Medicines and Healthcare products Regulatory Agency
Business Plan 2017-18

April 2017
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Contents

Executive Summary

1. Introduction

2. Financial context

3. Strategic objectives for 2017-18:
   - Aim 1 - Vision, scope and partnerships
   - Aim 2 - Enabling innovation
   - Aim 3 - Vigilance
   - Aim 4 - Secure global supply chains
   - Aim 5 - Organisational excellence

4. Core business

Annex A – Strategic objectives for 2017-18
Annex B – Performance targets
Annex C – Performance metrics and future work
Annex D – Glossary
Executive summary

This business plan sets out how the Medicines and Healthcare products Regulatory Agency (the Agency) will deliver, in 2017-18, against its mission to enhance and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

The Plan summarises our key achievements over the last year (Chapter 1) and shows how the Agency will build on these to deliver Corporate Plan priorities in this, the last year of our current Corporate Plan 2013-2018.

2017-18 will be a challenging year as we respond to:

- rapid advances in medicines and medical technologies;
- a challenging financial context, and the need to focus on efficiencies through our operational transformation programme, as detailed in Chapter 2;
- challenges faced by partner organisations across the health sector; and
- the decision that the UK will leave the European Union.

To set the strategic framework for delivering this year’s business plan, the Corporate Executive Team and the Board have agreed 10 top priorities for the whole Agency this year. These are framed to enable the Agency to:

- continue to play a key role in protecting public health and promoting innovation throughout the coming year;
- navigate successfully the uncertainty posed by Brexit;
- develop and establish a global role for the Agency as an attractive regulator and beacon of scientific and clinical excellence; and
- facilitate the transition to the next Corporate Plan which will embed our envisaged model for operating in the post-Brexit landscape.

A summary of our top 10 priorities for 2017/18 is below:

1. Develop a proposed model for future regulation of medicines and medical devices in the UK, post-Brexit
2. Develop an international and enhanced national strategy for collaboration and engagement with key partners and stakeholders
3. Develop the next five year corporate plan for the Agency
4. Play a key role contributing to the Government’s Life Science Strategy
5. Expand the Clinical Practice Research Datalink (CPRD) further to support research and innovation
6. Deliver the new Patient Safety and Vigilance Strategy
7. Secure global supply chains for medicines and medical devices
8. Deliver our operational transformation programme
9. Secure sustainable funding for medical devices regulation
10. Make the Agency a good place to work for our staff and manage a seamless transition to our new accommodation at the Government Hub at Canary Wharf in 2018

These are described in further detail in Chapter 1. The plan – in particular Chapter 3 – provides detail on how we will deliver these priorities, with details on delivering ongoing core business in Chapter 4.
Chapter 1 – Introduction

This is the final annual Business Plan to deliver the 2013-18 Corporate Plan of the Medicines and Healthcare products Regulatory Agency (the Agency).

The Business Plan sets out in detail how we intend to deliver the Corporate Plan over the year. This is underpinned by divisional and centre plans, which link to individual staff objectives.

This also supports delivery of the Department of Health’s (DH) Single Departmental Plan, in particular:

- protecting and improving people’s health;
- research and innovation to optimise the life science and healthcare sectors and improve the nation’s health; and
- ensuring accountability to Parliament and the taxpayer.

The Chief Executive has overall responsibility for the delivery of the business, policies and priorities of the Agency and in particular is accountable to DH Ministers for delivery of this business plan.

In order to ensure that the focus of Agency activity is to deliver our 2017-18 priorities we have made some changes to the business plan format for this year, in particular:

- setting out the Top 10 priorities, across the agency as a whole, agreed by the Corporate Executive team and the Board;
- clear graphic introductions for each Corporate Plan strategic aim (see Chapter 3) and revisions to some terminology to facilitate better understanding; and
- overall, a shorter, sharper plan.

Some of our achievements over 2016-17

In addition to our day to day work regulating medicines and devices, some of our key achievements in year include:

- Brexit
  - Led timely, effective and influential response, on medicines and medical devices, to the European Union (EU) Referendum and HMG’s response to Brexit

- Cross-Whitehall innovation and growth agenda
  - Agency’s contribution to the Accelerated Access Review consolidated the Early Access to Medicines Scheme (EAMS)\(^3\)
  - Influential contribution to the Medicines Manufacturing Industry Partnership (MMIP) and Advanced Therapy Medicinal Products (ATMP) Manufacturing Taskforce Reports
  - Clinical Trials Regulation – led action and engagement to ensure we will implement by October 2018

- Drove forward work on key EU legislation to protect public health including


\(^2\) As set out in Chapter 3, changes to terminology include revising Corporate Plan strategic ‘themes’ to ‘aims’ and evolving ‘activities’ into ‘objectives’ which are then sub-divided into ‘deliverables’ and ‘commitments’.

\(^3\) Also, worth noting continued success of EAMS with 17 promising innovative medicine (PIM) designations and three positive scientific opinions published this year.
Devices and in vitro diagnostic (IVD) regulations – completed negotiations and will bring new regulations into force in May 2017 with external engagement well underway; influencing EU approach through coordinating transition at European level, including non-Member States

- Falsified Medicines Directive – agreed with industry practical steps for implementation; engaged across Europe to ensure harmonized arrangements put in place
- Tobacco Products Directive - led implementation of E-Cigarettes legislation and completed preparatory work ahead of transition changes to notifications in May 2017

- Led work to promote collaboration between global regulators through harmonisation, reciprocal agreements and mutual reliance, in particular implementation of the mutual reliance initiative with U.S. Food and Drug Administration (FDA) for acceptance of UK and U.S. inspection standards
- Continued to grow the Clinical Practice Research Datalink (CPRD) and increase uptake of its services
- Continued to build closer and stronger collaboration with the DH and partners in the health and care system, enabling work to deliver shared goals on public health and innovation in line with the DH Shared Delivery Plan
- Continued to develop constructive partnership working with industry, facilitating action to reduce regulatory burden and progress considerations around future regulatory models post-Brexit
- Led further roll out of the Operational Transformation programme to ensure the Agency has the systems it needs to continue as a leading global regulator
- Further strengthened the capabilities of the National Institute for Biological Standards and Control (NIBSC) by developing its cutting edge technologies to support counterfeit testing and ensure it remains a global leader in standardisation and control of biological medicines
- Completed the development of seven World Health Organisation (WHO) international standards to underpin consistent manufacture and accurate measurement of biological medicines and diagnostics, including standards in response to global health emergencies
- Established the Patient Safety and Vigilance strategy to lead the further development and improvement of incident response and safety reporting for medicines and medical devices
- Opened the new British Pharmacopoeia-NIBSC herbal testing laboratory
- Signed protocol between the Agency and the General Pharmaceutical Council on the Distance Selling Logo
- Launched a major public-facing campaign on the risks of fake medicines and medical devices, reaching over 30 million people in the first six months
- Achieved excellent results in a Benchmarking of European Medicines Agencies audit
- Successful start in delivering new People Strategy, illustrated through improved year on year engagement across the agency and remaining in upper quartile of Civil Service organisations for second consecutive year
- Launched Agency’s apprenticeships scheme, including initial success focussing on work-based management training programme.
Our focus for 2017-18

Our mission is to enhance and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research

Our focus for 2017-18 is two-fold:

i  to deliver the commitments in the Corporate Plan 2013-18 and the Corporate Plan refresh 2016, and

ii  to respond to the result of the 23 June 2016 referendum that UK will exit the EU.

Given that the Agency works closely with and within the EU we are fully engaged in supporting the Government in positioning itself to influence negotiations positively and shape the post-Brexit regulatory framework for medicines and medical devices.

To set the strategic framework for delivering this year’s business plan, the Corporate Executive Team and the Board have agreed 10 top priorities for the whole Agency this year. These are intended to complement the more detailed deliverables, targets and metrics – set out later in the plan and in addition to the day to day work regulating medicines and devices – and are framed to enable the Agency to:

•  ensure that the Agency continues to play a key role in protecting public health and promoting innovation throughout the coming year;
•  successfully navigate the uncertainty posed by Brexit;
•  develop and establish a global role for the Agency as an attractive regulator and beacon of scientific and clinical excellence; and
•  facilitate the transition to the next Corporate Plan which will embed our envisaged model for operating in the post-Brexit landscape.

These top 10 priorities are:

1. To develop consensus around a proposed model for future regulation of medicines and medical devices in the UK, post Brexit which protects public health, facilitates innovation, and minimises burden on industry in order to influence and support HMG negotiations and make the UK an attractive global regulator. (Aim 1)

2. To develop an international strategy and enhanced national strategy for collaboration and engagement with key partners and stakeholders to facilitate better regulation, innovation, and delivery of our strategic priorities. (Aim 1)

3. To develop the next five year corporate plan for the Agency which builds on our unique capabilities and drives a competitive global edge that works for industry and the Agency, so we can flourish as an influential and respected regulator within the UK and internationally. (Aim 1)

4. Building on our track record in innovation, early access to medicines and the Accelerated Access Review, to play a key role in contributing to the Government’s Life Science Strategy to deliver systems which support innovation in medicines, medical devices, and genomics. (Aim 2)

5. To expand CPRD further to provide data and services to support research and innovation. (Aim 2)
6. For the purposes of enhancing public health, to deliver the new **Patient Safety and Vigilance Strategy** which aligns medicines, medical devices and blood vigilance functions. *(Aim 3)*

7. To **secure global supply chains for medicines and medical devices** through global strategic alliances, including harmonisation of standards, information sharing, inspection and enforcement, underpinned by programmes to educate the public on the dangers of falsified medicines and fake medical devices. *(Aim 4)*

8. Through our **operational transformation programme**, to deliver a portfolio of improvements for our staff and our customers, which build on our position as an outstanding regulator and establishes the Agency at the leading edge of digital technology. *(Aim 5)*

9. To secure **sustainable funding** to improve the allocation of resources between industry and wider Government in **medical devices regulation**. *(Aim 5)*

10. To make the Agency a **good place to work for our staff**, including managing a **seamless transition to our new accommodation** at the Government Hub at Canary Wharf in 2018 in a way which maximises our employee’s input to working practices / design and maintains a high quality service to our customers. *(Aim 5)*

Detail on how we will deliver these priorities is provided in Chapter 3 below and ongoing core business is set out in Chapter 4.
**Structure of this plan**

The remainder of this plan is structured as follows:

<table>
<thead>
<tr>
<th>Chapter 2</th>
<th>Overview of the financial context in which we are operating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 3</td>
<td>Our key strategic objectives for 2017-18 to progress delivery of our 2013-18 Corporate Plan</td>
</tr>
<tr>
<td>Chapter 4</td>
<td>Overview of our ongoing core business – including notable work in addition to our strategic objectives in Chapter 3</td>
</tr>
<tr>
<td>Annex A</td>
<td>Tables collating the strategic objectives set out in Chapter 3, including:</td>
</tr>
<tr>
<td></td>
<td>i. overview of Corporate Plan strategic aims / allocation of supporting objectives</td>
</tr>
<tr>
<td></td>
<td>ii. collated strategic deliverables</td>
</tr>
<tr>
<td>Annex B</td>
<td>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</td>
</tr>
<tr>
<td>Annex C</td>
<td>Metrics relating to our core business – to be monitored over time to develop our understanding of our performance</td>
</tr>
</tbody>
</table>

As usual, we will monitor delivery against the strategic objectives set out in Chapter 3 and the Targets, Metrics and further performance related work set out in Annexes B and C on a quarterly basis throughout the forthcoming year.
Chapter 2 – Financial context

Overview

The Agency operates as an Executive Agency and 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 DH with approximately 10% of its revenue from fees charged for services.

- **NIBSC** derives approximately 65% of its revenue from fees charged for services, including the sale of biological standards, and from research funding. DH provides the remaining 35% to finance its important public health functions.

