Medicines & Healthcare products
Regulatory Agency

OFFICIAL SENSITIVE

Business Plan

2019-20

Quarter 1 status report: 1 April to 30 June 2019

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

Public health and partnerships

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	
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; and • support our staff in an organisational culture change
Explore how we improve data capture / knowledge management from patients and the public
Increase visibility of regulatory decision making to external partners, patients and the public

1a(ii)	**Acting on lessons learned from/implications of the Infected Blood Inquiry on the Agency's ways of working and impact**
Key deliverable	
Review and improve our data management	

Identifying relevant information:

- Set up a working group for inquiries so that we can quickly move to pull the relevant search strategy together and get a clear view of what searches are needed.
- The contract and procedures around the off-site storage of information is to be reviewed to ensure there is a reliable reference to all information that is held off site in this way.

Incomplete Information Asset Registers (IARs)

- Remediating the IARs to ensure that all information is captured.

Accessibility of records –

- That the microfiche held by the Agency be digitised. For an external firm to digitise, the best quote was £11,000. However, the Agency can hire a microfiche scanner for £500 per month, including installation, if the resources were committed internally.
- An alternative approach would be to carry out an indexing exercise which will highlight similarities between the microfiche and those records transferred to The National Archives, to prioritise digitisation need.

Indexing of Paper Records

- A proposal to remediate the problems with the paper records inventory has had funding agreed with policy. The proposal is for a 12-month project to begin destructions, transfers to The National Archives, and remediate the issues with the inventory, to be managed by Transformation Division. It will cost circa £25,000 but predicted cost savings in storage means the project is effectively cost neutral. It is requested that CET support the records management remediation proposal and agree continued funding and recruitment strategy for this project.

Lack of understanding of Public Inquiries

- An education strategy.

Unclear roles, responsibilities and process

- Work to create a policy and procedure for responding to public inquiries.

1a(iii)	**UK implementation of the new Medical Devices Regulations (expected to come into force by May 2020) and In Vitro Diagnostic Regulations (expected to come into force by May 2022)**
Key deliverable	
Active support to the sector to support future compliance with the increased standards set out in the new medical devices and IVD regulations	

1a(iv)	**UK implementation of the new clinical trials regulations (expected to apply end of 2020)**
Key deliverable	
Expanding the combined ways of working pilot with the HRA; working together to develop the necessary Information Technology (IT) systems to support this	

1a(v)	**Progressing Falsified Medicines work (subject to EU Exit)**
Key deliverable	
Supporting UK stakeholders to bring them into compliance with the safety features as laid out by the delegated regulation	

1a(vi)	**Expanding the population coverage of CPRD data**
Key deliverable	
Increasing to 20% population coverage	

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• **1a(i)** Public consultation on how we engage/involve patients in our work drafted; patient engagement a key focus of Managers' Conference in May; cross-Agency Patient and Public Engagement (PPE) champions network well established. • **1a(i)** continued to promote the FakeMeds and Yellow Card Scheme campaign messages, expanding target audience awareness/engagement • **1a(iii)** Continued communications support for implementation of MDR/IVDR, including development of communications plan for upcoming public consultation • **1a(iii)** re-evaluated project plan, identifying high priority areas and leads and continuing to implement key elements of the operational plan. Rolled out Agency-wide training on the new Regulations • **1a(iv)** The pilot is expanding; development teams in MHRA and HRA working together to develop the required integrations between systems • **1a(iv)** Six MHRA/HRA workshops to agree the requirements and scope of the minimum viable product to support scale-up of Combined Ways of Working. • **1a(iv)** MHRA and HRA began development 'sprints' for the integrated system	• **1a(i)** Launch public consultation and hold engagement events in London and Devolved Administrations to support the consultation; publish new patient engagement page on GOV.UK • **1a(i)** focus on delivering communications and stakeholder engagement to support launch and public consultation • **1a(i)** focus on targeted communications to engage segmented audiences; utilising new channels to reach public & healthcare professionals; and encourage further media coverage of campaigns. • **1a(ii)** Update of Information Asset registers throughout 2019/20 • **1a(ii)** preparing communications plan for educating on public inquiries • **1a(ii)** Policy for public inquiries will be reviewed by the Agency's Policy & Procedures committee in Q2. • **1a(iii)** publish a consultation and impact assessment addressing national provisions to provide clarity to the sector in areas that are subject to individual member state decisions. • **1a(iii)** guidance to support industry during the transition to MDR/IVDR implementation, focusing on stakeholders that will be regulated under the regulations for the first time. • **1a(iv)** Build work has started on the systems with a go-live date of November 2019 for the system-supported combined ways of working.

