Medicines & Healthcare products
Regulatory Agency

Business Plan

2019-20

April 2019

Contents

Executive summary

Our role is to protect and improve the nation's health through world-leading science, expertise, data and regulation, working in close partnership with other health and care bodies. We provide evidence-based information, advice and guidance to government, the NHS, industry and the public on medicines, medical devices and blood products.

UK patients have the right to expect that – whatever happens as the UK leaves the EU – they will continue to have speedy access to safe, effective medicines and medical devices, and that the UK will continue to support innovation and clinical trials to develop and deliver new healthcare products. We are committing to delivering on this.

This business plan sets out the Agency's ambition and vision for 2019/20 to deliver against those expectations.

Our goal as a leading global and national regulator is to deliver stability of services for patients, business and our partners across the health and care sector in a year of considerable uncertainty and change. We will ensure continuing speedy access to safe, effective medicines and medical devices taking an end to end approach from product ideas through clinical trials, development and manufacture to safe usage. And we will take agile and speedy action where safety issues are identified, fully engaging with patient concerns and working with health partners to enhance safe practice.

We will do this through:

- building on existing regulatory products and deploying these to support innovation further and continue to assure the safe manufacture, sale and supply of medicines and medical devices
- engaging more intelligently with patients and the sector to increase understanding of medicines and medical devices safety issues, and increase our impact and influence on clinical practice to ensure the safe use of products
- using big data, working in partnership with NHSX, NHS Digital and other key stakeholders across the sector, and enabling earlier action responding to safety signals, by transforming our data capture and capability
- supporting research by academia, industry and the health sector
- continuing to play a leading role in assuring standards for pharmaceuticals and biological medicines nationally and across the world
- leading international efforts to address the regulation of emerging technologies and novel products, not least genomics and artificial intelligence/medical apps
- augmenting our efforts to source, engage and support our staff in a culture which encourages and sustains the skills we need to deliver our new priorities and shared vision

Introduction

The Medicines and Healthcare products Regulatory Agency ("the Agency") is an Executive Agency of the Department for Health and Social Care (DHSC) and acts as a Government Trading Fund.

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.

We comprise three distinct yet complementary business centres: the Medicines and Healthcare products Regulatory Agency (the MHRA), the National Institute for Biological Standards and Control (the NIBSC) and the Clinical Practice Research Datalink (the CPRD).

CPRD NIBSC MHRA

The Agency has a globally unique concentration of expertise in data, standards and regulation in a single organisation. We offer our customers a full range of services and products which is not replicated anywhere else in the world:

- Clinical practice is informed by and contributes to regulatory evidence
- Global standards are underpinned by and enhance regulation
- Real world data underpin regulation and protect patients

All of the above unite to benefit patients and enable us to protect public health and improve lives.

These are the strengths we draw from to maintain our position as an outstanding regulator and beacon of scientific and clinical excellence.

Our Corporate Plan 2018-23 set the direction for what the Agency would do over this five-year period, organised around five strategic aims:

The Chief Executive has overall responsibility for the delivery of the business, policies and priorities of the Agency and is accountable to the Agency Board, DHSC and Ministers for delivery of this business plan, which is underpinned by detailed internal reporting and delivery mechanisms.

The Agency continues to face substantial uncertainty and change in 2019/20. Exiting the European Union (EU) is a major strategic challenge, not least in preparing for different outcomes leading up to it. The Agency continues to face unprecedented change in 2019/20 as a result of exiting the European Union (EU).

Throughout this period, we remain focussed on delivery of central issues to the Agency:

- how the Agency will engage more intelligently with patients and the broader healthcare system to ensure risks are understood, patients are fully engaged and properly informed, and the healthcare system responds appropriately when issues are raised
- the lessons learnt from the Infected Blood Inquiry
- how we ensure the Agency is resilient to cyber security risks as well as the challenges of regulating Artificial Intelligence (AI)/machine learning and health apps, alongside the opportunity to get ahead of the game by being agile in our approaches
- our ongoing active support for innovation in medicines and medical devices
- driving innovation in the way we regulate, for example ensuring the safe supply of products for medicinal use containing cannabis
- ensuring the Agency's resilience through this year of uncertainty, including through our Operational Transformation programme

Given the scale of challenge and uncertainty in the coming year, it will be particularly important to keep the focus on all parts of the organisation – the regulatory centre, NIBSC and CPRD – both in their own right and for what that means for the overall impact of the organisation on public health and patient safety.