- **CPRD** is operated as a joint arrangement with the DH's National Institute for Health Research, via the DH Science, Research and Evidence directorate, 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 central corporate costs. The key principle is that there is no cross-subsidy.

As set out in the 2013-18 Corporate Plan, and reconfirmed in the Corporate Plan Refresh 2016, the Agency is already operating in a financially challenging context. The regulatory environment has become more competitive and increasingly global. With Brexit on the horizon and the Agency’s future role yet to be defined there are many uncertainties about the Agency’s financing in the future. As this develops, the Agency will be undergoing operational transformation over the next three years as it replaces its aging systems. In doing so, we will assess the benefits of each investment proposal to ensure that each delivers appropriate returns and efficiencies. As part of this, we will explore with our sponsor department whether we can draw on our retained earnings to fund the investment required rather than pass on the costs to those we regulate.

The trading fund model supporting the regulatory centre is designed to be responsive to growth and contractions of business, while ensuring that the Agency is always resourced to discharge its 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 and seeking efficiencies in order to maintain a balanced budget.

Funding for devices regulation remains at half the level of 2003 funding in real terms and whilst a number of efficiency measures have been taken, this is against a backdrop of an increase in adverse incident reporting, which has more than doubled since 2007, and an increasing volume and complexity of work due to revolutionary technological advances and new Medical Device Regulations being introduced in 2017/18. There are proposals underway to introduce a levy for vigilance from Devices manufacturers that, if successfully implemented, would replace the majority of DH funding for this area. However, this requires primary legislation and indications from DH are that it is unlikely to secure the Parliamentary time. DH funding has been confirmed for 2017/18.

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

CPRD will work to progress the objectives in its strategic plan as a world leading health data provider, increasing the volumes of data available and developing value adding tools and services to support public health research.
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 objectives before interest payable and dividends expressed as a percentage of average capital employed.

For 2017/18 this will require the following funding to be made available by the DH:

- **Devices regulation** - £8.1m confirmed plus £1m for capital investment in further efficiencies (as provisionally discussed between DH/Agency Finance but to be confirmed in early 2017/18)
- **CPRD** - a continued commitment to the joint arrangement is required as set out in the CPRD 2016-2021 Strategic Plan
- **NIBSC** - as discussed between DH/Agency Finance, the requirements are as follows:

<table>
<thead>
<tr>
<th>£m</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.5</td>
<td>Revenue funding – the same cash as 2015/16 and 2016/17 (confirmed)</td>
</tr>
<tr>
<td>4.0</td>
<td>The estimated dividend that NIBSC will have to generate as part of the trading fund</td>
</tr>
<tr>
<td>6.5</td>
<td>The estimated value of the cost of holding NIBSC’s assets</td>
</tr>
<tr>
<td>6.0</td>
<td>NIBSC capital programme for 2017/18 (provisional)</td>
</tr>
<tr>
<td><strong>29.0</strong></td>
<td>£m TOTAL</td>
</tr>
</tbody>
</table>

**Capital Programme**

The Agency will continue to make capital investments in all three centres in 2017/18 to support its business and corporate plans.

All capital investments are set out in business cases which must be formally approved and subject to appropriate governance arrangements before budgets are made available

**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 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.

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4 Provisionally discussed with DH but to be confirmed in early 2017/18.
5 The procurement pipeline is published on the “Contracts Finder” portal found at https://online.contractsfinder.businesslink.gov.uk
Chapter 3 – Key strategic objectives for 2017-18

This chapter sets out the strategic objectives for 2017-18 which – combined with the wider portfolio of work undertaken over the last four years – should ensure delivery of our 2013-18 Corporate Plan and Corporate Plan Refresh 2016.

Our Top 10 priorities are set out in Chapter 1.

As usual, the strategic objectives underpinning these will follow the Corporate Plan structure’s five strategic aims below.

As explained in our corporate plan documents, we describe Aims 2, 3, and 4 – shown in the middle of Figure 1 above – as the ‘whats’.

➢ Enabling innovation, joining up and improving vigilance across medicines and devices, and securing global supply chains are central to what the Agency seeks to achieve.

We describe Aims 1 and 5 – respectively shown at the core and outer circle of Figure 1 above – as the ‘hows’.

➢ These are goals in their own right but also act as enablers for delivering the ‘whats’.

These are delivered through our strategic objectives, which are subdivided into:

As flagged earlier, we’re now referring to Corporate Plan strategic ‘themes’ as ‘aims’ and evolving ‘activities’ into ‘objectives’. We feel this change in terminology better reflects the relationship between the agency’s overarching, five strategic aims and the more detailed objectives that are intended to deliver these.
• **deliverables** - where a concrete output is planned; and
• **commitments** - important, strategic functions which support our overall aims.

Often, there is judgement call to be made about, under which aim, a strategic objective should be placed (e.g. working with our partners to ensure the safety of medicines and medical devices would encompass Aims 1, 3 and 4).

In what follows, we’ve allocated this year’s objectives to whichever one of the five Corporate Plan strategic aims we feel is best served by the ultimate deliverables and commitments planned. For ease of reference, we’ve set out our broad allocation in a table at the start of Annex A.

1. **Vision, scope and partnerships**

This section sets out the overarching plans which will guide our work in 2017-18.

This year, supporting HMG in its Article 50 negotiations through developing an innovative, world class regulatory offer will form the core of our strategic priorities. Likewise, creating a new five-year corporate plan to help us navigate the post-Brexit world – working afresh with our UK, EU and international partners – will be key to our ultimate success.

**Progressing our post-Brexit strategy**

Our aim, post-Brexit, is to develop a world-leading, financially stable, medicines and medical devices regulatory system that gives patients timely access to safe, effective medicines and supports a flourishing life sciences sector.

One of our top priorities this year is:

_To develop consensus around a proposed model for future regulation of medicines and medical devices in the UK, post Brexit which protects public health, facilitates innovation, and minimises burden on industry in order to influence and support HMG negotiations and make the UK an attractive global regulator._
The key components are:

- **HMG Brexit negotiation support**: influencing / supporting HMG in its EU negotiations through development of key strategies which follow below.

- **European engagement strategy**: working out future relationship and engagement with our European counterparts in a post-Brexit context, including the potential for ongoing co-operation in EU regulatory procedures.

- **Optimal UK regulation strategy**: developing in parallel an innovative, world-class, financially stable regulatory offer based around more rapid and agile assessments, enhanced support for business and joined up regulatory and Human Tissue Authority (HTA) assessments.

- **Commercial development strategy**: developing a plan which analyses commercial development opportunities in the approach to Brexit and beyond, and facilitates the Agency’s future financial stability to enable it to deliver its public health remit.

- **Communications and reputation strategy**: effectively communicating the uniqueness of our agency’s refreshed model to our key stakeholders will be key to our future success.

- **People strategy**: ensuring the agency has the right skills in place now and in the future.

Specific deliverables in 2017-18 include:

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1a</td>
<td>Develop proposed model for future regulation of medicines and medical devices in the UK which protects public health, drives innovation, minimises burden on industry and makes the UK an attractive global regulator throughout the year ahead.</td>
</tr>
<tr>
<td>1b</td>
<td>Develop clear programme for implementing Innovation Plan, with focus on projects which can contribute to UK growth throughout the year ahead.</td>
</tr>
<tr>
<td>1c</td>
<td>Support Brexit Taskforce in delivering a stakeholder and customer engagement strategy throughout the year ahead.</td>
</tr>
<tr>
<td>1d</td>
<td>Increase contacts within patient representative and strategic stakeholder organisations across the EU as part of the Brexit engagement and strategic stakeholder strategy work throughout the year ahead.</td>
</tr>
<tr>
<td>1e</td>
<td>Within new Brexit context, refresh and deepen the agency’s commercial and international work in a way which works for both industry and the Agency throughout the year ahead.</td>
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</table>

In addition, we are committed to influencing and supporting HMG negotiations through ongoing:

- co-ordination and provision of input into cross-HMG considerations throughout the Brexit negotiation process;
- leadership of Agency Brexit Task Force; and
- relationship management with EU / international partners and wider stakeholders, which includes building consensus among interested partners for proposed UK model.

**Building partnerships, collaboration and engagement**

Working collaboratively across Government, with the NHS and other key players in the health and care system, industry, and internationally to improve public health and promote innovation remains a key priority for the Agency. We recognise the challenges the NHS and other partners face and

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7 See ‘Building partnerships, collaboration and engagement’ below for specific deliverables.
seek to support them to deliver their objectives.

This year, in the context of developing our post-Brexit and corporate strategies, it is even more important:

**To develop an international strategy and enhanced national strategy for collaboration and engagement with key partners and stakeholders to facilitate better regulation, innovation, and delivery of our strategic priorities.**

In particular:

- **International strategy**: building on the development of an innovative, attractive, post-Brexit regulatory offer, play a leading role in global discussions about the future regulatory environment for pharmaceuticals and devices; actively engage in global vigilance and inspection partnerships, consider strategic alliances with other regulators worldwide.

- **Europe**: actively and positively fulfilling our duties as a current member of the EU

- **HMG, DH and its supporting agencies / public bodies**: work closely with DH to deliver strategic objectives in the Single Departmental Plan; embed the Agency as a key partner across the health sector in promoting public health and patient safety.

- **Devolved Administrations (DAs)**: further strengthen engagement, especially in the Brexit context, to ensure the Agency continues to represent the whole UK in Europe and internationally, as appropriate.

- **Industry**: further strengthen constructive working relationships with industry through Medicines Industry Liaison Group (MLG) and Medical Devices Liaison Group (MDLG) to enhance proportionate regulation and collaborative working in the life sciences sector.

- **Academia**: continue to build academic partnerships and scientific capability to support the safe and effective development of key innovative medicines and technologies and improved safety monitoring.

- **Health and Social Care system**: extending our collaboration with the NHS and wider public health and healthcare system partners on areas of shared concern.

- **Healthcare professionals**: developing further partnership work with healthcare professionals and health system leaders to ensure that our safety information and regulatory action is embedded in clinical practice.

- **Public / patients**: providing stakeholders with further opportunities for dialogue with the Agency and strengthen their engagement and involvement early on in our projects and decision making.

Specific deliverables in 2017-18 include:

<table>
<thead>
<tr>
<th>Internationally</th>
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<tr>
<td><strong>1f</strong></td>
<td>Provide effective chairmanship and secretariat of International Coalition of Medicines Regulatory Authorities (ICMRA), setting clear strategic direction and agreed governance arrangements throughout the year ahead.</td>
</tr>
<tr>
<td><strong>1g</strong></td>
<td>Develop deeper relationships with key countries (e.g. China and India) and, in a Brexit context, other leading global regulators as part of a coherent international strategy</td>
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</tbody>
</table>
throughout the year ahead.

1h Reinforce networks outside EU by expanding International Medical Device Regulators Forum (IMDRF) and bilateral relationships outside EU, including FDA, throughout the year through (a) development and publication of successive IMDRF event terminology and (b) identification of new IMDRF working groups and shared areas for future collaboration throughout the year ahead.

### Europe

1i Continue to engage in Heads of Medicines Agencies (HMA) discussions, including leadership of the innovation workstream, input to other project areas and support to EU Telematics/IT strategy. Deliver updates on the innovation workstream at all HMA meetings in 2017/18 throughout the year ahead.

1j In line with Tobacco Products Directive / E-Cigarettes legislation, implement a system to check and publish e-cigarette notifications and safety reports by June 2017.

1k Broaden strategic relationship with Ireland with aim of formalising through written agreement by end quarter two.

1l Establish an EU combined working group of medicines and medical device regulators on borderlines and combination products with willing parties to develop a consistent approach to regulation by end quarter three.