• **1a(iv)** continued work to promote the Combined ways of Working pilot to additional sponsors • **1a(v)** Navigated delay to EU Exit, implementing a process for non-FMD compliant stock to be released in a safe way if critical to UK supply • **1a(v)** Worked with other national regulators across UK to ensure appropriate inspection and enforcement of FMD • **1a(v)** Prepared options for UK-only system for falsified medicines in No Deal, and updating on enforcement to date • **1a(v)** Ongoing communications to stakeholders in the medicines supply chain to encourage FMD implementation and compliance • **1a(vi)** Population coverage increasing from 15% to 17%	• **1a(iv)** The test strategy for the integrated system will be agreed by end July; 'sprints' to be completed by end September. • **1a(iv)** workshop for sponsors taking part in the pilot • **1a(iv)** Engaging with HRA on communications relating to the Combined Ways of Working pilot including the delivery workshop • **1a(v)** Decisions on maintaining or revising our position on non-FMD compliant stock • **1a(v)]** Working with stakeholders to bring them into compliance • **1a(v)** Engagement with stakeholders to inform agreed Government position for No Deal • **1a(v)** Updates on implementation, new guidance and progress reports will be delivered to stakeholders as information becomes available

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

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; and
- 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
Develop a formal plan to prioritise the Agency's statutory work – post EU Exit - once the future position is clear

<u>Q1 (look back on key achievements between 1 April and 30 June 2019)</u>	**<u>Q2 (forward look to key plans for 1 July to 30 September 2019)</u>**
• Our work to ensure stakeholders are aware of the new systems we have developed that allow continued operations in a no-deal Brexit scenario was scaled back in line with Government prioritisation.	• As a no-deal Brexit scenario becomes a re-continued priority for the Agency, our work to onboard customers with the new systems we have developed will ramp up accordingly. • Potential further guidance to stakeholders

• Published no deal guidance on the website up until confirmation of the delay to Article 50 on 11 April. • Prepared over 100 edits to existing content in the event no deal took place, working across the organisation to clarify and agree wording, page withdrawals and new content • Regular email updates to industry stakeholders with details of the signing of the no-deal Statutory Instruments (SI), promotion of European Systems Contingency webinars and published guidance on operational changes intended to be enacted in the event of no deal. • Email to over 250 companies summarising all of the MHRA's no-deal guidance published to date.	• Engagement industry events planned to cover the Future Economic Partnership jointly run by DHSC, OLS and MHRA.

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 health care 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	
Establish and run a patient safety partnership across the UK health sector (including in Scotland, Wales and Northern Ireland)	

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	
Align processes and information sharing with NICE, especially around targeted assessment	
Joint action with CQC, the Royal Colleges and others on access to medicines (e.g. opioids)	

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	
Work in partnership to explore the expansion of Scan4Safety and UDI throughout the health service	