We recognise that the Agency is not as well-known as it could be amongst health professionals and the wider health and care sector and that we need to build the Agency's profile with industry, professionals and sector partners to excel and ensure speedy access and patient access. This means that we need to:

- set out more clearly the linked nature of our three centres and how the Agency is global in outlook, regulation, standards and science
- articulate a clear global vision setting out that the Agency is open for business, not least for clinical trials, whatever the form our exit from the EU takes
- further develop the message about the innovative aspects of our regulation and how we can support companies to work with the UK after we leave the EU
- continue to engage with and support the Independent Medicines and Medical Devices Safety Review
- further enhance our joint working with partners across the health and care sector to influence the way the wider health and care system works to ensure that decisions and recommendations are understood and acted on in a timely way

The Agency is committed to delivering against public and patient expectations of engagement and transparency and to delivering real changes in the way we conduct patient and public engagement. This will include ensuring the patient voice is heard and listened to in licensing new medicines and medical devices, and in addressing safety issues.

This plan, then, sets out our priorities for the year not just to maintain continuity over the next few months through the uncertainty of exiting the EU, but also to address the changes we need to deliver and what the Agency can offer to the health sector, patients and public, industry, and Government.

Some of our achievements in 2018/19

In addition to our day to day work regulating medicines and devices, some of our key achievements in 2018/19 include the following:

- working closely with DHSC and wider government – as well as with industry, research and patient representative groups – on the UK's exit from the EU. This includes comprehensive Day 1 contingency Statutory Instruments prepared and laid to time, alongside production of detailed Technical Guidance
- further strengthening the UK's role in international forums and bilateral relationships through Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) and new agreements/engagement with a range of global regulators, including a new memorandum of understanding (MoU) with Russia
- fully engaged with the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Cumberlege, including providing evidence on three areas of focus (mesh, valproate and hormonal pregnancy tests) and suggestions on how the healthcare system collectively could improve how it responds to issues raised by patients
- enhancing our national strategy for collaboration and engagement with key partners and stakeholders to facilitate better regulation, innovation, and delivery of our strategic priorities: working closely with the National Institute for Health and Care Excellence (NICE) on aligning processes; sharing intelligence with the Care Quality Commission (CQC) and the Health Research Authority (HRA) (including publication of joint guidance); and working closing with the National Institute for Health Research (NIHR) on technical areas to ensure protection of public health
- supporting the Government's Life Sciences Industrial Strategy through horizon scanning; delivering the Sector Deal 1 commitments on clinical trials and accelerated product licensing and via the work of the Innovation Office which handled a further 200 enquiries in 2018/19 (compared to 144 in 2017/18), a total of 772 enquiries since it began
- granting 19 Promising Innovative Medicine designations and four Early Access to Medicines Scheme opinions in oncology, dermatology and for the nervous system
- collaborating with other regulators on Advanced Therapy Medicinal Products through the Regulatory Service for Regenerative Medicine ('One Stop Shop') and collaborating with the Cell and Gene Therapy Catapult and industry on the Advanced Therapy Treatments Centres
- further expanding the Clinical Practice Research Datalink (CPRD): providing data and services to support public health research; signing up more than 1,350 GP practices (or 1 in 7 in the UK), making more than 35m patient lives available for public health research; increasing population coverage to 17%; and implementing a more streamlined observational research pricing model to ensure sustainability for our public health research services
- wider incorporation of product-specific risk factors in relation to our risk-based inspections programme to ensure inspection resource is focussed on areas of highest risk to patients
- bringing the final part of the Falsified Medicines Directive into force in February 2019 and supporting UK stakeholders to bring them into compliance with the safety features as laid out by the delegated regulation
- successful bid to the Regulators' Pioneer Fund for a project aimed at producing synthetic datasets to help innovators validate software and apps to be able to bring them to market at the earliest, safest opportunity

- further securing global supply chains for medicines and medical devices through our 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, and our work on the ICMRA Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) initiatives, reducing the diversion of products from the legitimate supply chain

- consulting on the strategy for pharmacopoeial public quality standards for biological medicines

- contributing to the prevention, treatment and diagnosis of disease through 12 new NIBSC developed International Standards being adopted by the World Health Organisation (WHO) Expert Committee for Biological Standardisation

- our #FakeMeds behaviour campaign, which helps consumers avoid dangerous fake medical products sold online, won a number of national awards

- development and DHSC approval of the Operational Transformation Programme Business Case, which sets the scope and ambition for change over the next five years

