Medicines & Healthcare products
Regulatory Agency

Business Plan

2020-21

External 27 March 2020

Executive Summary

The Agency is driving forward a substantial strategic and cultural change through 2020-21. In part this responds to the need to develop a new and effective regulatory model, but this also reflects a new focus on involving and engaging with patients, enabling patient access to new innovative medicines and devices, and speedier response to risks to patient safety and public health.

Our role is to protect and improve patient health by enabling the earliest access and high-quality supply of safe, effective and innovative products through proportionate and reasonable, evidence-based decisions on risks and benefits. We will work in close partnership with other health and care bodies to provide evidence-based information, advice and guidance to government, the NHS, industry and the public on medicines, medical devices and blood products.

Now that the UK has left the European Union (EU), we will continue to support the Government to deliver its legal obligations under the Withdrawal Agreement and prepare for its new relationships with the EU and the rest of the world. To do this, we will continue to work closely with the Department of Health and Social Care to ensure the UK regulatory environment works in the best interests of patients, industry and our partners across the health and care system. This is to ensure that:

- Patients continue to have speedy access to safe, effective medicines and medical devices;
- the development of innovative new medicines and medical products is supported in the UK; and
- the UK life-sciences industry is able to flourish.

We will deliver the relevant recommendations from the Independent Medicines and Medical Devices Review chaired by Baroness Cumberlege. We are committed to taking 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 develop new ways of engaging with patients – swiftly responding to their questions and concerns; and involving them in regulatory decision-making.

Introduction

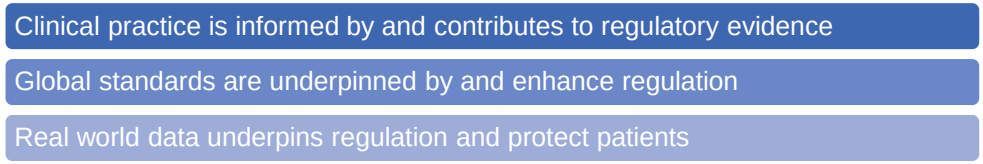
The Medicines and Healthcare products Regulatory Agency (“the Agency”) is an Executive Agency of the Department for Health and Social Care (DHSC).

Our mission is to protect and improve public health by enabling the earliest access and high-quality supply of safe, effective, and innovative products through proportionate, data-driven decisions on risk and benefits.

Our vision is to be a global exemplar in public health and patient safety, enabled through regulation, and at the forefront of innovation.

We comprise three complementary business centres: the MHRA regulatory centre, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD).

This gives the Agency 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:



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.

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.

Strategy

The Agency is driving forward a substantial programme of strategic and cultural change.

In part, this responds to the need to develop a new and effective regulatory model now that the UK has left the EU.

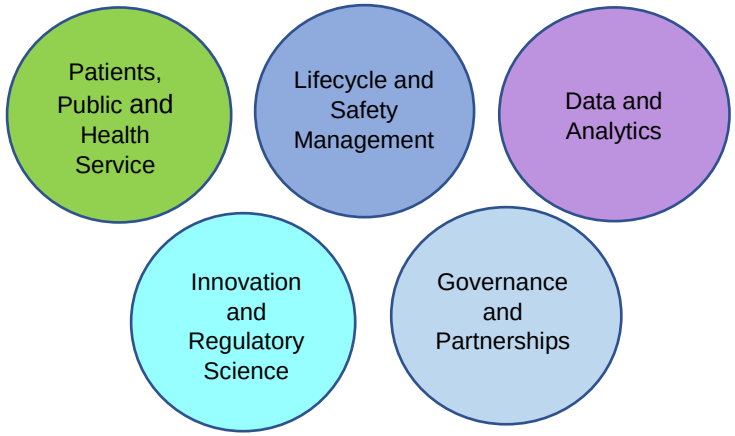
But this also reflects a new focus on involving and engaging with patients, enabling patient access to new innovative medicines and devices, and speedier response to risks to patient safety and public health. The Agency is also redefining its innovation offer.

The Agency wants to protect and improve patient health by enabling the earliest access and high-quality supply of effective and innovative products through proportionate, data-driven decisions on risk and benefits.

We will be a global exemplar in public health promotion and patient protection, operating at the forefront of innovation.

This will be achieved by delivering a step-change in our practical impact on clinical practice across the health service, helping patients, and the public to make informed decisions about medicines and medical devices.

To achieve this, the Agency is focusing on five strategic goals:



This plan lays the groundwork for the Change Strategy and is focused on delivering three fundamental shifts:

A changed focus on UK access to products	Focus on UK patient access to highly innovative products, with oversight of safety and clinical impact from earliest (including "experimental") use
Transformed post-market surveillance	Shift life-cycle monitoring to systematic data-driven analysis of real-world use in the NHS, underpinned by data analytics and increased Artificial Intelligence (AI) capacity
Impact	Engage patients in the Agency's work, drive real influence on clinical practice and enable patients to make informed decisions.