### UK

1m Refresh the Patient and Public Engagement Strategy to build on existing forums of patient engagement (UK Reclassification Platform; Patient Group by end quarter two.

### Agency

1n Establish a regular engagement forum with academic and research organisations by end quarter one.

1o Put in place a strategic stakeholder strategy to formalise the management of the Agency’s engagement with strategic stakeholders by end quarter two.

In addition, we are **committed** to:

**Internationally**
- working through WHO and ICMRA to show leadership and develop improved patient safety systems and continue to use international platforms and forge new partnerships

**Europe**
- implementing existing EU legislation
- influencing / leading work within the EMA
- taking a leading role in the development of Co-ordinated Clinical Trial assessment in Europe for multiple Member State Clinical Trials
- contributing to the EU regulatory network throughout the year, ensuring that we remain within the upper quartile in our contributions to (co) rapporteurship appointments, scientific advice appointments and the preferred Reference Member State (RMS) for DCP (decentralised procedure) work in cases where the UK is involved, and remain actively involved with the various EU committees
- playing a leadership role on devices through:
  - driving the implementation of the Competent Authorities Medical Devices (CAMD) strategy as a member of CAMD Executive
  - being a lead partner for EU Joint Action on market surveillance (JAMS)
  - providing EU leadership on IMDRF initiatives on:
    - Medical Devices Single Audit Programme
    - Medical Device Nomenclature Working Group
    - Registration Working Group
UK

- Enhancing partnerships across the UK and health sector to ensure Agency strategic priorities are delivered, including broadening partnership agreements and arrangements for information sharing as appropriate; holding regular touch-base meetings; and working with others to rapidly respond to any urgent matters with potential public health implications.
- Continuing to lead constructive engagement with the DAs in the Brexit context, to ensure the Agency can continue to represent effectively the whole UK in Europe and internationally, and that DA issues are addressed in the Agency.
- Continuing to enhance constructive working relationships with industry, including through quarterly MLG and MDLG meetings, to deliver our strategic objectives and consider regulatory models in the Brexit context.
- Providing more formal opportunities for patients to input into agency and licensing decision making, particularly as part of the EAMS process.

Agency

- Maintaining and strengthening key academic partnerships with a focus on vibrant relationships and demonstrating how they support the Institute’s and the Agency’s work and mission, through collaborative research, teaching and joint appointments.

Developing our 2018-23 corporate strategy

One of our top priorities this year is:

To develop the next five year corporate plan for the Agency which builds on our unique capabilities and drives a competitive global edge that works for industry and the Agency, so we can flourish as an influential and respected regulator within the UK and internationally.

We propose, through 2017/18, to prepare a full five-year Corporate plan for 1 April 2018 to 31 March 2023 which gives us a framework for navigating and addressing the Brexit-related uncertainty we know we face.

On current timelines, this will mark the conclusion of the first stage of Article 50 negotiations and enable a focus on transition during the initial stages. In particular, we will explore how we move towards operating in different modes – within UK, with the EU, and internationally.

The key deliverable is:

1p Working across the Agency and with key strategic stakeholders, develop a new corporate plan for the Agency for 2018-2023 which responds to the changing landscape introduced by the EU referendum and positions the Agency as a strong national regulator in a global environment by end quarter four.
2. Enabling innovation

Supporting and championing safe innovation is a hallmark of the agency’s overarching strategy. This year, we are dividing our strategic objectives into the four key areas below:

![Figure 3 – Aim 2: Enabling innovation](image)

**Supporting Innovation and Growth in Life Sciences**

One of our top priorities this year is:

*Building on our track record in innovation, early access to medicines and the Accelerated Access Review, to play a key role in contributing to the Government’s Life Science Strategy to deliver systems which support innovation in medicines, medical devices, and genomics.*

We will continue to actively embed this through the following:

- **Accelerated Access Review (AAR):** actively support the implementation of the recommendations of the Accelerated Access Review in line with the Government’s response.

- **Early Access to Medicines Scheme (EAMS):** work with other partners in the OLS-chaired EAMS task group to continue to manage, ensuring applications for the Promising Innovative Medicines designation and the EAM Scientific opinions are processed within the fast-tracked timetable, supporting earlier access of patients to these medicines to address unmet medical need.
• **Innovation Office & Regulatory Advice Service for Regenerative medicine (RASRM):** work through our Innovation Office (and counterparts in other organisations such as NICE) to provide joined-up regulatory and scientific advice and customer service to industry; expand the support offered to innovative businesses, especially small and medium-sized enterprises (SMEs), and academia via the Innovation Office and increase awareness of our innovation support work; continue to support and grow the Regulatory Advice Service for Regenerative Medicine (RASRM) with the Human Tissue Authority, the Human Fertilisation and Embryology Authority and the Health Research Authority to support the growth of the advanced therapies sector in the UK.

• **Medicines Manufacturing industry partnership (MMIP):** contribute to the regulatory workstream of this initiative that aims to create a Long-term Strategic Partnership between industry and the Government to drive an increase in UK manufacturing and exports.

• **Advanced Therapy Manufacturing taskforce implementation:** work in support of the joint Government/industry report published on 23 November 2016.

Specific deliverables in 2017-18 include:

| 2a | For the MMIP regulatory workstream, develop a paper that demonstrates how companies can use regulatory flexibilities in relation to manufacturing, licensing and inspection by end quarter two. |

In addition, we are committed to:

- contributing fully to AAR implementation following the Government response, working closely with other relevant health sector bodies;
- continuing to develop and support EAMS;
- continuing to participate in EU systems to support earlier access to innovative products, e.g. Priority Medicines scheme (PRIME) and adaptive pathways;
- working with NICE to provide joined-up scientific advice and customer service to industry;
- working with industry to understand new challenges in manufacturing for emerging products and technologies, e.g. ATMPs, digitalized, distributed and continuous processes and supply chains and ensure the regulatory regime is future-proofed; and
- taking forward ATMP manufacturing task force report recommendation 6 to "develop a long-term regulatory strategy and plan for the MHRA to lead in global standards, supporting the scientific activities and international outreach of NIBSC" for implementation in 2019.

**Innovative regulatory and legislative measures**

We will continue to lead delivery of innovative regulatory and legislative measures and work with industry to promote access to innovative self-care products including:

- **Clinical Trials:** A key priority as we transition to a regulatory framework outside the EU will be to ensure that the UK remains one of the best places in the world for science and innovation. The UK applied sustained pressure to successfully reform the current Clinical Trials Directive in the best interests of enabling new treatments to be developed for the benefit of patients and we will continue to work with EMA, Member States and the Commission to prepare for implementation of the Clinical Trials Regulation. The UK will influence proportionate and robust clinical trial assessment as part of a coordinated review. Nationally, we will promote increased collaboration with the Health Research Authority and devolved administrations to align further the processes for scientific and ethical review.

- **Devices:** New EU regulations for medical devices and IVD devices are aimed to improve
standards and encourage innovation. For example, the UK’s inclusion of an ‘in-house’ manufacturing exemption will facilitate continued innovation within hospitals, but within a consistent protocol. The alignment of UK requirements with these new regulations are expected to be comprehensive, but will depend on the outcome of Brexit negotiations.

- **Repurposing of old medicines for new uses:** Drug repurposing refers to studying older drugs where patent and marketing exclusivity has expired to see if they can also be used to treat other diseases. DH has been looking at drug repurposing in the NHS, and we have taken part in roundtable discussions co-chaired by the Association of Medical Research Charities. We will continue to support this work and, where necessary, inform researchers how the licensing process and MHRA scientific advice can support this work.

- **Evaluate the effectiveness of the changed regulatory process for reclassification of medicines.** In November 2016, MHRA agreed with industry a new assessment process and timetable for national major or standard reclassification applications, including combinations with simple abridged procedures. The aim of the new process and timetable is to streamline the reclassification process by providing a specific, dated, predictable timetable with key contact milestones for contact between the Assessors and the Applicant. It is anticipated that the new process will increase efficiency for both MHRA and the applicant and provide more predictability for companies when planning the introduction of a new OTC medicine onto the market. In 2017/2018 the process will be evaluated in light of experience in use to determine whether it is achieving its objectives and amended, if necessary, in the light of experience.

Specific deliverables in 2017-18 include:

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<th>Commence implementation of the new Medical Device and IVD regulations through:</th>
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<td>2b</td>
<td>• establishing plans, governance arrangements and transition guidance by end quarter one;</td>
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<td>• supporting production of collaborative guidance and tertiary legislation through proactive input into EU and Member State fora by end quarter four; and</td>
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<td>• revising MHRA processes and policy development on Member State derogations by end quarter four.</td>
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<tr>
<td>2c</td>
<td>Promote increased collaboration between MHRA and the Health Research Authority to ensure balanced and risk based regulation of clinical trials by end quarter four.</td>
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<tr>
<td>2d</td>
<td>Evaluate the effectiveness of the changed regulatory process for reclassification of medicines by end quarter four.</td>
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</table>

In addition, we are committed to:

- ensuring we transition to a new regulatory framework for clinical trials that means the UK remains one of the best places in the world for science and innovation
- leading EU Implementation task force for the Medical Device and IVD regulations
- supporting DH and AMRC work on repurposing.

**Real world evidence / data**

We are committed to working closely with wider Government initiatives to improve data and scientific evidence to underpin research and innovation, including through further growth of CPRD.

One of our top priorities this year is:

*To expand CPRD further to provide data and services to support research and innovation.*
Work in this area is divided into:

- **CPRD**: We will continue to grow CPRD and increase the volume of data available for observational and interventional public health research including promoting uptake of CPRD’s innovative real world data services to support post-marketing pragmatic clinical trials and novel intervention studies.

- **FDA/21st century cures**: The 21st Century Cures Act, enacted in 2016 in the USA, includes provisions on real world evidence including potential FDA pilot opportunities to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements. We will liaise with FDA colleagues to see how RWE is being used in their assessment processes and where lessons can be learnt.

- **Joint work with NICE**: to coordinate on opportunities to highlight UK thought leadership and system alignment in major international initiatives that include work in this area.

Specific deliverables in 2017-18 include:

| 2e | Expand routine data linkage to include data from GP practices using EMIS software by end quarter three. |
| 2f | Progress work with pragmatic trials to achieve one ongoing trial plus one new study with a signed contract by end quarter four. |

In addition, we are committed to:

- discussing the 21st Century Cures Act with FDA and what provisions the USA might make to evaluate the use of real world evidence;
- monitoring and actively participating in EMA discussions and ongoing efforts in respect of real world data;
- working with NICE to coordinate on opportunities to highlight UK thought leadership and system alignment in major international initiatives that include work in this area such as:
  - **MIT NEWDIGS (New Drug Paradigms)** initiative meetings which are shaping global industry and regulator thinking in this space;
  - **IMI projects, such as ADAPT-SMART** which aim to show how robust new methods of RWE collection and synthesis could be adopted earlier in pharmaceutical research and development and the healthcare decision making process;
  - **EMA initiative on registries**, which aims to increase use of good existing registries for the benefit-risk monitoring of medicines, adaptive pathways, innovative product strategies and health technology assessment;
  - **HMA/EMA Big Data Taskforce** which has been established to focus on mapping and describing the emerging challenges of big data – data sets too large or complex for traditional data processing applications;
- working with IMDRF Registries to adopt common data sets to widen devices data pools; and
- using Scan for Safety initiatives to adopt GS1 (which includes the Unique Device Identifier) standards in healthcare records for safety signal detection.
New areas of scientific development, research and horizon scanning

The Agency will build expertise in critical emerging areas of regulatory science, and scientific capacity to support key innovative areas of product development through:

- **Horizon scanning**: We will strengthen the cross-Agency horizon scanning function to identify important innovative technologies and trends and new products and ideas, and explore the potential benefits of linking up with other organisations’ horizon scanning activities.