- improvements to the Agency to make it a better place to work for our staff with a focus on health and wellbeing including an enhanced programme of activities and workshops, trained mental health champions, sports clubs and gym discounts, an external employee assistance provider and a new occupational health provider; alongside a focus on talent & learning opportunities, including management training

- successful transition to our new accommodation at the Government Hub at Canary Wharf

Finance

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 by DHSC with approximately 10% of its revenue from fees charged for services.
- **NIBSC** derives approximately half of its revenue from fees charged for services, including the sale of biological standards, and from research funding. DHSC provides the remaining funding to finance its important public health functions.
- **CPRD** is jointly funded by MHRA and DHSC's National Institute for Health Research but managed and operated by MHRA with DHSC having oversight through membership of the CPRD Executive Committee.

EU Exit has a fundamental impact on the Agency, notably the regulator. Financially, EU Exit has a significant impact on the Agency's income while considerable resource and finances are being diverted to support operational readiness for the various EU Exit scenarios.

The Agency faces additional financial challenges as a result of new device regulations and necessary investment in an Operational Transformation programme.

During this period of uncertainty, it is important to position the Agency so that it continues to offer the greatest possible contribution to public health in the UK.

Funding and Financial objective

EU Exit and the Operational Transformation Programme are having a profound impact on the Agency's finances. To address these financial pressures the Agency is taking the following steps:

DHSC has committed to support the Agency in adjusting to its changing financial circumstances. This support will help to ensure that the regulator is able to maintain its expertise throughout this period of uncertainty while having to invest in contingency arrangements under various EU Exit scenarios.

Ongoing DHSC Funding

For 2019/20, DHSC has indicated that the following ongoing funding will be made available. However, as DHSC's 2019/20 budgets have yet to be formally confirmed these figures should be considered as provisional until formal confirmation of 2019/20 budgets has been provided by the Department.

- Devices regulation – £8.1m plus £1m for capital investment
- CPRD – a continued commitment to the joint arrangement as set out in the CPRD 2016-2021 Strategic Plan. In 2019/20 there are no new commitments to be funded over and above the past contributions.
- NIBSC – funding is expected to remain largely at previous years' levels.

Key actions to deliver our corporate strategy in 2019/20

This section sets out the key actions for 2019-20 to support delivery of the five strategic objectives in our Corporate Plan 2018-23.

	1. Protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products through enhanced partnerships in the UK and internationally
	2. Support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences
	3. Deliver robust proactive surveillance for medicines and medical devices to achieve measurable public health benefit
	4. Ensure the medicines and medical devices supplied are sufficiently safe
	5. Be an exemplar of organisational excellence and efficiency

These, enhanced by our scientific expertise, will ensure the delivery of the statutory role and functions of the Agency including:

- our **regulatory role** in authorising and regulating clinical trials; licensing medicines; acting as the UK competent authority for medical devices and monitoring the performance of notified bodies; vigilance and market surveillance of medicines and medical devices; enforcement action on safety issues and breaches of regulations; inspections including partnerships with other regulators; regulating the safety and quality of blood and blood components; good laboratory practice monitoring authority for the UK; and regulating e-cigarettes
- our role in **assuring standards** including standards for biological medicines and test procedures; laboratory testing for biological medicines, and British Pharmacopoeial standards
- our role in **research and information** including provision of real-world longitudinal data and facilitating patient recruitment to trials
- our role in supporting innovation in medicines and medical devices
- our responsibility to **account to Government** for delivery of statutory requirements
- our role to **advise** on the safety of medicines and health care products and public health

1. We will protect public health and promote patient safety by ensuring the safety, efficacy and quality of medicines and healthcare products through enhanced partnerships in the UK and internationally

1a. protecting public health and ensuring the safety and quality of medicines and health care products in the UK	1b. responding to the challenges of EU exit	1c. building stronger partnerships, collaboration and engagement across the UK healthcare sector	1d. further developing our international strategy

Overall outcomes sought:

- More effective in dealing with public health issues
- Improved customer and patient access to Agency products and services
- Improved customer experience
- Increased collaboration with health partners
- Improved reputation
- Increased flexibility to improve ability to adapt to meet future needs or exploit future opportunities

1a: With Government and strategic partners we will deliver our statutory functions to protect public health and ensure the safety, efficacy and quality of medicines and health care products in the UK

We will engage fully with the issues raised by and outcomes of two independent challenges: the Independent Medicines and Medical Devices Safety Review and the Infected Blood Inquiry. We will evolve our culture and supporting systems to more intelligently engage patients on an ongoing basis for the benefit of UK public health. This will include addressing potential changes to our processes and the way we regulate.

