilities for any government policy and to engage actively with wider Department of Health objectives.

This will include continuing to support growth, innovation and the life sciences agenda, and ensuring a proportionate approach to regulation. Working with other parts of the agency and other government departments, we will progress UK objectives in the negotiation of EU legislation on devices regulation, and ensure active management of any risks arising from implementation of EU legislation on clinical trials, the Falsified Medicines Directive and the e-cigarette elements of the Tobacco Products Directive. 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. In a UK context, we will continue to help the agency deliver its responsibilities effectively through working productively with partners in the health and care system and across Whitehall. We will also continue to ensure that the agency offers 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:

Leading the agency's communications, external relations and information, including media, digital, stakeholder, patient and public, marketing, promotion and employee communications activities, underpinned by the updated communications and reputation strategy. We will handle issues and identify proactive communications opportunities using an integrated approach to communications. We will manage effective customer and information services. We will manage relationships with the media, both proactively and reactively, and will continue to build relationships with important media outlets and journalists. We will manage the agency's brands and positioning. We will continue to improve the agency's relationship with healthcare professionals and the public, and engagement with stakeholders building on work established last year. We will support the agency's digital presence and further improve our use of social media. We will support effective employee communications, facilitating two-way discussion and engagement with our staff. We will manage a programme of events and speaker opportunities, generating income for the agency. Our approach to account management / business partnering and cross-divisional working will continue to be at the centre of our approach.

Annex A – Performance targets

No.	Activities	2015-16 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% (fatal and serious only) 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 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 • 10 days for Parenterals

No.	Activities	2015-16 Targets
		• 15 days for Haemostasis • 60 days for vaccines
PM7	**CPRD activity**	a) To enable 280 research studies in 2015/16.
		b) To increase the population cover of primary care data within the CPRD system to 20% by the end of the financial year.
PM8	**Answering Freedom of Information requests, letters and Parliamentary Questions**	a) Respond to all requests under the Freedom of Information Act within 20 working days (or within permitted extension).
		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.

Annex B – Performance metrics and future work

Performance metrics:

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

Work volumes

- Number of CAP (co) rapporteurships allocated to the UK

- Number of appointments of UK as coordinator for CHMP scientific advice

- Number of applications received
    - Incoming Decentralised Procedures (UKCMS) – Number of applications received
    - Outgoing Decentralised Procedures (UKRMS) – Number of applications received
    - Clinical trials of medicines, including the number of applications for:
        - First in Human trials
        - Phase 1 trials
        - Phase 2/3 trials
        - Phase 4 trials
    - Clinical investigation notifications for medical devices, including class of device
    - PIM designation
    - EAMS scientific opinion

- British Pharmacopoeia Chemical Reference Substances sales (in £ms)

- NIBSC
    - Number of standards shipped
    - Number papers and scientific papers authored
    - Research contract and grant income won (£ms – annually in March)
    - Number of standards established (annually in October)

- 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.
    - Number of drug alerts
    - Yellow card reports made by (a) healthcare professionals (b) the public
    - Total number of UK spontaneous fatal adverse drug reaction reports received.
    - Total number of UK spontaneous serious adverse drug reaction reports received.

Capacity, efficiency and capability 2015/16

- Aggregate number of Inspections / UK and overseas
- Number of companies inspected where critical findings discovered
- Number of new investigations opened
- Number of defendants charged and number of cases
- Number of defendants convicted and number of cases
- Number of defendants acquitted and number of cases
- Number of counterfeit medical products discovered in the legitimate supply chain
- 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 of learning and development days per member of staff
  - Time to fill vacancies
  - Number of posts reduced against annual target for the budgetary savings

Future work:

In addition, to the targets set out in Annex A and the metrics set out above, the agency is committed to carrying out further performance related work as follows:

- undertake a review of regulatory actions finalised by VRMM since June 2014, whose impact can be monitored, to prioritise these and to agree a systematic approach to outcome measurement;

- identify two drugs or drug classes where measurement of the outcome of regulatory action will be planned prospectively, via appropriate post-authorisation studies;

- develop an action plan to demonstrate how incident reporting to the yellow card scheme and the resulting regulatory activity contribute to the Sign Up to Safety campaign; and

- explore possible means of measuring the impact of certain aspects of its devices work and seek to develop some meaningful metrics.