- **Genomics, Precision Medicine and next generation sequencing**: work in this area covers medical devices, medicinal products, and standards. It covers new diagnostics such as next generation sequencing to support precision medicine, as well as gene therapies and gene editing. This work can help to make earlier and more accurate diagnoses of diseases, identify which treatments will be most effective for disease subtypes, identify genetic causes of adverse reactions and help with real world performance of drugs and devices. The House of Commons Science and Technology Committee have an ongoing inquiry and we expect to give oral evidence next year.

- **Software, apps and artificial intelligence**: we will continue to work with other Government Departments, competent authorities and regulatory bodies to develop appropriate regulation in these rapidly advancing areas.

**Regenerative medicine/Advanced Therapies**: We support the regenerative medicine community through workshops and scientific advice that can be joint with NICE. We have expertise across the Agency and throughout the product lifecycle. This package helps make the UK an attractive place globally to develop regenerative medicine. We will continue to work with other regulators through the RASRM on options for optimal UK regulation post Brexit and with the European Commission on its proposal for GMP for ATMPs.

- **Biological medicines**: NIBSC will build expertise in critical emerging areas of regulatory science to underpin the safety and efficacy of next generation biological medicines

- **Dementia**: we are supporting DH work to implement the recommendations in Raj Long’s report through DH dementia governance boards.

- **Anti-microbial resistance**: we are supporting DH and industry initiatives to see more products developed to tackle this through active participation in the UK Antimicrobial Resistance Strategy’s High Level Steering Group.

Specific deliverables in 2017-18 include:

| 2g | Strengthen horizon scanning function through recruitment, delivery of 2016/17 report and prioritised action plan for 2017/18 by end quarter four. |
| 2h | Now the newly established specialist sequencing resource is available, apply it to cutting edge research projects across the divisions by end quarter three. |
| 2i | Lead research to facilitate the development and evaluation of new bacterial vaccines by end quarter four. |
| 2j | Deliver a study of immune responses in the humanised mouse immune system model for investigation of a range of biologics, including for example stem cells, immune-check-point tumour therapeutics, novel targeted adjuvants, and vaccines against human pathogens such malaria and tuberculosis by end quarter four. |
| 2k | Evaluate and establish novel approaches for studying the role of the gut microbiome in human disease throughout quarters three and four. |
In addition, we are **committed** to:

- supporting DH work on genomics;
- active involvement in initiatives to further development of stratified and personalised medicine;
- working with partners to develop guidance which facilitates a combined understanding of medical device regulation and the closely linked aspects of data sharing and software governance to encourage UK innovation in software, apps and artificial intelligence;
- supporting wider Government work on Regenerative medicine/Advanced Therapies;
- agreeing business cases to develop/grow standards programme to enter WHO programme for biological medicines and diagnostic assays;
- ensuring Agency contribution to regulatory discussions on dementia in line with Government priority; and
- active participation in the UK Antimicrobial Resistance Strategy’s High Level Steering Group.
3. Vigilance

The Agency will continue to play a leadership role in the development of EU and global networked vigilance for medicines and devices to enhance public safety through leading delivery of the Patient, safety and vigilance strategy.

**Patient Safety and Vigilance Strategy**

One of our top priorities this year is:

*For the purposes of enhancing public health, to deliver the new Patient Safety and Vigilance Strategy which aligns medicines, medical devices and blood vigilance functions.*

The Patient Safety and Vigilance Strategy strategic vision is two-fold:

1. safer healthcare products through a world-leading system of proactive safety management, enabled through digital technologies

2. achieved by working in partnership with the NHS, across the health and care system, and internationally, using and exploiting digital technologies.

This will be delivered through the four key areas set out in Figure 4 above.
**Safety reporting / evidence**

The first area involves the effective capture of information from incident reports and wider scientific evidence base, including social media information and other technologies.

Specific deliverables in 2017-18 include:

| 3a | Grow digital safety reporting by working with Government Digital Service on delivery of a mobile responsive website and platform for adverse drug reactions; falsified and defective medicines; and medical devices by end quarter four. |
| 3b | Development of mobile friendly reporting and a formalised signal detection methodology for devices during 2017 and into 2018. |

In addition, we are committed to:

- continuing to improve reporting of adverse reactions to medicines through the Yellow Card scheme; and
- playing a leadership role in the EU Vigilance Medical Device Expert Working Group including chairing the following sub-groups:
  - Revised Manufacturer Incident Reporting Form
  - Revision of the Field Safety Notice Form and guidance
  - Development of Periodic Safety Update Report
  - Development of Device Specific Vigilance Guidance on Cardiac Implantable Electronic Devices (CIED).

**Signal detection and management**

Our aim is to improve signal detection capability through utilising new tools and methodologies as these evolve.

Specific deliverables in 2017-18 include:

| 3c | Work with NHS Improvement to agree a joint approach to developing a successor system to National Reporting and Learning System (NRLS), based on opportunities coming out of the development of the Patient Safety Incident Management System (PSIMS) Project by end quarter one. |
| 3d | Work with the Patient and Public Engagement Expert Advisory Group to advise on the development of new guidance on the provision of high quality information for patients, following publication of a report on shortcomings with some statutory information by end quarter four. |

In addition, we are committed to:

- developing strategy and operational response to challenge of growing introduction of digital tools in healthcare;
- developing a joint blood strategy with NHS Blood and Transplant and Serious Hazards of Transfusion (SHOT) to achieve better joint working; and
- developing a replacement to the Central Alerting System (CAS) to improve the targeting of patient safety alerts / messages and associated responses for the Agency and partners across the healthcare sector for delivery in 2018/19.
**Analysis / assessment**

We seek better use of real world data and wider vigilance data pools - such as CPRD and national / international registries - to support our benefit risk assessment.

Specific deliverables in 2017-18 include:

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<td>3e</td>
<td>Agree deliverables around a common approach to benefit risk assessment following a mapping exercise on how signals are handled by end quarter one.</td>
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<tr>
<td>3f</td>
<td>Continue to develop work on a joint strategy with CPRD on use of real world data to improve vigilance capability by end quarter four.</td>
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</table>

In addition, we are committed to:

- further strengthening mechanisms for effective data sharing and analysis with UK, EU and international partners to access wider vigilance data pools and support early detection of emerging issues.

**Risk management and communication**

One of our aims is to review how risk management may be improved so we may deliver and target safety and learning messages most effectively.

Specific deliverables in 2017-18 include:

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<tr>
<td>3g</td>
<td>Organise a health summit of key stakeholders in Q1 to begin to formulate how all forms of safety messages to the healthcare system can be better targeted to result in action to improve patient safety by end quarter one.</td>
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<tr>
<td>3h</td>
<td>Establish internal consensus on drug device combination products through publishing updated guidance notes, aimed at Industry and Notified Bodies by end quarter one.</td>
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<tr>
<td>3i</td>
<td>Publish guidance on Human Factors of Medical Device and Combination Products by end quarter two.</td>
</tr>
<tr>
<td>3j</td>
<td>Review experience of risk management planning to support early access to medicines and consider implications for improved efficiency and effectiveness of the process by end quarter four.</td>
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In addition, we are committed to:

- improvements in management of follow up across the NHS;
- working effectively with other regulators in the EU and internationally to ensure we transmit timely, high-quality information; and
- contributing to any national or international crisis management on emerging pathogens.
4. Secure global supply chains

As the medicines and devices industries have become increasingly globalised, it 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.

One of our top priorities this year is:

To secure global supply chains for medicines and medical devices through global strategic alliances, including harmonisation of standards, information sharing, inspection and enforcement, underpinned by programmes to educate the public on the dangers of falsified medicines and fake medical devices.

Our work in this area covers:

- Oversight of comprehensive inspection programme
- Ensuring compliance with standards that apply to the manufacture and supply of medicines and medical devices on the UK market
- Enforcement of medicines and medical devices legislation
- Developing international standards and reference materials for biologics
- Wider efforts to address falsified medicines and fake medical devices

**Figure 5 – Aim 4: Secure global supply chains**

**Oversight of comprehensive inspection programme**

The Agency gives consumers confidence in the quality and safety of their medicines through a global and domestic, effective and robust inspection regime which ensures adherence to mandatory guidelines and protocols.

Key commitments this year include:

- progress implementation of the signed mutual reliance initiative with U.S. FDA for acceptance of UK and U.S. inspection standards;
- continuing the role of chair of the Pharmaceutical Inspection Co-operation Scheme; and
- work associated with the International collaboration of Medicines Regulatory Authorities.
**Compliance with pharmacopoeial standards**

The Agency also gives consumer confidence in medicines through the development and use of robust pharmacopoeial standards.

Key commitments this year include:

- publishing the consultation outcomes on our ‘Strategy for pharmacopoeial public quality standards for biological medicines’ and then implementing it;
- ongoing support for the WHO’s initiative on Good Pharmacopoeial Practices to harmonise working practices and standard setting processes;
- progressing international inspectorate and pharmacopoeia staff exchange programmes (e.g. with India and/or China); and
- more generally, to further build international and domestic collaborative initiatives to promote global appetite to adopt harmonised standards and to influence international activities and regulatory direction that help further secure global supply chains of medical products (e.g. with China, USA, India and Europe).

**Enforcement of medicines and medical devices legislation**

Further, the Agency gives consumers confidence in medicines and medical devices through appropriate and timely enforcement action to combat criminal and fraudulent activity that contravenes legislation and or presents a risk to public health.

Key commitments this year include:

- ongoing international annual initiative to raise awareness of the dangers of purchasing medicines and medical devices via the illegitimate/unprotected supply chain;
- expansion of investigation into diversion of medicines from the legal to the illegal supply chain; and
- development of an intelligence picture for medical devices.

**International standards and reference materials for biologics**

As the world’s leading developer and supplier of the international standards and reference materials necessary to underpin accurate measurement and consistent manufacture of biologics, NIBSC’s work is central to increasing global access to high quality products, and supporting the development of new medicines.

Specific deliverables in 2017-18 include:

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<th>4a</th>
<th>Completion of programme to support the clinical safety and efficacy of biopharmaceuticals through developing WHO International Measurement Standards by end quarter three.</th>
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<td>4b</td>
<td>Provision of vaccine candidate strains and potency reagents to support timely supply of influenza vaccines for Northern and Southern Hemispheres by end quarter four.</td>
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<td>4c</td>
<td>Support the polio eradication programme by ensuring ability to prepare and distribute suitable reference materials post eradication, provide vaccine control/vaccine development and environmental surveillance by end quarter four.</td>
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<td>4d</td>
<td>Support and facilitate innovation in the development of safe and efficacious Advanced Therapies through Accession, Characterisation, Banking and distribution of three EUTCD (Clinical) grade embryonic stem cell lines suitable for use in clinical trials by end quarter four.</td>
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<td>4e</td>
<td>Promote and establish the role of biological activity standards in the regulatory framework for monoclonal antibodies, and to confirm their importance in controlling the potency and efficacy of these medicines through development of WHO international reference standards for</td>
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</table>
Rituximab and Infliximab by end quarter four.

Develop new reference materials for Emerging infections, e.g. Ebola, Zika, MersCoV, identified by WHO and the UK’s Vaccine Network by end quarter four.

In addition, we are committed to:

- developing a forum of public sector stakeholders to drive forward the defence of the role of public standards in the Bio-similars environment; and
- implementing a strategy for Biological Quality Standards.

Wider efforts to address falsified medicines and fake medical devices

Lastly, there are wider initiatives to address the dangers of falsified medicines and fake medical devices, including programmes to educate the public.