In particular, we will

1a(i)	**Contributing to system wide response to the Independent Medicines and Medical Devices Safety review, including a fundamental review of our engagement with UK patients and the public to impact public health and patient safety**
Key deliverable	Why?
Develop a new patient, public and stakeholder engagement strategy to improve the information we provide, and feedback we receive, about medicines and medical devices, which includes: • horizon scanning for issues on which to engage earlier • listening to / learning from patients' concerns and experiences to influence our processes and communications • support our staff in an organisational culture change	To ensure a much more intelligent approach to patient and public engagement with: • public involvement integral to our decision-making • patient safety at the heart of what we do
Explore how we improve data capture/knowledge management from patients and the public.	• Improved patient experience and increased data to triangulate against adverse incident reports and improve decision-making
Increase visibility of regulatory decision making to external partners, patients and the public.	• Increased transparency, trust and confidence in the regulatory process • Stakeholders feel engaged and listened to

1a(ii)	**Acting on lessons learned from/implications of the Infected Blood Inquiry on the Agency's ways of working and impact**
Key deliverable	Why?
Review and improve our data management.	To be able to access records to respond to / inform future Inquiries.

1a(iii)	**UK implementation of the new medical devices regulations (expected to come into force by May 2020) and In Vitro Diagnostic (IVD) regulations (expected to come into force by May 2022)**
Key deliverable	Why?
Active support to the sector to support future compliance with the increased standards set out in the new medical devices and IVD regulations.	Help the sector feel more prepared for future compliance, which will enhance UK patient safety.

1a(iv)	**UK implementation of the new clinical trials regulations (expected to apply end of 2020)**
Key deliverable	Why?
Expanding the combined ways of working pilot with the HRA; working together to develop the necessary Information Technology (IT) systems to support this.	UK is prepared for compliance with the new regulations/maintains its position as a good place to do clinical research, resulting in UK patients having access to innovative new medicines.

1a(v)	**Progressing Falsified Medicines work (subject to EU Exit)**
Key deliverable	Why?
Supporting UK stakeholders to bring them into compliance with the safety features as laid out by the delegated regulation.	Improved protection for UK patients from falsified medicines.

1a(vi)	**Expanding the population coverage of CPRD data**
Key deliverable	Why?
Increasing to 20% population coverage.	Access to a large patient pool to recruit into clinical studies and for real world patient safety and vigilance studies.

1b: With Government and strategic partners we will prioritise action to deliver our statutory function in response to the challenges of the UK's exit from the EU

Responding to EU Exit will remain a top priority for the whole Agency, in particular ensuring the Agency is resilient after exiting the EU and continues to deliver its statutory functions.

To achieve this, we will:

- support the Government by informing the UK's position in future negotiations with the EU and other trading partners
- ensure, in the event of the UK leaving the EU without a deal, that we are ready to operate as a fully national operator from the point of EU Exit
- continue to ensure the appropriate governance and accountability structures are in place to monitor and assess the impact of EU Exit
- continue our senior leaders and wider teams' close working relationship with DHSC to support the health and care system post EU Exit
- work closely with DHSC and other arm's length bodies to help manage any potential frontline public health risks arising from EU Exit
- continue our work to reinforce, and where possible strengthen, the Agency's global role and regulatory relationships, whatever the outcome of EU Exit

Key deliverable	**Why?**
Develop a formal plan to prioritise the Agency's statutory work – post EU Exit - once the future position is clear.	To ensure the Agency's resilience in protecting public health through delivering its statutory functions and maintaining its global role.

1c: We will enhance our public health impact through building stronger partnerships, collaboration and engagement across the UK healthcare sector to improve clinical practice and protect public health across the UK

Further enhance joint working and impact across the UK healthcare sector through collaborative working; linking up and actively influencing clinical practice through provision of data/evidence and expertise; and embedding vigilance in healthcare systems. In particular, we will:

1c(i)	**Further enhance joint working with Government, the devolved nations and across the UK healthcare sector to improve our impact on public health and deliver related improvement actions including**
Key deliverable	Why?
Establish and run a patient safety partnership across the UK health sector (including in Scotland, Wales and Northern Ireland).	• Enhanced information sharing on medicines and medical devices safety issues across the sector • Speedy and clear communication to the public and healthcare professionals to improve clinical practice and patient understanding • Effective management of key multi-agency safety actions across the healthcare system

1c(ii)	**Continue to enhance partnership working through established and new periodic partnership meetings including with the devolved administrations, NICE, CQC, and industry bodies**
Key deliverable	Why?
Align processes and information sharing with NICE, especially around targeted assessment.	Enabling rapid access to innovative medicines for patients and making the UK life sciences sector more attractive post-EU Exit.
Joint action with CQC, the Royal Colleges and others on access to medicines (e.g. opioids).	To protect patient and public health by regulating access to medicines that could cause harm.