Annex C – Collated strategic activities for 2015-16

No	Activity	Outputs
1 – Vision and scope of our work		
1A	Licencing/VRMM/IE&S contribution to the EU regulatory network	To ensure that MHRA is a leading contributor to procedural work in the EU regulatory network, including: • ensuring that we remain within the upper quartile in our contributions to Rapp/co-rapp appointments for the various EU committees, scientific advice appointments and the preferred RMS for DCP work in cases where the UK is involved • significant involvement at EU level at the Good Manufacturing, Pharmacovigilance and Good Clinical Practice Working Groups
1B	Devices contribution to the EU regulatory network	Continue to chair CAMD Executive to maximise collaboration between Member States to improve market surveillance and vigilance as a key mechanism in enhancing product safety.
1C	Devices contribution to the EU regulatory network	Review and revise roles and responsibilities of all European working groups to ensure clarity of purpose and duplication of activities by end quarter two.
1D	Devices contribution to the EU regulatory network	Continue to lead for Europe on medical device single audit program (MDSAP) under the IMDRF programme and clarify European position on implementation of elements of MDSAP in the EU by end quarter three.
1E	Licensing to take a leading role in the development of Co-ordinated Clinical Trial assessment in Europe for multiple Member State CTs.	Develop a UK assessment template in preparation for implementation of the Regulation and promote for adoption by European colleagues and to liaise with the HRA on how to coordinate the ethics aspect of Part 1 assessment by end quarter one.
1F	Engagement with Health and Social Care Network	Implement strengthened arrangements for responding to health incidents through structured engagement with key partners in the Health & Social Care Network – with collaboration mechanisms with priority partners in place by end quarter three.
1G	Policy and wider agency cross-Whitehall Ebola work	Actively contribute to cross-Whitehall work about future clinical trials of vaccines and other activities, which includes: • deploying first production runs of trials from the start of 2015; • preparing for wider and subsequent waves of trials, including other vaccines as they develop and prepare for all options up to mass vaccination, if necessary / practically possible and scientifically justified; and • developing thinking on the use of convalescent plasma and a range of treatments

1H	NIBSC development of new standards and reference materials	Develop and supply reference for standardising ebola serological analysis and virus detection to enable internationally harmonised assays by end quarter four.
1I	NIBSC building scientific strength for future needs	Introduce new NIBSC/ Academia biologics fellowship scheme by end quarter two.
1J	NIBSC building scientific strength for future needs	Establish regular strategic links with two major research funding organisations by end quarter three.
1K	NIBSC building scientific strength for future needs	Completion of further two MOUs with academic centres by end quarter four.
1L	Prepare for future scientific needs	Agency to prepare for completion of 2015 Horizon Scanning exercise by end quarter three.
2 – Bringing innovation and new products speedily and safely to patients		
2A	Policy and wider agency contribution to the Innovative Medicines and Medical Technologies Review	Ensure MHRA contribution to the review led by the Office for Life Sciences helping to maximise existing initiatives and to identify further initiatives where possible.
2B	NIBSC supporting innovation through provision of scientific expertise, products and services	Develop and deliver in collaboration with BIA a strategy to improve links with small and medium-sized enterprises (SMEs) for provision of technical advice on innovative biologics development by end quarter four
2C	NIBSC supporting innovation through provision of scientific expertise, products and services	Develop strategy for provision of reference materials to support development of Precision Medicines by end quarter two.
2D	Licensing to promote and develop innovation office	Contribute to an interim report on the Innovation Office by end quarter one.
2E	Licensing to promote and develop innovation office	Conduct evaluation of the scheme one year on by end quarter three.
2F	Licensing/Devices/NIBSC/IE&S to encourage harmonisation of classification decisions and regulation of innovative combination medicine/medical device products	Continued participation in EU Innovation Office network and preparation of reflection paper on borderline/combination products (for EU Innovation Office network meeting in quarter one).
2G	Licensing/VRMM Early Access to Medicines Scheme (EAMS)	Review and amend processes, including effectiveness of risk management plans, based on experience from early applications and as EAMS relationship with NICE and NHSE evolves by end quarter four.