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

Q1 (look back on key achievements between 1 April and 30 June 2019)	Q2 (forward look to key plans for 1 July to 30 September 2019)
• **1c(ii)** continued discussions with devolved nations about the use of Central Alerting System (CAS). • **1c(ii)** Agreed with NICE a joint process for NICE technology appraisal and MHRA regulatory processes in England and Wales in the event of no-deal Brexit. • **1c(ii)** established an Opioids Stakeholder Network to provide input from stakeholders to support the review of opioids. • **1c(iv)** At the end of April 2019 policy lead for Scan4Safety in England was passed to NHSX. MHRA will work with NHSX on this once it become clear what plans NHSX has for taking Scan4Safety forward. • **1c(iv)** MHRA has been in discussion with the Welsh Government about the possible adoption of a Scan4Safety type approach in Wales and Devices DIOG provided major input to a seminar in UDI adoption, which the Welsh Government ran for NHS Wales in Cardiff in June 2019.	• **1c(i)** exploring whether the creation of a Patient Safety Network could be subsumed into the work of the National Patient Safety Alert Committee (NaPSAC). • **1a(ii)** progressing a charging and service model for CAS, to discuss further with the Devolved Administrations. • **1c(ii)** continuing to work closely with NICE on information sharing arrangements to support faster access to market for industry and faster access to medicines for patients. • **1a(ii)** engagement events in September with Devolved Administrations to support the consultation on how we engage/involve patients in our work • **1c(iv)** Enhancing/strengthening engagement with clinicians to influence practice and impact patient safety • **1c(iv)** DIOG is seeking to have further discussions with the Scottish Government on UDI adoption by NHS Scotland in late July 2019.

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	
Implementation of the MoUs with China and Russia and re-signing of MoU with India	
New regulatory capacity building projects and training outside UK	

1d(ii)	**Further expanding our leading role on standards and control of biological medicines**
Key deliverable	
Continue work programme of developing biological reference materials for endorsement by WHO Expert Committee on Biological Standardisation	

Q1 (look back on key achievements between 1 April and 30 June 2019)	Q2 (forward look to key plans for 1 July to 30 September 2019)
• **1d(i)** Russia – we've provided answers to a number of technical GMP queries and joined two inspections being performed by SID & GP in the UK • **1d(i)** India – CEO visited India in May and raised MoU • **1d(i)** China – finalised workshop proposals for the Prosperity Fund programme with FCO • **1d(ii)** An internal Standards Review meeting took place in Q1 to review proposals for new or replacement standards that are to be submitted for the WHO ECBS meeting in October 2019	• **1d(i)** Russia – a technical discussion via teleconference on EU GMP • **1d(i)** India – hope to receive a copy of the MoU from India in July • **1d(i)** China –begin planning for delivery workshops in Q3 • **1d(ii)** Continue to develop proposals for WHO ECBS meeting in October 2019

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

Enhancing innovation

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	
Scale up delivery of real world patient recruitment services through the Interventional Research Services Platform	

2a(ii)	**Further enhance the Early Access to Medicines Scheme**
Key deliverable	
Define a supportive framework for the collection of real-world data, working with industry and other partners	

2a(iii)	**Further enhance the work of the innovation office to support development and marketing of new innovative medicines and healthcare products**
Key deliverable	
Develop pilot primary care synthetic benchmarking dataset, as part of successful Regulators' Pioneer Fund bid	

2a(v)	**Support UK as a magnet for life sciences through optimising and accelerating pathways to market for new innovative products**
Key deliverable	
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	

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• **2a(i)** Secured 2 agreements in principle to run PIC studies via the platform • **2a(ii)** Presentation of MHRA's approach to collect Real World Data (RWD) in EAMS at OLS task force meeting • **2a(ii)** Development of a template for companies to provide the agency with their proposals to collect data; template released via OLS to stakeholders for comment and amendment • **2a(ii)** Soft pilot with interested company regarding RWD from MHRA perspective • **2a(iii)** Communications plan to promote the MHRA Innovation Office to academics and transfer technology offices	• **2a(i)** Maintain talks with 5 other leads in order to secure further AiPs • **2a(ii)** Amend data collection template following comments from stakeholders • **2a(ii)** Firm up internal and external processes and publish the template and guidance on the MHRA's EAMS webpage regarding approach to collect RWD • **2a(iii)** Continue with peer review and testing with industry partner • **2a(iii)** Implementation of communications plan to promote the IO in September • **2a(v)** Active participation at AAC and other related meetings