1c(iii)	**Work with UK government and healthcare organisation to expand use and future capability of UK healthcare datasets and systems data capture for medicines and medical devices in order to widen and strengthen the use of real-world evidence**
Key deliverable	Why?
Work in partnership to explore the expansion of Scan4Safety and UDI throughout the health service.	To develop a clean and searchable data-set.

1c(iv)	**Enhancing/strengthening engagement with clinicians to influence practice and impact patient safety**
Key deliverable	Why?
Development of an Expert Advisory Group to increase clinician input into the regulation of AI and Software (see 2bi).	To further improve patient safety.

1d: We will enhance our public health impact through building stronger partnerships, collaboration and engagement including through further development of our international strategy

We will further develop our international strategy to build strategic links beyond Europe and maintain the Agency's global influence including through our chair of ICMRA and participating in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the International Medical Device Regulators Forum and the International Pharmaceutical Regulators Programme.

1d(i)	**Engaging with key organisations to further international work and build strategic links to support collaborative efforts to protect public health and promote patient safety, including working with international regulators to ensure safe and continued supply to the UK**
Key deliverable	Why?
Implementation of the MoUs with China and Russia and re-signing of MoU with India.	By supporting such international partnering, it helps improve speed and efficiency for regulatory approval of innovative drugs, including those with unmet needs, benefiting patients through faster market access.
New regulatory capacity building projects and training outside UK.	Improve the quality of regulation around the world which, in turn, benefits UK through: • increased global safety data • faster market access to innovative medicines and vaccines for patients • increased opportunities for the life sciences sector internationally

1d(ii)	**Further expanding our leading role on standards and control of biological medicines**
Key deliverable	Why?
Continue work programme of developing biological reference materials for endorsement by WHO Expert Committee on Biological Standardisation.	To support the clinical safety and efficacy of biopharmaceuticals and standardisation of diagnostic assays.

2. We will support and enhance innovation and accelerate routes to market to benefit public health and be a magnet for life sciences

2a: supporting innovation and growth in Life Sciences

2b: developing and delivering innovative regulatory and legislative measures

2c: responding to priority areas of scientific development

Overall outcomes sought:

- Support development of new technologies/products for the benefit of public health
- Improved effectiveness in dealing with public health issues (both in addressing safety concerns and access to medicines/medical devices)
- Improved customer and patient access to Agency products and services relevant to innovation
- Increased value of products and services to customers and patients
- Accelerating time to market for new products
- Safeguarding investment in UK Life Sciences industry
- Increased collaboration with health partners
- Increased flexibility to improve our ability to adapt to meet future needs or exploit future opportunities

2a: We will support innovation and growth in Life Sciences

Building on our track record in innovation, we will work with the Office for Life Sciences and the Accelerated Access Collaborative to deliver the Life Sciences Industrial Strategy, in particular our aspects of the Life Sciences Sector Deal 2. Key deliverables are detailed further below but include:

- supporting innovative trial design
- developing a framework for point-of-care manufacture
- developing regulatory pathways for genomics
- using AI to improve identification of safety signals
- enabling the use of secondary care data to support research

2a(i)	**Make the UK a good place for research and clinical trials**
Key deliverable	Why?
Scale up delivery of real-world patient recruitment services through the Interventional Research Services Platform.	Improve efficiency of patient recruitment into clinical studies.

2a(ii)	**Further enhance the Early Access to Medicines Scheme**
Key deliverable	Why?
Define a supportive framework for the collection of real-world data, working with industry and other partners.	Greater support to gather the evidence they need to underpin licensing applications and part of promoting patient access/safety.

2a(iii)	**Further enhance the work of the Innovation Office to support development and marketing of new innovative medicines and healthcare products**
Key deliverable	Why?
Develop pilot primary care synthetic benchmarking dataset, as part of successful Regulators' Pioneer Fund bid.	Validation of algorithms, including machine learning/artificial intelligent algorithms in medical devices, to help make the UK attractive to diagnostic companies looking to develop and test products.