2H	Licensing to develop joint advice with NICE	Further develop and promote joint MHRA/ NICE scientific advice as well as other MHRA support mechanisms and licensing flexibilities by end quarter four.
2I	Devices to promote and develop medical device apps	Continue to promote the safe use of medical apps working with NHSE digital, HSCIC, NICE and other medical/professional colleges/bodies with Quarterly report on progress from quarter two.
2J	Devices to promote and develop medical device apps	Issue updated guidance for medical apps developers, healthcare clinicians and others to educate on what is required to maximise safety and regulatory compliance by end quarter two.
2K	Devices to promote and develop medical device apps	Review and evaluate resource operational and strategic requirements for this fast developing area by end quarter four.
2L	Policy/Devices contribution to medical device legislation in the UK/EU	Continue to press for closure of the negotiation of the revision of the devices legislation ensuring final provisions are proportionate, unambiguous and implementable by end quarter four.
2M	Policy/Devices contribution to medical device legislation in the UK/EU	Continue preparations for implementation of the revised legislation, anticipating key changes where possible (for instance on joint audits of notified bodies and transparency) and working with stakeholders to deliver a smooth and effective transition.
2N	IE&S/Policy/NIBSC/Licensing Advanced Therapies Medicinal Products (ATMP)	Ensure the proposed revision to the ATMP regulation results in a more enabling proportionate legislation in line with Regenerative Medicines Expert Group (RMEG) report by end quarter four.
2O	CPRD to build effective working relationships with key partners to effectively complement our capabilities	Collaborative working exercises undertaken and/or MoUs signed with key partners, including Health and Social Care Information Centre (HSCIC), Farr, National Health Service England (NHSE), Genomics England, National Institute of Health and Research (NIHR), Clinical Research Network (CRN), and Academic Health Scientific Networks (AHSN)
2P	Increase numbers of organisation having access to CPRD	Promote CPRD among stakeholders and industry to widen the range of use of CPRD, which may be measured through numbers of unique clients, numbers of observational studies undertaken, numbers of clinical trials in which CPRD services are provided
2Q	CPRD expansion of clinical trials	Roll out CPRD data tools to aid patient recruitment and data capture for the delivery of clinical trials and interventional studies.
2R	CPRD access to wider range of linked datasets	Continue to work towards access to a wider range of additional linked datasets based on criteria such as customer demand, public health benefit and previous negotiations with data custodians with a target of adding a further two datasets linked to primary care data by the end of 2015/16.
2S	VRMM access to self-medication	Hold three meetings of the UK platform for reclassification of non-prescription medicines in order to ensure sound regulatory decisions are made with maximum stakeholder engagement and to reach a common approach by stakeholders to supporting patient and consumer access to non-prescription medicines by end quarter four.

3 – Strengthening surveillance		
3A	Clinical engagement for devices	Implementation and evaluation of Stephenson report actions to ensure sufficient and appropriate level of clinical input for safe management of devices through building systematic and collaborative relationships with leading clinical institutions and developing a sustainable database of accredited clinical expertise which would be available by end quarter two.
3B	Devices Expert Advisory Committee	Formal response to Stephenson report by end quarter one.
3C	Devices Expert Advisory Committee	As part of implementation of Stephenson report, continue forming the Devices Expert Advisory Committee (DEAC) – ensuring appropriate representation as a gateway to expert clinical advice for MHRA – to reinforce and build new links across the clinical community in UK healthcare. (First meeting expected by end quarter two.
3D	Unique Device Identifier	Devices working with Portsmouth Hospitals to implement agreed pilot programme to incorporate implant bar codes (UDIs) into existing hospital patient electronic record systems and to store the information locally by end quarter two.
3E	Unique Device Identifier	Devices working with CPRD and HSCIC to develop national information standards for the incorporation of UDI information (device and production identifiers) into suitably anonymised central records (HESS, care, data or other) as required in SCCI Statement of Need (SoN) – SCCI2025 by end quarter four.
3F	NIBSC to increase strength and breadth of biologics testing capability	Implement strategy to increase efficiency and resilience of testing capability by end quarter four.
3G	NIBSC to increasing strength and breadth of biologics testing capability	Extend range of products under test by end quarter four.
3H	Vaccines vigilance	Complete an initial project within VRMM to refine and further develop internal systems and methods for pharmacovigilance of vaccines, with oversight from the VISION Network by end quarter one.
3I	VRMM incident reporting and contribution to safe care	Lead the further development of incident reporting systems to embed Yellow Card reporting into NHS and the care system and champion reporting as an indicator of safe care with NHS and ALB stakeholders by end quarter four.
3J	VRMM to lead the SCOPE Joint Action for pharmacovigilance	Lead the SCOPE Joint Action for pharmacovigilance according to agreed milestones including, holding a forum for SCOPE stakeholders to provide update on progress and deliverables by end quarter 3.
3K	Adverse Drug Reaction (ADR) reporting application	VRMM to evaluate the Yellow Card mobile App delivered by the WEB-RADR project based upon feedback on the prototype launched at the end of 2014/15, conduct a survey and deliver enhancements based on user feedback by end quarter four.