Specific deliverables in 2017-18 include:

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<td>4f</td>
<td>Develop new reference materials for Emerging infections, e.g. Ebola, Zika, MersCoV, identified by WHO and the UK’s Vaccine Network by end quarter four.</td>
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In addition, we are committed to:

- putting in place the legislation requiring the FMD safety features for medicines packaging by February 2019;
- strengthening collaboration with DH, EMA and other stakeholders to mitigate risk of medicines shortages;
- continuing to support DH roll out of global GS1 and PEPPOL (Pan European Public Procurement On-Line) standards for medical devices to support e-procurement as a key enabler for ‘track and trace’ activity⁸; and
- taking a decision on signing of Medicrime Convention by year-end.

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⁸ This would involve hospitals scanning barcodes on the patient wristband and on the device, into the patient record, to enable product safety recalls to be managed, facilitating prompt recall of affected patients upon receipt of a product recall notice, together with identification and isolation of faulty products. (Source – “DH GS1 and PEPPOL standards in Health Care - Demonstrator sites” (June 2015)
5. Organisational excellence

Organisational excellence is key to innovating internally, delivering an excellent service in a competitive environment, and fostering innovation in the UK life sciences sector.

It is divided into the five key areas noted above, which are further described in relevant sub-sections below.

5A – People strategy

The Agency seeks to establish ourselves as an employer of choice, with a complement of people and a sustainable pipeline to meet the needs of an expert, innovative organisation which is adaptive to changing requirements.

One of our top priorities this year is:

To make the Agency a good place to work for our staff, including managing a seamless transition to our new accommodation at the Government Hub at Canary Wharf in 2018 in a way which maximises our employees’ input to working practices / design and maintains a high quality service to our customers.

Specific deliverables in 2017-18 include:
5Ai  Upskilling recruiting managers in the principles and practice of good recruitment including selection techniques, and issues such as equality and diversity by end quarter three.

5Aii  Progress the talent management strategy with milestones including roll out of career pathways, succession planning and leadership development throughout quarters three and four.

5Aiii Complete implementation of the Oracle HR Information system with related operational efficiencies, improvements in data quality and workforce informatics and related planning by end quarter four.

In addition, we are committed to:

- developing and implementing a long-term apprenticeship approach which supports the Agency’s skills requirements and meets the Civil Service target (HR)
- increasing awareness of the entire reward package (financial and non-financial) available to staff

5B – Operational transformation

We are in the process of developing and delivering an operational transformation plan to manage the introduction of flexible modern applications and a shift to digital platforms which will enable an enhanced customer experience.

This is sub-divided into:

- **Customer experience**: continue to put the customer at the heart of our businesses, increasing customer responsiveness through a new customer experience strategy - using the opportunities of digital investment and applying new Government Digital Service (GDS) design standards - to provide more customer focused and easy to access services for patients, healthcare professionals, and industry

- **Data/information**: integrating and transforming business and data management systems, processes and applications to increase capabilities and reduce burdens on staff

- **Service optimisation**: working with DH on wider digital health technologies agenda, replace the legacy technologies and platforms that are at end of life and use the opportunity to review and change services and processes in support of the Agency’s public health remit

- **Foundation Services**: deliver the underpinning infrastructure, platforms and capabilities to support the delivery and operation of the new services and ways of working.

The implementation of digital technologies provides the Agency with the opportunity to redefine services, change processes and gain efficiencies.

One of our top priorities this year is:

*Through our operational transformation programme, to deliver a portfolio of improvements for our staff and our customers, which build on our position as an outstanding regulator and establishes the Agency at the leading edge of digital technology.*

Specific deliverables in 2017-18 include:

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9 As we consider each business case to replace and upgrade services, we will scrutinise the benefits identified on a case by case basis as part of that process.
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<th>Service optimisation</th>
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In addition, we are committed to:

- building **digital, data and technology capability to:**
  - reform IT IMD to be capable of delivering transformation;
  - develop IT IMD staff to manage an excellent IT supply chain;
  - support the agency in improving digital, information and PPM skills;

- developing and maintaining digital services for our users that meet Government service standards and receive digital spend control approval as appropriate; and

- continuously exploring opportunities for further efficiencies: embedding digital services within the Agency; implementing the Agency’s efficiency programme; maximising synergies within the various functions of the Agency and closer working with other system players.

**5C – Finance and commercial strategy**

Our aim is to continue to strengthen the Agency’s financial resilience and explore opportunities to grow revenues and export the Agency’s expertise. This includes investing in the agency’s public health influence and impact across regulation, science and the use of real-world data.

One of our top priorities this year is:

**To secure sustainable funding to improve the allocation of resources between industry and wider Government in medical devices regulation.**

Specific deliverables in 2017-18 include:

| 5Ci | Securing sustainable funding for the regulation of Medical Devices, including considerations of options to introduce a new fees regime throughout the year ahead. |
| 5Cii | Development of a dedicated Agency evidence store at the NIBSC site by end quarter one. |
| 5Ciii | Consider and consult on any changes to medicines and other existing fees throughout quarters two and three with the aim of introducing any appropriate changes by 1 April 2018. |
| 5Civ | Continue to maximise external revenue potential - deliverables:  
  - refresh of NIBSC’s 5 year Financial Model by end quarter two;  
  - further developing and evolving the new Grants Office by end quarter three; and  
  - delivery of agreed pharmacopoeial revenue share standards programme by end quarter four. |
| 5Cv | Deliver the agency budget for 2016-17, refresh all aspects of the strategic financial elements of the Corporate Plan and establish the financial framework to enable investments to proceed by end quarter four. |

**5D – Regulatory Excellence**

We seek to improve the quality of regulatory policy making and delivery across the Agency - championing proportionate regulation, whilst bringing innovative products to market safely and quickly. This includes responding to the Business Impact Target to reduce regulatory burdens on industry and influencing the regulatory agenda in the UK, Europe and globally.

Specific deliverables in 2017-18 include:

| 5Di | Embed robust process for regulatory policy development and delivery across the Agency |
to ensure high quality regulation and robust engagement with partners throughout the year ahead.

5Dii Work with partners to develop a model for regulation in the post-Brexit environment throughout the year ahead.

5Diii Complete by end August post-implementation review of the HMRs 2012 to ensure implementation has been effective and proportionate, and make any appropriate changes by end quarter two.

5Div Work closely with industry to develop and deliver proportionate regulation – including any monetisable savings within the DH Business Impact Target and any possible savings from the way we produce and amend our guidance in 2017/18 return by end quarter four.

5E – Communications and reputation strategy

Our aim is to continue to build the agency’s reputation and profile as a leading global regulator, and for science and research, and maximise opportunities to market, promote and develop our products and services so they continue to meet changing customer needs and exceed expectations.

Specific deliverables in 2017-18 include:

5Ei Develop new marketing and communications plan for the Innovation Office and the Regulatory Advice Service for Regenerative Medicine by end quarter one.

5Eii Implementing consistent use of brand guidelines throughout CPRD branding throughout the year ahead.

5Eiii Within the Joint Patient Safety Strategy, deliver key Project on improving Risk throughout quarters two to four.

5Eiv As part of the new marketing plan for the Agency, carry out customer insight research for BP by end quarter two, NIBSC by end quarter three, and Licensing by end quarter four.

5Ev Review the Agency’s brands and brand positioning by end quarter three.

5Evi Develop communications package to promote the Agency as a centre of expertise for Advanced Therapies and celebrate the success of NIBSC by end quarter four.

5Evii Transfer NIBSC to the same ISO 9001 certification body, as the rest of the Agency, to streamline our processes and ensure one cohesive quality management system by end quarter two.

5Eviii Then, update Agency from ISO 9001:2008 certification to updated standard ISO 9001:2015 to reflect changes to current business thinking and improve our ways of working by end quarter four.

In addition, we are committed to:

- supporting communications around the implementation of the Clinical Trials Regulations;
- continuing to build employee communications and effective engagement in the areas of change management, accommodation, digital capability and smart working; and
- supporting the Digital Transformation and Workplace programme with internal communications.
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 components for transfusion in the UK and the British Pharmacopoeia (BP). 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 marketplace 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.

Licensing

The Licensing division within MHRA is responsible for assessing and approving applications for national and European marketing authorisations. These may be for new medicinal products (new active substances), new routes of administration or new formulations of existing drugs, generic drugs, parallel import applications, or herbal and homeopathic products.

In addition, the Licensing division has the responsibility for assessing and granting clinical trial authorisations. The division is also responsible for the Early Access to Medicines scheme. The work of the division is fully supported by a dedicated European Service Management function, including the Centralised Procedure and Mutual Recognition and Decentralised teams.

The Licensing division also acts as one of the national competent authorities for the consultation by a Notified Body for devices which incorporates a medicinal product. The division supports innovation through provision of a scientific advice service and hosts the Innovation Office and RASRM which also support academic groups and SMEs in navigating the regulatory framework.

Core business in 2017/18 will include:

- continuing its regulatory work of assessing new marketing authorisation and variation submissions for all chemical and biological medicinal products within high level targets;
- national, herbal, homeopathic, parallel import applications and Notified Body consultations being assessed within appropriate timescales;
- ensuring the operational efficiency of the independent scientific expert advisory structure to provide full and appropriate advice to the licensing authority and to ensure any decisions made are robust;
- continuing to provide a full range of regulatory and scientific advice service to stakeholders, including via the provision of national scientific advice, Committee for Medicinal Products for Human Use (CHMP) Scientific Advice Working Party, the Regulatory Information Service, and the clinical trials helpline; and
- responding to Freedom of Information requests and official correspondence and publishing UK public assessment reports for new marketing authorisations and major non-safety variations of clinical importance within target times.
Vigilance and Risk Management of Medicines (VRMM)

The purpose of VRMM is to protect public health by promoting the safe use of marketed medicines and undertaking planned risk management for new medicines, including those for children, supported with high quality product information. The division undertakes a variety of important initiatives in relation to pharmacovigilance and risk management of medicines, in particular the development of the Yellow Card Scheme, our early warning system for the identification of previously unrecognized adverse drug reactions.

Core business in 2017/18 will include:

- identifying safety signals from reporting data and other sources, assessing benefit-risk and implementing risk-proportionate action, pursuing a strategy to align (where appropriate) systems for medicines and devices;
- using real world data to evaluate signals and conduct critical appraisals of benefit risk, and to carry out outcome studies following medicines regulatory action;
- providing high quality information for healthcare professionals and patients and communicating updates through a range of media, improving guidance for industry and involving patients;
- making more medicines more widely available, both for self-medication and by ensuring the delivery of better medicines for children through implementation of the EU Paediatric Regulation; and
- operationalising the role of the Agency as Competent Authority under the Tobacco Products Directive.

Inspection, Enforcement & Standards (IE&S)

IE&S are responsible for ensuring compliance with the standards that apply to the manufacture and supply of medicines on the UK market. This is achieved by licensing, inspection and enforcement across the full lifecycle of medical products, including manufacturers, wholesale dealers and importers of medicines, distance sellers of medicines and by inspecting clinical trials, toxicology laboratories and pharmacovigilance systems.

Core business in 2017/18 will include:

- collaboration across Inspection, Enforcement and British Pharmacopoeia as part of an international strategy;
- the Inspectorate driving regulatory compliance through its programme of risk based inspections undertaken in the UK and overseas, whilst reacting to and containing any critical incidents;
- Enforcement developing strategies and taking action, as necessary, including reactive, proactive and multi-agency initiatives including the annual Operation Pangea;
- the British Pharmacopoeia and Laboratory Services Group progressing development of its content, products and services to meet the evolving needs of our users across the globe;
- the Divisional Business Unit seeking continuous improvement in stakeholder service to industry, managing a range of applications, and working to progress the Divisional Transformation project across IE&S business; and
- the Regulatory Assessment Unit continuing to oversee changes to legislation, managing Inspection Action Group and defective medicine referrals and its Borderline Section undertaking determinations of product status.
**Devices**

Devices division’s purpose is to optimise, enhance and improve patient outcomes through risk based regulation and dynamic innovation of medical devices.