2a(v)	**Support UK as a magnet for life sciences through optimising and accelerating pathways to market for new innovative products**
Key deliverable	Why?
Play a prominent role in helping innovative technologies reach patients in a timely manner through engagement with the Accelerated Access Collaborative as the umbrella organisation for health innovation.	Smooth regulatory pathway for advanced technologies.

2b: We will develop and deliver innovative regulatory and legislative measures including through our offer to research and clinical trials

We will respond to the challenges of regulating new and innovative products and production methods, as scientific advances take us into new and exciting areas in medicines and medical devices. This year, we will:

2b(i)	**Develop new, agile regulatory and legislative measures including new regulatory approaches to AI, machine learning, biologicals, cannabis-based products, drug-device combination products etc, and evaluate opportunities for innovative reclassification of medicines**
Key deliverable	Why?
Develop an Expert Clinical Working group to inform the regulation of AI/software as medical devices.	Increased partnership work with clinicians on AI and software to increase patient safety.

2b(ii)	**Encourage harmonisation of classification decisions and appropriate regulation of innovative combination medicine/medical device products. In particular in** **(i) drug-device combination products** **(ii) medicines device borderline**
Key deliverable	Why?
Develop proposals for regulation of alternate site manufacturing for medicines and medical devices.	Appropriate control of products.

2b(iii)	**Evaluate the opportunities for innovative reclassification of medicines in the context of the new relationship with the EU**
Key deliverable	Why?
Review of guidance to streamline reclassification of products in the UK where they may safely be suppled without prescription.	Increase the range of medicines available for over-the-counter sale where it is safe to do so.

2c: We will be responsive to priority areas of scientific development including new products, product types and production methods/methodologies

We will continue to support emerging scientific and technological advance through horizon scanning and other initiatives. This includes systematically identifying innovative technologies, trends, new products and ideas and linking up with other national and international horizon scanning initiatives, in particular, the national horizon scanning, and demand signalling coordinated through the Accelerated Access Collaborative. In addition, we will maintain the following:

2c(i)	**Active involvement in initiatives to further the development of stratified and personalised medicine**
Key deliverable	Why?
With partners, develop a clear UK regulatory pathway for genomic medicines and genomic tests, as part of Life Sciences Sector Deal 2.	Accelerate developments in precision medicine so that treatments can be directly targeted to patients based on their genetic profile.

2c(ii)	**Innovation in vigilance**
Key deliverable	Why?
Establish the first “Yellow Card Biobanks”, as part of Life Sciences Sector Deal 2.	Identify genetic factors for predisposition to adverse drug reactions (ADRs) so that certain patients can be identified and offered alternative treatments therefore avoiding harms.
Develop the WEB-RADR platform offering to increase access to reporting systems and information for medicines and devices.	Improved access to information and reporting systems, and quality of information collected by the pharmaceutical industry.

2c(iii)	**Biological standards to support emerging scientific products**
Key deliverable	Why?
Developing biological standards for innovative vaccines and diagnostics.	To support the development of vaccines and diagnostics to reduce antibiotic use.

3. We will deliver robust, proactive surveillance for medicines and medical devices including through:
- improved use of real-world data
- enhanced information sharing

Overall outcomes sought:
• More effective in dealing with public health issues (safety and access) • Increased value of products and services to customers and patients • Improved customer experience • Improved reputation

Through delivery of our Patient Safety and Vigilance Strategy, we protect public health and promote patient safety. We are focused on responding to the challenges of providing real-time benefit risk information to support patients' and healthcare professionals' decisions and optimising the wide range of data sources in safety and vigilance work supported by digital systems and tools.

We will continue to focus on safeguarding public health through robust pharmacovigilance alongside**:**

3(i)	**Enhanced vigilance and surveillance of medicines and medical devices**
Key deliverable	Why?
A joint review of the management of Medical Device Adverse Incidents and Adverse Drug Reaction from initial receipt to initial signal detection and prioritisation.	More integrated, efficient and effective systems for receipt of safety information from numerous data sources on a common IT platform with a unified and flexible team.
Investigate the potential for mandatory reporting of suspected adverse drug reactions.	Improved reporting from healthcare professionals on suspected adverse drug reactions to identify safety issues earlier.