• **2a(v)** Active participation at AAC meetings to provide regulatory insight into proposed processes; regulatory comments on the ToR and proposed framework of the AAC • **2a(v)** Contribution to horizon scanning process	• **2a(v)** Provision of horizon scanning data, where appropriate and no conflict of interest or confidentiality issues identified • **2a(v)** Consideration of how EAMS might fit into the AAC pathway

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	
Develop an Expert Clinical Working group to inform the regulation of AI/software as medical devices	

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	
Develop proposals for regulation of alternate site manufacturing for medicines and medical devices	

2b(iii)	**Evaluate the opportunities for innovative reclassification of medicines in the context of the new relationship with the EU**
Key deliverable	
Review of guidance to streamline reclassification of products in the UK where they may safely be suppled without prescription	

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• **2b(i)** looking at the use of 3D printing in innovative settings including within hospitals, and how this will be regulated going forward. • **2b(iii)** Revised guidance is in draft form and under consultation internally	• **2b(ii)** Scoping paper to be developed by August 2019 to seek funding from DHSC under life sciences sector deal • **2b(iii)** Consultation with industry on revised guidance

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	
With partners, develop a clear UK regulatory pathway for genomic medicines and genomic tests, as part of Life Sciences Sector Deal 2	

2c(ii)	**Innovation in vigilance**
Key deliverable	
Establish the first "Yellow Card Biobank", as part of Life Sciences Sector Deal 2	
Develop the WEB-RADR platform offering to increase access to reporting systems and information for medicines and devices	

2c(iii)	**Biological standards to support emerging scientific products**
Key deliverable	
Developing biological standards for innovative vaccines and diagnostics	

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• **2c(i)** Worked with external partners including UK pharmacogenetic network to generate the outputs and report from the 2018 workshop. • **2c(i)** Successfully bid for OLS funding for the Genomics workstream for capacity building to deliver the streamlined regulatory process. • **2c(i)** Collaborated with several international Pharmacogenetic networks to develop a global forum to facilitate data acquisition and analysis. • **2c(ii)** WEB-RADR platform has continued to develop, with development completed to enable migration of existing components to the strategic platform • **2c(ii)** Two new countries (Armenia and Ghana) launched onto the WEB-RADR platform. • **2c(ii)** Early scoping work for Yellow Card Biobank; Strategy for Yellow Card Biobank agreed by CET	• **2c(i)** Finalise and Publish the Workshop report. • **2c(i)** Evaluate impact on and need for integration with existing licensing procedures and need for additional procedures. • **2c(i)** Consider need for legislative support to enable pathways. • **2c(ii)** Prepare business case in July 2019 for funding from DHSC for Yellow Card Biobank scoping work. • **2c(ii)** Stakeholder engagement with genomics and biobank experts in August 2019. • **2c(iii)** Continued review by the Standards Programme Board for further biological standards projects

• **2c(iii)** Ten new projects endorsed for (1st) WHO international standards supporting 5 different specialist areas including emerging diseases, paediatric care, flow cytometry and diagnosis of bacterial infection.	

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	
A joint review of the management of Medical Device Adverse Incidents and Adverse Drug reaction from initial receipt to initial signal detection and prioritisation	
Investigate the potential for mandatory reporting of suspected adverse drug reactions	

3(ii)	**Strengthening international safety surveillance**
Key deliverable	
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	

3(iii)	**Further integrate real world data and rigorous science**
Key deliverable	
Monitoring the effectiveness of risk minimisation following all major safety reviews	