As Competent Authority for medical devices in the United Kingdom, core business in 2017/18 will include:

- designating and auditing Notified Bodies for their competence to fulfil their regulatory responsibilities\(^\text{10}\);
- monitoring the medical devices market for compliance with regulatory requirements and for compromises to human health or safety arising from a device or group of devices;
- taking appropriate response to issues arising from monitoring and surveillance;
- registering manufacturers of Class 1 devices and custom made devices; and
- authorising clinical investigations.

**Clinical Practice Research Datalink (CPRD)**

CPRD, jointly funded by the MHRA and the National Institute of Health Research (NIHR), is the UK’s preeminent research service providing access to anonymised NHS data for public health research. CPRD services are designed to maximise the way anonymised NHS clinical data can be used to improve and safeguard public health. In addition to supporting high quality observational research, CPRD is developing world leading services based on using real world data to support clinical trials and intervention studies.

2017-18 activities of note in addition to strategic work in the business plan will include:

- in collaboration with the Royal College of GPs, CPRD will provide feedback on drug prescribing, at an individual patient level, to GP practices contributing to CPRD;
- promoting the uptake of CPRD’s innovative services supporting real world post marketing pragmatic trials;
- significantly increasing the amount of data available to support observational and interventional research; and
- commencing the development of a joint research strategy with Vigilance and Risk Management of Medicines division.

**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.

2017-18 activities of note in addition to strategic work in the business plan will include:

- continuing to meet our statutory requirement to develop and supply analytical methods and

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\(^{10}\) This includes overseeing the notifiable bodies that assess decontamination units providing services to other organisations.
internationally approved measurement standards for biological medicines in conjunction with WHO and other global partners, including those standards that support innovative biological medicines and diagnostic tests, such as advanced therapies, next generation sequencing for diagnosis, and biosimilar medicines;

• continuing to build synergistic links with the British Pharmacopeia, working closely with other global standards organisations (in particular Europe, United States, China, South Korea) to promote the need for harmonised approaches to assuring the quality of biological medicines, whilst seeking to build the global reach and influence of our standards;

• continuing to 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\textsuperscript{11};

• maintaining a broad-based relevant and peer-reviewed regulatory science research programme, achieving the deliverables of the Regulatory Science Research Unit (RSRU) programme and using this as a platform to attract additional external support for work relevant to our standardisation and control mission and to increase income we have available to support important research and collaborations with key academic partners; and

• continuing 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.

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, DH, 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, Finance and Procurement delivers effective and efficient credit control, cash management and the allocation of sales receipts.

Core business in 2017/18 will include:

• continuing 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;

• continuing 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;

• continuing 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

\textsuperscript{11} This will include developing new capacity for testing medicines in line with anticipated demand, aiming to ensure that the UK retains broad expertise in medicines testing that can be deployed in the event of health emergencies or problems relating to biologics and exploring the possibility of becoming an EU Reference Laboratory for in vitro diagnostic devices.
sure appropriate contracts are put in place to mitigate risk; and

- maintaining close relations with the DH, its Arms’ Length Bodies and Cabinet Office functions to maintain compliance with legislation and Government policy.

**Human Resources**

The HR division supports the Agency in the management of its key resource – its people. The division will implement the People Strategy with a particular focus on the utilisation of workforce related intelligence (hard and soft data) to inform tactical and strategic decision making and linked activities.

Core business in 2017/18 will include:

- *workforce planning and resourcing* - ensuring we retain and attract the skilled resources needed to deliver Agency aims through robust workforce / succession planning;
- *performance, leadership & management* - ensuring our leadership and management community are skilled at setting future direction, engaging people, developing capability, and effectively managing performance at all levels;
- *training & development* - ensuring we develop skilled people through access to ongoing development;
- *talent and career management* – ensuring the Agency identifies and develops its managers of the future, including people with leadership potential; and
- *reward, recognition and engagement* – ensuring a reward package that attracts, motivates and retains staff and recognises the contribution staff make individually and as teams, so the Agency is seen as a great place to work.

**Information Management**

In addition to the Digital Strategy delivery, the Information Management division will be undergoing reform to deliver the Operational Transformation of the agency.

Core business in 2017/18 will include:

- IT service and commercial management in a multi-source model;
- integration of NIBSC into the IT Operating Model;
- information management and strengthening cyber security;
- applying data and information standards;
- delivering new digital services and technology;
- leadership and coordination of programme and project management (PPM); and
- re-focussing existing Information Processing Unit (IPU) service provision, through the IPU Reform programme, around three distinct service components: customer care services, data guardian services and validation services.

**Policy:**

The Policy division will continue to help the Agency to deliver its responsibilities for DH and wider Government policy and objectives. This will include ensuring the Agency delivers timely answers to Parliamentary Questions (PQs), Freedom of Information Act (FOIA) requests and administrative complaints - working together with the operational divisions of the Agency - as well as leading robust policies and processes for business continuity and fraud management.
Core business in 2017/18 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, progressing UK objectives in the negotiation of EU legislation and actively managing implementation of EU legislation on clinical trials, medical devices and the Falsified Medicines Directive;
- supporting and coordinating Agency input into key strategic initiatives at EU and international level, including work on the operational and financial sustainability of the EU regulatory network and as ICMRA secretariat;
- continuing to help the Agency deliver its responsibilities and priorities effectively through working constructively across the Agency and with partners in the health and care system, across Whitehall and with the Devolved Administrations; and
- continuing to ensure the Agency offers a high-quality service and accounts to Ministers for delivery of priorities and targets in line with the DH remit letter.

Communications:

Communications division will continue to develop and deliver high-quality, targeted communications and marketing activities, managing communications channels and content, and reaching our audiences to achieve the desired action and impact. This is underpinned by the Agency’s communications and reputation strategy. We’ll do this by continuing to put account management at the centre of our approach.

Core business in 2017/18 will include:

- anticipating and managing the communications aspects of Agency issues and crises, particularly those of a high profile attracting media and social media interest;
- planning targeted content that is creative, relevant, targeted, considered authoritative and acted on as required;
- generating business for the Agency through effective marketing, generating income through our events programme, and supporting the agency’s growth agenda;
- handling all enquiries, safety and risk communications to a high standard, and improving the whole Agency’s approach to customer service;
- effectively supporting the scientific and regulatory work of the Agency by providing a high-quality customer-focused library and information service;
- bringing customer and stakeholder insight into the Agency, and using this to develop products and services to meet customers’ needs, and support the Agency’s Digital Transformation Strategy;
- helping the organisation to effectively manage external relationships, with an emphasis on thought leadership, partnership and collaborative working;
- supporting effective employee communications, facilitating two-way discussion and engagement with our staff;
- maximising the use of digital channels and actively improving digital capability;
- providing effective governance of communications and digital spend; and
- evaluating the effectiveness and outcomes of our work using appropriate metrics and building on this for the future.
### Annex A – Strategic objectives for 2017-18

#### i. Overview of Corporate Plan strategic aims / allocation of supporting objectives

<table>
<thead>
<tr>
<th>Aim 1 – Vision, scope and partnerships</th>
<th>Building partnerships, collaboration and engagement*</th>
<th>Developing our 2018-23 corporate plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progressing our post-Brexit strategy*</td>
<td>International strategy</td>
<td>New five year Corporate Plan which will facilitate Agency’s updated model of operation in the post-Brexit landscape</td>
</tr>
<tr>
<td>▪ HMG Brexit negotiation support</td>
<td>▪ EU</td>
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<tr>
<td>▪ European engagement strategy</td>
<td>▪ Enhanced national strategy</td>
<td></td>
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<tr>
<td>▪ Optimal UK regulation strategy</td>
<td>▪ HMG, DH and its supporting agencies / public bodies</td>
<td></td>
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<tr>
<td>▪ Commercial development strategy</td>
<td>▪ Devolved Administrations (DAs)</td>
<td></td>
</tr>
<tr>
<td>▪ Communications and marketing strategy</td>
<td>▪ Industry</td>
<td></td>
</tr>
<tr>
<td>*These strategic objectives relate to post-Brexit context</td>
<td>▪ Academia / science base</td>
<td></td>
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<td></td>
<td>▪ Healthcare professionals</td>
<td></td>
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<tr>
<td></td>
<td>▪ Public / patients</td>
<td></td>
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<tr>
<td>▪ International strategy</td>
<td>▪ New five year Corporate Plan which will facilitate Agency’s updated model of operation in the post-Brexit landscape</td>
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<tr>
<td>▪ EU</td>
<td>▪ Enhanced national strategy</td>
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<tr>
<td>▪ Enhanced national strategy</td>
<td>▪ HMG, DH and its supporting agencies / public bodies</td>
<td></td>
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<tr>
<td>▪ Devolved Administrations (DAs)</td>
<td>▪ Industry</td>
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<tr>
<td>▪ Industry</td>
<td>▪ Academia / science base</td>
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<tr>
<td>▪ Academia / science base</td>
<td>▪ Healthcare professionals</td>
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<td>▪ Public / patients</td>
<td>▪ New five year Corporate Plan which will facilitate Agency’s updated model of operation in the post-Brexit landscape</td>
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</table>

#### Aim 2 – Enabling innovation

<table>
<thead>
<tr>
<th>Supporting Innovation and Growth in Life Sciences</th>
<th>Innovative regulatory and legislative measures</th>
<th>Real world evidence / big data</th>
<th>Priority areas of scientific development, research and horizon scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Accelerated Access Review</td>
<td>▪ Clinical Trials</td>
<td>▪ CPRD</td>
<td>▪ Horizon scanning</td>
</tr>
<tr>
<td>▪ EAMS</td>
<td>▪ Devices</td>
<td>▪ FDA/21st Century Cures Act</td>
<td>▪ Genomics/stratified medicine</td>
</tr>
<tr>
<td>▪ EU PRIME and Medicines Adaptive Pathways to Patients (MAPPs)</td>
<td>▪ Repurposing of old medicines for new uses</td>
<td>▪ Joint work with NICE on:</td>
<td>▪ Software, apps and artificial intelligence</td>
</tr>
<tr>
<td>▪ Innovation Office &amp; Regulatory Advice Service for Regenerative medicine (RASRM)</td>
<td>▪ Re-classification / self-medication</td>
<td>▪ MIT NEWDIGS</td>
<td>▪ Regenerative medicine/Advanced Therapies</td>
</tr>
<tr>
<td>▪ Medicines Manufacturing industry partnership</td>
<td></td>
<td>▪ IMI Projects</td>
<td>▪ Dementia</td>
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<tr>
<td>▪ Advanced Therapy Manufacturing taskforce</td>
<td></td>
<td>▪ EMA initiative on registries</td>
<td>▪ Anti-microbial resistance</td>
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<tr>
<td>implementation</td>
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<td>▪ HMA/EMA Big Data Taskforce</td>
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<td></td>
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<td>▪ Work on IMDRF Registries</td>
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<td>▪ GS1 initiatives to develop safety signal detection capability</td>
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</table>

*These strategic objectives relate to current commitments, some of which simultaneously facilitate the transition to post-Brexit context*
<table>
<thead>
<tr>
<th>Aim 3 – Vigilance</th>
<th>Aim 4 – Secure global supply chains</th>
<th>Aim 5 – Organisational excellence</th>
</tr>
</thead>
</table>
| ▪ Patient, safety and vigilance strategy  
  o Safety reporting / evidence  
  o Signal detection and management  
  o Analysis / assessment  
  o Risk management and communication | ▪ Oversight of comprehensive inspection programme  
  ▪ Compliance with pharmacopoeial standards  
  ▪ Enforcement of medicines and medical devices legislation  
  ▪ International standards and reference materials for biologics  
  ▪ Wider efforts to address falsified medicines and fake medical devices | ▪ People strategy  
  ▪ Operational transformation  
    o Data/information  
    o System optimisation  
    o Customer experience  
  ▪ Finance and commercial strategy  
  ▪ Regulatory Excellence strategy  
  ▪ Communications strategy |
### A - ii. Collated strategic deliverables