3(ii)	**Strengthening international safety surveillance**
Key deliverable	Why?
To deliver the objectives in our grant from the Bill and Melinda Gates Foundation to support improved safety monitoring of medicines in low and middle-income countries	Help national safety monitoring centres identify risks and benefits early and take appropriate regulatory action to support global heath

3(iii)	**Further integrate real world data and rigorous science**
Key deliverable	Why?
Monitoring the effectiveness of risk minimisation following all major safety reviews	Improved information on the effectiveness of risk minimisation to facilitate further improvements in future

4. We will ensure that the medicines and medical devices which are supplied are sufficiently safe through

- enhanced systems
- strong international partnerships and collaboration
- educating consumers

Overall outcomes sought:
• More effective in dealing with public health issues (safety and access) • Increased value of products and services to customers and patients • Improved customer experience • Improved reputation • Increased access to information

We will continue to strengthen our global positioning and reach, influencing the safe production and supply of medicines and medical devices. This includes:

4(i)	**Taking a strategic and collaborative approach – working across the Agency and sector - to manage/improve:** • **facilities/sectors where serious non-compliance is prevalent** • **legitimate online sale/supply** • **incidents and defective/substandard products such as valsartan, pyrrolizidine alkaloids, etc.** • **risk minimisation and mitigation strategies such as pharmacopoeial standards**

Key deliverable	Why?
Working with partners we will participate in a cross-Government review of digital provision of healthcare in UK, inc. online selling and prescribing of medicines.	To identify legislative gaps to support safer delivery of online services resulting in the sale/supply of a prescription medicine.

4(ii)	**Ensuring regulatory compliance with the standards that apply to the manufacture and supply of medicines across the UK market**
Key deliverable	Why?
Risk based programme of inspections to ensure compliance with GXP[1] requirements.	To ensure the quality of medicines which enter the legitimate supply chain and that Marketing Authorisation Holders and Clinical Trial Sponsors maintain systems which allow the safety of medicines to be monitored though the product life cycle.

4(iii)	**Enforcement strategies and taking action, as necessary**
Key deliverable	Why?
Prepare for Operation Pangea XII.	To protect public health by collaborating, sharing intelligence and bringing offenders to justice.
Prepare for Operation Mismed – Europol Operation (subject to EU Exit, but MHRA would still participate).	To protect public health by collaborating, sharing intelligence and bringing offenders to justice and with the aim of providing evidence to prioritise the illicit pharmaceutical trade as a European priority.
Make effective use of new legislation to disrupt criminal networks and reinvest the proceeds of crime into initiatives to protect public health.	To encourage innovation and disrupt criminal networks.

4(iv)	**Work of our British Pharmacopoeia and Laboratory Services group**
Key deliverable	Why?
Implement Agency strategy for pharmacopoeial public quality standards for biological medicines, including progressing work on developing standards for complex biological medicines such as advanced therapies.	To assure the quality of existing and new medicines and enable innovation.

[1]These include Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Pharmacovigilance Practice (GPvP).

4(v)	**Continuing to educate and work with stakeholders in Good Practices**
Key deliverable	Why?
Deliver symposium in all areas of GXP.	• Provide information to stakeholders on compliance expectations and best practice • Enhance overall levels of compliance in all areas of GXP through clear regulatory advice

4(vi)	**Promoting and reinforcing the role of biological activity standards in the biosimilars regulatory framework through the establishment of WHO International reference standards**
Key deliverable	Why?
Work with cross Agency colleagues and external partners to reinforce the role of biological activity standards in the biosimilars regulatory framework through the establishment of WHO International reference standards, the publication of opinion pieces and presentations at key meetings.	To ensure safety and efficacy of new medicines coming onto the market.

5. We will be an exemplar of organisational excellence and efficiency through our

- Operational transformation programme;
- Resourcing Strategy
- Communications.

Overall outcomes sought:

- Increased value of products and services to customers and patients
- Improved customer experience
- Reduced operating costs for existing services
- Increased revenues
- Increased flexibility to improve ability to adapt to meet future needs or exploit future opportunities
- Increased staff engagement
- Improved and enhanced organisation capabilities

5a: Through our Operational Transformation programme we will deliver a flexible and efficient organisation able to respond effectively to market and customers

Operational Transformation is the Agency's proactive response to the need for investment in change to enable improved efficiency and productivity; replace our ageing IT systems; respond to changing customer needs and the need for greater efficiencies.
The Operational Transformation programme is split into seven workstreams representing the different 'services' we offer, each led by a Director sponsor. Each workstream contains multiple projects to help it deliver its objectives. It seeks to take the Agency through three transition states of Affordable, Adaptable and Agile, with annual reviews of cost and benefits aligned to the budget planning cycle.
Whilst this is a five-year programme of activity, the focus for this financial year will be to help create an affordable Agency and develop projects that will realise £11.4m of benefits through increased revenue and reduced operational cost in the 2019-20 financial year.