4 – Safe products and secure supply in globalised industries		
4A	Devices EU Joint Action plan	Shared leadership of first ever European Joint Action for device compliance and enforcement activity, which includes taking a lead role in a critical training and inspection pilot for future cross-EU joint actions in market surveillance from quarter one.
4B	IE&S role in International Collaboration with regulators to promote harmonisation and an uncompromised supply of medical products	Develop a wider strategy for the MHRA's Inspection, Enforcement and Standards (IE&S) division's involvement in China, USA & India international policy making use of interactions via symposia/ training, including workstreams relating to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) by end quarter two.
4C	IE&S role in International Collaboration with regulators to promote harmonisation and an uncompromised supply of medical products	International Coalition of Medicines Regulatory Agencies (ICMRA) GMP project to establish a working framework by end quarter two.
4D	IE&S role in International Collaboration with regulators to promote harmonisation and an uncompromised supply of medical products	To enable utilisation of other Inspectorates outcomes in national Risk Based Inspection programmes by end quarter four.
4E	IE&S role in contingencies to mitigate risk of shortages in the supply chain	Initiatives with DH and others to avoid overdependence on vulnerable sources through continuing to collaborate with EMA and other stakeholders to mitigate risks of medicines shortages ongoing quarter one to quarter four.
4F	Enforcement international Influence	Participate in, influence and develop international strategies and initiatives both unilaterally and collaboratively that support enforcement activity ongoing quarter one to quarter four.
4G	British Pharmacopoeial International Influence	Contribute to and participate in Pharmacopoeial Harmonisation activities to strive to achieve high quality standards across the global landscape.
4H	British Pharmacopoeial International Influence	Collaborative initiatives to promote development of international partnerships (to include work with China, USA, India and Europe including making use of interactions via symposia, meetings & conferences) ongoing quarter one to quarter four.
4I	Policy / IE&S role in Falsified Medicines Directive	Implementation of Logo for distance selling over the internet in 2015.

4J	Policy / IE&S role in Falsified Medicines Directive	Overseeing implementation of safety/security features in medicines which include anti tampering and 2D barcoding of listed products following enactment of the delegated act by end quarter three – then ongoing implementation to 2019.
4K	NIBSC development of international standards and reference materials	Completion of planned 15/16 work programme to support the clinical safety and efficacy of biopharmaceuticals through developing WHO International Measurement Standards by end quarter three.
4L	NIBSC development of international standards and reference materials	Provision of vaccine candidate strains and potency reagents to support timely supply of influenza vaccines for both Northern and Southern Hemispheres by end quarter four.
4M	IE&S/Comms to promote the safe purchase of medicines / devices	Develop a strategic threat assessment that identifies existing and emerging threats by end quarter one.
4N	IE&S/Comms to promote the safe purchase of medicines / devices	Complete a control strategy that details activities to address the identified threats by end quarter two.
4O	Comms to promote the safe purchase of medicines / devices	Comms to develop and deliver supporting plan for patient facing campaign on counterfeit medicines and medical devices by end quarter two.
4P	Licensing to develop guidance for devices used with (or incorporated into) medicinal products.	Collaborating with Devices Division and Notified Bodies, address the need for guidance both within the Agency and for Industry and Notified Bodies in the area of drug-device combination products by end quarter four.
5 – Achieving excellence – a well-run, efficient and effective organisation		
5A	New approach to Devices funding	Deliver a funding scheme that allows the MHRA to recover its anticipated costs of device regulation in 2016/17 through a new periodic fee, adjustments to existing fees and minor central funding through gaining Ministerial agreement to fees proposal and launching formal consultation quarter two.
5B	Finance Strategy and Budget	Deliver the agency budget for 2015-16 and achieve the third year of the Corporate Plan's financial strategy by end quarter four.
5C	Increasing external income NIBSC	Implement new pricing and marketing strategies for standardisation and control in line with 5 year financial model by end quarter four.
5D	Policy development of Regulatory Excellence	Continue effective delivery of our Regulatory Excellence Programme, including quarterly collaboration with industry through our Medicines Liaison Group, to ensure a managed and proportionate approach to regulation.
5E	IT Strategy & IMD Operating Model	Set the direction to guide our investment and move to a different delivery model with multiple suppliers sourced through the Digital framework by end quarter two.
5F	IMD Business Services & Corporate and compliance	Agree Business Service Roadmap identifying savings from the Application Management Contract and initiate some early projects on this roadmap such as Devices and Business Intelligence by end quarter one.