<table>
<thead>
<tr>
<th>Ref</th>
<th>Deliverables</th>
<th>Due Date</th>
<th>Lead division / centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIM 1 – Vision, scope and partnerships</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1a</td>
<td>Develop proposed model for future regulation of medicines and medical devices in the UK which protects public health, drives innovation, minimises burden on industry and makes the UK an attractive global regulator.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1b</td>
<td>Develop clear programme for implementing Innovation Plan, with focus on projects which can contribute to UK growth</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1c</td>
<td>Support Brexit Taskforce in delivering a stakeholder and customer engagement strategy</td>
<td>Q1-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>1d</td>
<td>Increase contacts within patient representative and strategic stakeholder organisations across the EU as part of the Brexit engagement and strategic stakeholder strategy work.</td>
<td>Q1-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>1e</td>
<td>Within new Brexit context, refresh and deepen the agency’s commercial and international work in a way which works for both industry and the Agency.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1f</td>
<td>Provide effective chairmanship and secretariat of International Coalition of Medicines Regulatory Authorities (ICMRA), setting clear strategic direction and agreed governance arrangements.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1g</td>
<td>Develop deeper relationships with key countries (e.g. China and India) and, in a Brexit context, other leading global regulators as part of a coherent international strategy.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1h</td>
<td>Reinforce networks outside EU by expanding International Medical Device Regulators Forum (IMDRF) and bilateral relationships outside EU, including FDA, throughout the year through (a) development and publication of successive IMDRF event terminology and (b) identification of new IMDRF working groups and shared areas for future collaboration</td>
<td>Q1-Q4</td>
<td>Devices</td>
</tr>
<tr>
<td>1i</td>
<td>Continue to engage in Heads of Medicines Agencies (HMA) discussions, including leadership of the innovation workstream, input to other project areas and support to EU Telematics/IT strategy. Deliver updates on the innovation workstream at all HMA meetings in 2017/18.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>1j</td>
<td>In line with Tobacco Products Directive / E-Cigarettes legislation, implement a system to check and publish e-cigarette notifications and safety reports by June 2017.</td>
<td>Q1</td>
<td>VRMM</td>
</tr>
<tr>
<td>1k</td>
<td>Broaden strategic relationship with Ireland with aim of formalising through written agreement</td>
<td>Q2</td>
<td>Devices</td>
</tr>
<tr>
<td>1l</td>
<td>Establish an EU combined working group of medicines and medical device regulators on borderlines and combination products with willing parties to develop a consistent approach to regulation</td>
<td>Q3</td>
<td>Devices</td>
</tr>
<tr>
<td>1m</td>
<td>Refresh the Patient and Public Engagement Strategy to build on existing forums of patient engagement (UK Reclassification Platform; Patient Group)</td>
<td>Q2</td>
<td>Comms</td>
</tr>
<tr>
<td>1n</td>
<td>Establish a regular engagement forum with academic and research organisations</td>
<td>Q1</td>
<td>Comms</td>
</tr>
<tr>
<td>1o</td>
<td>Put in place a strategic stakeholder strategy to formalise the management of the Agency’s engagement with strategic stakeholders</td>
<td>Q2</td>
<td>Comms</td>
</tr>
<tr>
<td>1p</td>
<td>Working across the Agency and with key strategic stakeholders, develop a new corporate plan for the Agency for 2018-2023 which responds to the changing landscape introduced by the EU referendum and positions the Agency as a strong national regulator in a global environment</td>
<td>Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>Ref</td>
<td>Deliverables</td>
<td>Due Date</td>
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<tr>
<td><strong>AIM 2 – Enabling innovation</strong></td>
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<tr>
<td>2a</td>
<td>For the MMIP regulatory workstream, develop a paper that demonstrates how companies can use regulatory flexibilities in relation to manufacturing, licensing and inspection.</td>
<td>Q2</td>
<td>IE&amp;S</td>
</tr>
</tbody>
</table>
| 2b | Commence implementation of the new Medical Device and IVD regulations through:  
• establishing plans, governance arrangements and transition guidance (by Q1);  
• supporting production of collaborative guidance and tertiary legislation through proactive input into EU and Member State fora (Q4); and  
• revising MHRA processes and policy development on Member State derogations (Q4) | Q1-Q4 | Devices |
<p>| 2c | Promote increased collaboration between MHRA and the Health Research Authority to ensure balanced and risk based regulation of clinical trials | Q4 | Licensing |
| 2d | Evaluate the effectiveness of the changed regulatory process for reclassification of medicines. | Q4 | VRMM |
| 2e | Expand routine data linkage to include data from GP practices using EMIS software | Q3 | CPRD |
| 2f | Progress work with pragmatic trials to achieve one ongoing trial plus one new study with a signed contract | Q4 | CPRD |
| 2g | Strengthen horizon scanning function through recruitment, delivery of 2016/17 report and prioritised action plan for 2017/18 | Q4 | NIBSC |
| 2h | Now the newly established specialist sequencing resource is available, apply it to cutting edge research projects across the divisions | Q3 | NIBSC |
| 2i | Lead research to facilitate the development and evaluation of new bacterial vaccines | Q4 | NIBSC |
| 2j | Deliver a study of immune responses in the humanised mouse immune system model for investigation of a range of biologics, including for example stem cells, immune-check-point tumour therapeutics, novel targeted adjuvants, and vaccines against human pathogens such malaria and tuberculosis. | Q4 | NIBSC |
| 2k | Evaluate and establish novel approaches for studying the role of the gut microbiome in human disease | Q3-Q4 | NIBSC |
| <strong>AIM 3 – Vigilance</strong> | | | |
| 3a | Grow digital safety reporting by working with Government Digital Service on delivery of a mobile responsive website and platform for adverse drug reactions; falsified and defective medicines; and medical devices. | Q4 | VRMM / Devices |
| 3b | Development of mobile friendly reporting and a formalised signal detection methodology for devices during 2017 and into 2018. | Q4 | Devices |
| 3c | Work with NHS Improvement to agree a joint approach to developing a successor system to National Reporting and Learning System (NRLS), based on opportunities coming out of the development of the Patient Safety Incident Management System (PSIMS) Project. | Q1 | VRMM / Devices |
| 3d | Work with the Patient and Public Engagement Expert Advisory Group to advise on the development of new guidance on the provision of high quality information for patients, following publication of a report on shortcomings with some statutory information. | Q4 | VRMM |
| 3e | Agree deliverables around a common approach to benefit risk assessment following a mapping exercise on how signals are handled | Q1 | VRMM / Devices |
| 3f | Continue to develop work on a joint strategy with CPRD on use of real world data to improve vigilance capability | Q4 | Devices / VRMM |</p>
<table>
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<tbody>
<tr>
<td>3g</td>
<td>Organise a health summit of key stakeholders in Q1 to begin to formulate how all forms of safety messages to the healthcare system can be better targeted to result in action to improve patient safety</td>
<td>Q1</td>
<td>Comms</td>
</tr>
<tr>
<td>3h</td>
<td>Establish internal consensus on drug device combination products through publishing updated guidance notes, aimed at Industry and Notified Bodies</td>
<td>Q1</td>
<td>Licensing</td>
</tr>
<tr>
<td>3i</td>
<td>Publish guidance on Human Factors of Medical Device and Combination Products</td>
<td>Q2</td>
<td>Devices</td>
</tr>
<tr>
<td>3j</td>
<td>Review experience of risk management planning to support early access to medicines and consider implications for improved efficiency and effectiveness of the process</td>
<td>Q4</td>
<td>VRMM</td>
</tr>
<tr>
<td>AIM 4 – Secure global supply chains</td>
<td></td>
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</tr>
<tr>
<td>4a</td>
<td>Completion of programme to support the clinical safety and efficacy of biopharmaceuticals through developing WHO International Measurement Standards</td>
<td>Q3</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4b</td>
<td>Provision of vaccine candidate strains and potency reagents to support timely supply of influenza vaccines for Northern and Southern Hemispheres</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4c</td>
<td>Support the polio eradication programme by ensuring ability to prepare and distribute suitable reference materials post eradication, provide vaccine control/vaccine development and environmental surveillance</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4d</td>
<td>Support and facilitate innovation in the development of safe and efficacious Advanced Therapies through Accession, Characterisation, Banking and distribution of three EUTCD (Clinical) grade embryonic stem cell lines suitable for use in clinical trials</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4e</td>
<td>Promote and establish the role of biological activity standards in the regulatory framework for monoclonal antibodies, and to confirm their importance in controlling the potency and efficacy of these medicines through development of WHO international reference standards for Rituximab and Infliximab</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4f</td>
<td>Develop new reference materials for Emerging infections, e.g. Ebola, Zika, MersCoV, identified by WHO and the UK’s Vaccine Network</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>4g</td>
<td>Secure approval for business case for continuing the UK communications campaign on ‘Fake Medical Products’ to increase public awareness of the dangers of purchasing medicines and medical products outside of the legitimate supply.</td>
<td>Q1</td>
<td>Comms</td>
</tr>
<tr>
<td>4h</td>
<td>Provide clear governance arrangements for the implementation of FMD safety features across the UK.</td>
<td>Q1-Q3</td>
<td>Policy</td>
</tr>
<tr>
<td>4i</td>
<td>Supervision of SecurMed (industry’s UK Medicines Verification Organisation) for the implementation of FMD safety features.</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>4j</td>
<td>Deliver communications work plan on substandard / spurious / falsely-labelled/ falsified medical products.</td>
<td>Q1-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>AIM 5 – Organisational excellence</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5A</td>
<td>People strategy</td>
<td></td>
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<tr>
<td>5Ai</td>
<td>Upskilling recruiting managers in the principles and practice of good recruitment including selection techniques, and issues such as equality and diversity</td>
<td>Q3</td>
<td>HR</td>
</tr>
<tr>
<td>5Aii</td>
<td>Progress the talent management strategy with milestones including roll out of career pathways, succession planning and leadership development.</td>
<td>Q3-Q4</td>
<td>HR</td>
</tr>
<tr>
<td>5Aiii</td>
<td>Complete implementation of the Oracle HR Information system with related operational efficiencies, improvements in data quality and workforce informatics and related planning.</td>
<td>Q4</td>
<td>HR</td>
</tr>
<tr>
<td>Ref</td>
<td>Deliverables</td>
<td>Due Date</td>
<td>Lead division / centre</td>
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<tr>
<td><strong>5B – Operational transformation</strong></td>
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</table>
| 5Bi | Align the Digital Strategy to support Business Strategy by:  
• responding to changes in direction as a result of Brexit decisions e.g. prioritisation, European systems  
• prioritising objectives against any new direction as outlined through Operational Transformation  
• updating benefits profiles in each business case in response to a new Corporate Plan. | Q1-Q4 | IMD |
| 5Bii | Gain agreement to implementation of a cross-Agency customer experience strategy which incorporates all three centres, undertaking comprehensive discovery work to support the strategy development | Q1 | Comms |
| 5Biii | Put in place a digital stakeholder management system, sourcing stakeholder information across the agency to assist in decision making and issue management. | Q3 | Comms |
| 5Biv | Put in place a corporate casework management system, to improve our handling of Freedom of Information (FoI) Act requests and a range of other corporate casework including: submissions and briefings to ministers, our Chief Executive and Chair, Parliamentary Questions (PQs), whistleblowing and internal fraud cases and complaints. | Q4 | IMD |
| 5Bv | Improve the cyber security and information assurance maturity of the agency through implementing the (a) recommendations of the cyber audit and (b) wider service improvement action plan | Q1-Q4 | IMD |
| 5Bvi | Maxmise benefits of the merged organisation - ensuring the IT portfolio programmes (Digital Workplace Programme (DWP) and Service Transition) enable the original requirements identified at merger to be realised. This includes shared infrastructure allowing full integration and collaboration. | Q4 | NIBSC |
| 5Bvii | Devices digital transformation:  
• implement Phase 1 (Registrations, Certificates of Free Sale and Account Management) by July 2017  
• start Phase 2 analysis (Humanitarians, Derogation, Clinical Investigations and Designation & Monitoring) by Q1 for delivery by Q4  
• phase 3 (Adverse Incidents and Signal detection) to be delivered by end Q4 | Q1-Q4 | Devices |
| 5Bviii | Deliver Digital Feasibility strategy for British Pharmacopoeia | Q1-Q4 | IE&S |
| 5Bix | Successfully transition whole Agency’s accounting (including NIBSC) to new Oracle Fusion system – including implementation of one agency approach and clearer process improvements. | Q2 | F&P |
| 5Bx | Delivering foundation services to:  
• implement digital platforms (ESB, case management, productivity, MDM)  
• remediate major issues on our infrastructure (WAN, LAN, storage, support)  
• deliver the technology strand of the accommodation move  
• transition NIBSC IT services | Q4 | IMD |
<p>| <strong>5C – Finance and commercial strategy</strong> | | | |
| 5Ci | Securing sustainable funding for the regulation of Medical Devices, including considerations of options to introduce a new fees regime | Q1-4 | Devices |
| 5Cii | Development of a dedicated Agency evidence store at the NIBSC site | Q1 | IE&amp;S |
| 5Ciii | Consider and consult on any changes to medicines and other existing fees with the aim of introducing any appropriate changes by 1 April 2018 | Q2-Q3 | Policy |</p>
<table>
<thead>
<tr>
<th>Ref</th>
<th>Deliverables</th>
<th>Due Date</th>
<th>Lead division / centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>5Civ</td>
<td>Continue to maximise external revenue potential - deliverables: Q2: refresh of NIBSC’s 5 year Financial Model; Q3: further developing and evolving the new Grants Office; and Q4: delivery of agreed pharmacopoeial revenue share standards programme</td>
<td>Q2-Q4</td>
<td>NIBSC</td>
</tr>
<tr>
<td>5Cv</td>
<td>Deliver the agency budget for 2016-17, refresh all aspects of the strategic financial elements of the Corporate Plan and establish the financial framework to enable investments to proceed.</td>
<td>Q4</td>
<td>F&amp;P</td>
</tr>
<tr>
<td><strong>5D – Regulatory excellence strategy</strong></td>
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<tr>
<td>5Di</td>
<td>Embed robust process for regulatory policy development and delivery across the Agency to ensure high quality regulation and robust engagement with partners</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>5Dii</td>
<td>Work with partners to develop a model for regulation in the post-Brexit environment</td>
<td>Q1-Q4</td>
<td>Policy</td>
</tr>
<tr>
<td>5Diii</td>
<td>Complete by end August post-implementation review of the HMRs 2012 to ensure implementation has been effective and proportionate, and make any appropriate changes</td>
<td>Q2</td>
<td>Policy</td>
</tr>
<tr>
<td>5Div</td>
<td>Work closely with industry to develop and deliver proportionate regulation – including any monetisable savings within the DH Business Impact Target and any possible savings from the way we produce and amend our guidance in 2017/18 return.</td>
<td>Q4</td>
<td>Policy</td>
</tr>
<tr>
<td><strong>5E – Communications and reputation strategy</strong></td>
<td></td>
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<tr>
<td>5Ei</td>
<td>Develop new marketing and communications plan for the Innovation Office and the Regulatory Advice Service for Regenerative Medicine.</td>
<td>Q1</td>
<td>Comms</td>
</tr>
<tr>
<td>5Eii</td>
<td>Implementing consistent use of brand guidelines throughout CPRD branding.</td>
<td>Q1-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>5Eiii</td>
<td>Within the Joint Patient Safety Strategy, deliver key Project on improving Risk</td>
<td>Q2-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>5Eiv</td>
<td>As part of the new marketing plan for the Agency, carry out customer insight research for BP (Q2), NIBSC (Q3) and Licensing (Q4)</td>
<td>Q2-Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>5Ev</td>
<td>Review the Agency’s brands and brand positioning</td>
<td>Q3</td>
<td>Comms</td>
</tr>
<tr>
<td>5Evi</td>
<td>Develop communications package to promote the Agency as a centre of expertise for Advanced Therapies and celebrate the success of NIBSC</td>
<td>Q4</td>
<td>Comms</td>
</tr>
<tr>
<td>5Evii</td>
<td>Transfer NIBSC to the same ISO 9001 certification body, as the rest of the Agency, to streamline our processes and ensure one cohesive quality management system.</td>
<td>Q2</td>
<td>NIBSC</td>
</tr>
<tr>
<td>5Eviii</td>
<td>Then, update Agency from ISO 9001:2008 certification to updated standard ISO 9001:2015 to reflect changes to current business thinking and improve our ways of working.</td>
<td>Q4</td>
<td>NIBSC</td>
</tr>
</tbody>
</table>
### Annex B – Performance targets