Q1 (look back on key achievements between 1 April and 30 June 2019)	Q2 (forward look to key plans for 1 July to 30 September 2019)
• **3(i)** Common Integrated Vigilance Services programme has been approved to move to a new system for management of medicines and device incident reports. • **3(ii)** grant work for the Gates Foundation is on track with further discussions for extending this work ongoing • **3(iii)** Methods for measuring the effectiveness of risk minimisation considered after each major safety review. Current focus on measuring the effectiveness of the valproate pregnancy prevention plan	• **3(i)** Produce the CIVS programme business case for review in September • **3(i)** Engage with stakeholders regarding mandatory reporting • **3(i)** This work will be the delivery mechanism for the vigilance components of the MDR Compliance project. The project will inform and provide mechanisms for how the CIVS project will receive all the MDR regulatory vigilance data

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 (e.g. valsartan, pyrrolizidine alkaloids, etc)** • **risk minimisation and mitigation strategies (e.g. pharmacopoeial standards)**
Key deliverable	
Working with partners we will participate in a cross-Government review of digital provision of healthcare in UK, including. online selling and prescribing of medicines	

4(ii)	**Ensuring regulatory compliance with the standards that apply to the manufacture and supply of medicines across the UK market**
Key deliverable	
Risk based programme of inspections to ensure compliance with GXP[1] requirements.	

4(iii)	**Enforcement strategies and taking action, as necessary**
Key deliverable	
Prepare for Operation Pangea XII	
Prepare for Operation Mismed – Europol Operation (subject to EU Exit, but MHRA would still participate)	
Make effective use of new legislation to disrupt criminal networks and reinvest the proceeds of crime into initiatives to protect public health	

4(iv)	**Work of our British Pharmacopoeia and Laboratory Services group:**
Key deliverable	
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	

4(v)	**Continuing to educate and work with stakeholders in Good Practices[2]**
Key deliverable	
Deliver symposium in all areas of GXP	

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	
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	

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

Q1 (look back on key achievements between 1 April and 30 June 2019)	Q2 (forward look to key plans for 1 July to 30 September 2019)
• **4(i)** Cross Regulatory Forum exploring options for changes to legislation to make the online provision of prescriptions safer for patients. • **4(ii)** first phase of the GDP OBERA inspection programme implemented with the commencement of 'Gateway' inspections. These inspections are designed to allow entry into the scheme. • **4(ii)** GCP continue to develop and use office-based assessments as an add on to complex inspections and for IAG follow-up work. • **4(ii)** Heightened inspectorate surveillance of patient specific medicines (Specials) to ensure compliance and risk to the supply chain. • **4(iii)** First quarter returns for AFO project have shown positive implementation with £212,000 seized and sent to the Home Office. The MHRA will be entitled to 50% of these seizures. • **4(iii)** Ongoing joint investigation with Italian authorities identifying criminality to penetrate UK regulated supply chain resulting the arrest of suspect. Ongoing activity to understand the scale of the impact to the UK supply chain. • **4(iii)]** Criminal court conviction of long-term MHRA subject (Operation Calla) involved in the illegal importation, sale and supply of medicines • **4(iv)** Presented at Biointegrates conference in London • **4(iv)** Planning to support communications about the next stages of implementation of the strategy on biological standards • **4(v)** Engagement with Industry on a range of GxP topics to continue our commitment to effective regulation through education as well as inspection. • **4(v)** Development of a collaboration with FDA and Health Canada to enhance information sharing and technical exchange in the areas of Laboratories, GCP and GPvP. • **4(vi)** Presented at PDA Conference on ATMPs and standards	• **4(i)** Discussion with DHSC on electronic prescribing of opioids • **4(ii)** Work is progressing on developing a GPvP office-based assessment programme providin the opportunity to widen the scope of inspectorate coverage to MA holders which have not previously been inspected • **4(ii]** Work to strengthen risk-based inspection process by building in an inspectorate orientated risk assessment as part of the licensing and VRMM assessment process. This will enhance risk-based methodologies and provide triggers for inspection of high-risk sites. • **4(iii)** Initial data submission to Interpol – Operation Pangea • **4(iii)** Operational phase supporting Operation Mismed (Europol) • **4(iii)** Continued AFO project activity in support of Op Galileo. • **4(iii)** Agree the communications approach to support the UKs role in Pangea XII • **4(iii)** Workshop with BIA and Cell & Gene Therapy Catapult in July on standards for advanced therapies • **4(iv)** Update on Strategy for pharmacopoeial public quality standards for biological medicines to be published on gov.uk in July/August • **4(iv)** Communications expected in August/September • **4(vi)** Meeting with key stakeholders in the US in July • **4(vi)** Meeting of working party BIO-DPS in August to consider performance and class-based approaches for monoclonal antibodies and other biotechnologically produced proteins • **4(v)** Development and delivery of international workshops with the US FDA which are streamed to an international audience of several thousand stakeholders. • **4(v)** Engaging with partners' education programmes such as WHO and USFDA, seeking to build capacity in India and China • **4(v)** Planning continues Jul-Sept, with delivery of the GCP non-commercial in September.