5G	IMD Business Services & Corporate and compliance	Improve Agency Information Management Compliance to produce a coherent approach to records management across the agency by end quarter three.
5H	IMD Business Services & Corporate and compliance	Implement a new HR and Finance Services technology by end quarter three.
5I	IMD Business Services & Corporate and compliance	Agree corporate casework solution and initiate the project by end quarter three.
5J	IMD infrastructure	Agree Infrastructure Outsourcing (IO) contract roadmap and transition plan to new suppliers and complete the transition to these suppliers by end quarter four.
5K	HR talent management	Implement MHRA talent management and succession strategy in line with the wider Civil Service framework for business critical, leadership and technical roles by end quarter one.
5L	HR strategic recruitment	Implement an approved strategic recruitment approach to attract, select, recruit and retain staff within Civil Service constraints for specialist areas and senior roles (including use of social media and flexible contract options to fill business critical roles) by end quarter two.
5M	HR career pathways	Identify ‘career pathways’ framework (which sets out clusters of related roles and possible options for career progression) to enhance and develop career development opportunities by end quarter three.
5N	Comms promoting the agency	Complete customer insight research for Licensing and British Pharmacopoeia as part of the agency Marketing Strategy by end quarter one.
5O	Customer service	Support improved customer services functions and consistency across the agency by developing a cross agency customer service plan by end quarter two.
5P	Comms employer brand campaign	Implement employer brand campaign to build the agency’s reputation as a desirable place to work and support our recruitment and retention approach by end quarter three.
5Q	Comms patient safety	Build our reputation for patient safety through collaborative working with healthcare professionals and others in the health and social care system by promoting integrated reporting and developing professional networks to promote patient safety by end quarter four.
5R	Comms patient and public engagement	Further develop the Patient Consultative Forum and hold at least three stakeholder meetings over the course of 2015/16 to gain feedback and input into specific topics by end quarter four.
5S	NIBSC academic engagement	Implement agreed corporate and divisional academic stakeholder interaction plan(s) by end quarter four.
5T	Support to licensing applicants	Licensing to arrange appropriate seminars and training events for interested parties on Clinical Trial Regulations, applications for generic products, Parallel Import issues and other LD initiatives including CCC variations and drug/device combination products from quarter one.

Annex D – Glossary

ADR	Adverse Drug Reporting
AHSN	Academic Health Scientific Networks
AL	Adaptive Licensing
AMR	Antimicrobial resistance
ASMFs	Active Substance Master Files
BIA	UK BioIndustry Association
BP	British Pharmacopoeia
CAMD	Competent Authorities Medical Devices
CAS	Central Alerting System
CHMP	Committee for Medicinal Products for Human Use
CPRD	Clinical Practice Research Datalink
DEAC	Devices Expert Advisory Committee
DH	Department of Health
EAMS	Early Access to Medicines Scheme
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
GHTF	Global Harmonization Task Force on Medical Devices
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HSCIC	Health and Social Care Information Centre
ICMRA	International Coalition of Medicines Regulatory Authorities
IE&S	MHRA's Inspection, Enforcement and Standards (IE&S) division
IMDRF	International Medical Devices Regulators Forum
IO	Infrastructure Outsourcing
IT	Information Technology
MAAs	Multiple Marketing Authorisation Applications
MDSAP	Medical Device Single Audit Program
MDSO	Medical Device Safety Officers
MHRA	Medicines and Healthcare products Regulatory Agency
MISG	Ministerial Industry Strategy Group
MMIP	Medicines Manufacturing Industry Partnership
NEWDIGS	MIT's NEW Drug Development ParadIGmS
NHS	National Health Service
NHSE	National Health Service England
NIBSC	National Institute for Biological Standards and Control
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health and Research
PIM	Promising Innovative Medicine
PRAC	Pharmacovigilance Risk Assessment Committee
PV	Pharmacovigilance
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SMEs	small and medium-sized enterprises
VRMM	MHRA's Vigilance and Risk Management of Medicines division
WEB-RADR	mobile app being developed for patients and healthcare professionals to report suspected adverse drug reactions
WHO	World Health Organisation

Medicines and Healthcare products Regulatory Agency Business Plan 2015-2016

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151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

T: 0203 080 6000
E: info@mhra.gsi.gov.uk
gov.uk/mhra