<table>
<thead>
<tr>
<th>No.</th>
<th>Deliverables</th>
<th>2017-18 Targets</th>
</tr>
</thead>
</table>
| PM1 | Medicines licensing – validation of applications | a) For Type IB\(^{12}\) and Type II\(^{13}\) 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 (MRP, DCP & CP) procedures: 97% assessed within the designated time  
95% of CP assessed within the designated time  
c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP, CP) 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 |

\(^{12}\) Type IB variations are minor changes to a market authorisation unlikely to have a significant impact on the quality, safety or efficacy of the medicinal product concerned which are neither a Type IA or Type II change, as defined in Commission Regulation EC 1234/2008.  
\(^{13}\) Type II variations are major changes to a market authorisation as defined in Commission Regulation EC 1234/2008, which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.
<table>
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<tr>
<th>No.</th>
<th>Deliverables</th>
<th>2017-18 Targets</th>
</tr>
</thead>
</table>
| PM6 | Standards and control | a) Biologics standards supply – a maximum average response time of 6.0 working days for all standards despatches  
b) Batch release activity – 99% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines:  
  - 10 days for Plasma Pools  
  - 10 days for Parenterals  
  - 15 days for Haemostasis  
  - 95% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: 60 days for vaccines |
| PM7 | CPRD activity | a) 90% of research applications to receive initial feedback from ISAC review within 21 working days  
b) Expand coverage to 1200 contributing GP practices across the UK  
c) Increase the number of CPRD licence holders to 52 |
| 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) Aim to return all responses to Parliamentary Questions (PQs) to the DH by noon on the date specified with less than 5% returned to the Agency by the Department for rewriting.  
c) Return Ministerial correspondence (POs) drafts to the DH within 4 working days of receipt in at least 90% of cases with less than 5% returned to the Agency by the Department for rewriting. |
| PM9 | Summary Evaluation Report reviews – TSE | a) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is available – An opinion must be provided within 4 weeks from the date in which the Notified Body informed the MHRA  
b) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is not available – an opinion must be provided within 12 weeks from the date in which the Notified Body informed the MHRA  
c) For Summary Evaluation reports received from other Member States – responses must be provided within the required timeframe to ensure timely response back to the Notified Body. |

14 RAG status: <90% = red; 90-99% = amber; 100% = green
Annex C – Performance metrics and further 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 Centralised Authorisation Procedures (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 2/4 trials
    - Phase 4 trials
  - Clinical investigation notifications for medical devices, including class of device
  - PIM designations
  - EAMS scientific opinions
- Number of Notified Bodies audits conducted (Surveillance, Re-designation, Witnessed, Follow up)
- Number of adverse incidents reported for Medical Devices
- British Pharmacopoeia Chemical Reference Substances sales (in £ms)
- NIBSC
  - Number of standards shipped
  - Number of OCABR batch release certificates issued
  - Number papers and scientific papers authored
  - Research grant income utilised (£ms – annually in March)
  - Number of new and replacement WHO international standards established (annually in October)
  - New innovative standards projects initiated WHO and non-WHO
- CPRD:
  - Number of GP practices signed up to CPRD
  - Number of currently registered patients on the CPRD database
  - Total number of patient lives on the CPRD database

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 2016/17

- 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 falsified medicines in the regulated supply chain at wholesale dealer level
- Number of falsified medicines in the regulated supply chain at patient level
- Number of fake devices incidents identified by Devices Compliance Team
- 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
Further work:

In addition to the targets set out in Annex B and the metrics set out above, the Agency is committed to carrying out further performance related work to develop outcome measures as follows:

**Medicines**

- review all regulatory actions finalised and communicated by VRMM within two months, assess where there is a need to monitor outcome, and prioritise these for further study; and

- ensure outcome monitoring is undertaken for all referral procedures where feasible, and that VRMM carries out at least two prioritised outcome studies.

**Devices**

- commit to developing a deeper understanding of the outcomes from the work we carry out and impact that they have on patient safety; and

- review the relationship between devices surveillance activities and health outcomes in order to inform our approach to the detection of early safety signals and development of our risk based targeted approach to surveillance activities.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAR</td>
<td>Accelerated Access Review</td>
</tr>
<tr>
<td>ATMPs</td>
<td>Advanced Therapy Medicinal Products (ATMPs)</td>
</tr>
<tr>
<td>BP</td>
<td>British Pharmacopoeia</td>
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<td>CAMD</td>
<td>Competent Authorities Medical Devices</td>
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<td>CHMP</td>
<td>Committee for Medicinal Products for Human Use</td>
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<tr>
<td>CPRD</td>
<td>Clinical Practice Research Datalink</td>
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<td>DAs</td>
<td>Devolved Administrations for Scotland, Wales and Northern Ireland</td>
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<tr>
<td>DH</td>
<td>Department of Health</td>
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<td>EAMS</td>
<td>Early Access to Medicines Scheme</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>F&amp;P</td>
<td>Finance and Procurement division</td>
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<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>HMA</td>
<td>Heads of Medicines Agencies</td>
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<td>HMG</td>
<td>Her Majesty's Government</td>
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<tr>
<td>HTA</td>
<td>Human Tissue Authority</td>
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<td>ICMRA</td>
<td>International Coalition of Medicines Regulatory Authorities</td>
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<tr>
<td>IE&amp;S</td>
<td>Inspection, Enforcement and Standards (IE&amp;S) division</td>
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<td>IMD</td>
<td>Information Management division</td>
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<td>IMDRF</td>
<td>International Medical Devices Regulators Forum</td>
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<td>IVD</td>
<td>in vitro diagnostic</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>JAMS</td>
<td>EU Joint Action on market surveillance</td>
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<td>MDLG</td>
<td>Medical Devices Liaison Group</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<tr>
<td>MLG</td>
<td>Medicines Industry Liaison Group</td>
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<tr>
<td>MMIP</td>
<td>Medicines Manufacturing Industry Partnership</td>
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<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NHS bodies</td>
<td>covers NHS England, NHS Scotland, NHS Wales and NHS Northern Ireland</td>
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<tr>
<td>NIBSC</td>
<td>National Institute for Biological Standards and Control</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<tr>
<td>NIHR</td>
<td>National Institute of Health and Research</td>
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<tr>
<td>PIM</td>
<td>Promising Innovative Medicine</td>
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<tr>
<td>PRIME</td>
<td>Priority Medicines scheme</td>
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<tr>
<td>RASRM</td>
<td>Regulatory Advice Service for Regenerative Medicine</td>
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<td>SMEs</td>
<td>small and medium-sized enterprises</td>
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<tr>
<td>VRMM</td>
<td>Vigilance and Risk Management of Medicines division</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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