In particular, we will:

- review the Agency's ways of working to improve efficiency and reduce operating costs to ensure statutory services are not impacted by the loss of income
- review our non-statutory services to explore ways of diversifying revenue streams and further commercialise elements of our business, such as British Pharmacopeia, Training and Events, etc., to improve quality of products on the market and support service delivery
- deliver more streamlined, effective and efficient Corporate Services, specifically Finance, Human Resources (HR) and IT, to enable the Agency to cope with the change load over the duration of the programme - the majority of this change relates to improving process efficiency, improving skills and capabilities and non-IT related change
- continue to build embedded change capability across the Agency

Key deliverable	**For what intended outcome**
Deliver an updated Operational Transformation Programme Business Case	To deliver a financially balanced business case that sets out delivery plans, expected costs and benefits
To define the sourcing model and update the Transformation and Digital Delivery suppliers required to support the Agency through transformation.	To reduce overall cost, improve quality and ensure the Agency has the capacity and capability in place to transform

5b: We will build staff resilience and deliver a strategy to ensure the Agency has the culture and skills mix to adapt to a changing environment over the next few years and beyond

We will ensure the resilience of the organisation through EU Exit to continue to be a leading regulatory authority.

In particular we will focus on the overarching culture of the Agency and on the practicalities of resourcing and development - strategically and flexibly aligning the workforce to our future state - including:

- development of professional, leadership and change related skills
- overall talent development, engagement and retention of staff
- different ways of sourcing, attracting and contracting new people

Key deliverable	Why?
Review and respond to staff feedback mechanisms such as quarterly HR metrics, Pulse Survey and annual People Survey results, and escalate to the CET/Board as required.	To ensure the effectiveness of our approach to staff resilience and take action as needed.

5c: Communications

We will continue to build the Agency's reputation and profile as a leading global regulator and for science and research.

We will maximise opportunities to market, promote and develop our products and services – informed by the patient voice - so they continue to meet changing customer needs, whilst also engaging with our staff.

We will engage with DHSC and our strategic partners to ensure there is clear and consistent guidance and communication to industry, including in relation to EU Exit.

Key deliverable	Why?
Deliver phases 2 and 3 of the FakeMeds campaign, and a Yellow Card campaign.	Target audiences aware of risks of buying products online and how to access safe products; reports via the Yellow Card app increased.

Annex A – DHSC requirements

In addition to the priorities and deliverables set out above, the Agency commits to delivering on a number of initiatives and expectations on which the DHSC will hold us to account. This includes delivering our statutory accountability to Parliament, not least providing answers to Parliamentary Questions in line with Government-wide targets. We will comply with all legal requirements falling to all public bodies including compliance with the Freedom of Information Act and responding to Freedom of Information Inquiries within statutory timeframes.

In particular, the Agency will work closely with the Department and across the health and care sector as relevant to:

- action to manage defective medicinal products and medical devices to protect the public
- action to tackle anti-microbial resistance (AMR)
- anticipate, manage and proactively handle medicines and medical devices incidents and issues, including media and stakeholder communications
- continue engagement with wider patient safety agenda to ensure alignment with other health and care partners on safety-critical issues
- continue engagement with the National Patient Safety Alerting Committee (NaPSAC) and working with Government and partners across the health and care sector to deliver Ministers' priorities for improving patient safety, ensuring that the Agency maximises its impact on clinical practice and patient understanding of medicines and medical devices safety issues through regulation of products and ongoing engagement with patients and partners
- continue promoting the EU settlement scheme and supporting EU citizens to apply; monitoring retention of specialist staff following the cessation of EMA work; and working with the Government to ensure the future immigration system facilitates the recruitment and retention health and care workers, from the EU and the rest of the world, particularly in the areas where there are shortages
- support digital health agenda, in particular through the new joint unit, NHSX, which will combine the best talent from government, the NHS and industry to bring the benefits of modern technology to every patient and clinician
- continue to build on systems and processes already in place to protect our systems from cyber-attack and other emerging threats