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

- Operational transformation programme;
- Resourcing Strategy; and
- 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 (e.g. British Pharmacopeia, Training & 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; and
- continue to build embedded change capability across the Agency.

Key deliverable
Deliver an updated Operational Transformation Programme Business Case
To define the sourcing model and update the Transformation and Digital Delivery suppliers required to support the Agency through transformation.

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
Customer workstream: • The growth and joined up marketing and Business Development projects have launched, with various activities planned or developed. • Detailed 1:1 discussion held with business units around their customer contact to inform system design **Operational Transformation Programme Business Case:** • Transformation Academy launched to build change capability and capacity within the Agency's existing staff. • Major programmes in priority workstreams mobilised (Customer, Safety and Surveillance and Corporate). • **Sourcing model**, • using Crown Commercial Services frameworks where possible, with pipeline planning	**Customer workstream:** • work up options for how customer contact is handled **Operational Transformation Programme:** • Plans in place to deliver FY2019/20 benefits. • Updated OT Business Case to DHSC in September • Sourcing model to be defined and key contracts awarded. • HR, Finance and Transformation Division (IT) change programmes underway. **Sourcing Model:** • Plan for major retender of Agency Networks contract. • Ongoing management of the sourcing/contracting pipeline with advanced planning to enable sourcing activities to be managed in a timely and efficient manner.

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; and
- different ways of sourcing, attracting and contracting new people.

Key deliverable
Review and respond to staff feedback mechanisms (e.g. quarterly HR metrics, Pulse Survey and annual People Survey results) and escalate to the CET / Board as required

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• Internal staff development initiatives. • Corporate Health & Wellbeing initiatives • Three new TOPRA apprenticeship starts and recruitment of 5 more additional apprentices in other fields underway • New models of contracting developed in partnership with the NHS • Cross-Agency Patient & Public Engagement (PPE) champions network is well established.	• Further roll out of the Grade 6/Grade 7 leadership development programme, CET Transformational Leadership Programme etc • People survey - preparation for the 2019 survey • Further apprenticeship scheme starts

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
Deliver phases 2 and 3 of the FakeMeds campaign, and a Yellow Card campaign.

Q1 (look back on key achievements between 1 April and 30 June 2019)	**Q2 (forward look to key plans for 1 July to 30 September 2019)**
• Continued to promote the FakeMeds and Yellow Card Scheme campaign messages, expanding target audience awareness and engagement through direct and stakeholder-led communications. • Published Yellow Card instructional videos for patients; emails to stakeholders to encourage promotion of phase 2 of Fake Meds campaign • Communications plan to promote the MHRA Innovation Office • Ran a meeting of the Valproate Stakeholders' Network in May to receive updates from health system and healthcare professional organisations' on how they are implementing the new measures, including the impact of the new guidance and what they are doing to address non-compliance, and to obtain stakeholder views on the next steps required.	• Engaging further segmented audiences through targeted communications and utilising new channels to reach the public, healthcare professionals • Seek input from patient groups on draft GOV.UK page on mesh; promote Yellow Card Scheme to mesh patient and clinician groups. • Implementation of the MHRA Innovation Office campaign in September.