In 2020-21, the Agency will:

- develop streamlined approaches to supporting **innovation** in medicines and medical devices, so that new products can come safely and more quickly to the UK market to the benefit of patients
- substantially reshape post-market vigilance to run proactive **life-cycle monitoring** of all the products we regulate
- further develop our data assets and **analytics capability** to underpin our regulation and safeguard patient health.
- begin to transform our ways of working to making a positive and system-wide impact on clinical practice and ensuring patients have good quality information so they can better understand benefits and risks and make informed choices on treatment options.
- develop a formal plan to prioritise the Agency's statutory work following January 2021, including international partnerships.

This will be underpinned by robust governance and strengthened partnerships across the health sector.

Priorities

Our priorities for 2020-21 are to:

1. set the foundations for longer-term strategic and cultural change to refocus the Agency to become patient-centred, involving patients in proportionate decision-making and becoming a trusted source of information to support patient and health professional decision-making about medicines and medical devices.

2. build on our science capability and unique data to develop a new compelling innovation offer, thus encouraging research and development of innovative new products in the UK to the benefit of patients, and the wider health and care system

3. develop and deliver an enhanced safety surveillance system across medicines and medical devices,

4. drive forward the Agency's efficiency agenda, cutting costs and focusing our resources – not least our world-leading science and clinical expertise – on actions which will most benefit patients and patient safety.

5. support DHSC in its preparations for the end of the transition period and future relationships with the EU and rest of world. This includes leading the delivery of an EU and Trade legislative programme to effectively perform our statutory functions and support the health of patients.

6. be ready for 1 January 2021 with new routes to market for medicines and medical devices.

7. as a regulator, working with the National Institute for Biological Standards and Control (NIBSC), play a full part in the national public health challenge caused by Covid-19.

OUR STRATEGIC GOALS

1. Patients, public and health service

We will ensure medical products are effective and acceptably safe. By making information and advice available to enable well-informed decisions by patients and healthcare professionals, we will ensure the Agency is trusted by patients, public and across the health sector. We will engage proactively with the public, patients, health services and healthcare professionals, and gather insight from patients to aid our decision-making and communications. We will achieve this through three strategic objectives:

- Putting patients first
- Making information more accessible
- Proactively publishing data, information and knowledge

In 2020-21 we will:	By
Develop by Q2 and deliver across the year a new patient and public engagement plan	Q2
Develop by end Q3 and deliver across the year a new healthcare professionals engagement plan	By Q3
Develop and embed across the organisation a patient-first culture	Q4
Improve our websites to make them more accessible for all users and enhance our links with other relevant websites	Q3
Develop proposals for a new notification platform, including for safety alerts to healthcare professionals	Q2
Review by Q2 and improve safety messaging	Q2
Develop proposals for more transparency on how we publish data and information	Q4

2. Innovation and regulatory science

The Agency proactively supports, enables, and delivers innovation, making the UK one of the best places in the world to develop innovative technologies and conduct clinical research. We will ensure patients get timely and safe access to the most advanced healthcare products. We will achieve this through three strategic objectives:

- To create innovative regulatory process
- To develop an integrated science offer to support innovation
- To improve regulatory science

In 2020-21 we will:	By
Test and be ready to launch for 1 January 2021 a dynamic and compelling market entry proposal	end Q3
Develop the National Accelerated Licensing route to operate from 1 January 2021, and publish relevant guidance, so that innovative products submitted to the UK can be authorised with a shorter timeline	end Q3

Develop and publish guidance on a new innovative UK licensing procedure for biosimilar products to operate from 1 January 2021	end Q3
Develop practical proposals and publish guidance on the use of Real-World Evidence in supporting clinical trial data and regulatory approvals to support innovation	Q3
Launch CPRD's real-word interventional research services.	Q3
Establish a network and financially sustainable model to deliver regulatory science across the healthcare system to evolve regulatory decision-making	Q3
Review Agency pre-market activities and develop a new Science Strategy to underpin work on innovation and life-cycle management	Q3
Deliver innovative biological standards	Q4

3. Lifecycle and safety management to improve proportionate decision-making in the interests of patients

We will align available data and information, including real-world evidence, to inform regulatory decisions on benefit-risk and safety throughout the lifecycle of a product, seeking the views of healthcare professionals and patients to inform decision-making and guidance we publish. We will achieve this through three strategic objectives:

- To embed state-of-the-art surveillance across medicines and medical devices
- To ensure the health system understands and acts on information and guidance
- To review regulatory services

In 2020-21 we will:	By
Establish by end Q1 the framework for a single signal detection process for medicines and medical devices as part of the programme for integrated vigilance system across medicines and medical devices.	end Q1
Develop a proportionate risk-benefit decision-making process aligned with the regulatory framework and including patient views	Q4
Deliver new IT systems for vigilance functions for medicines and medical devices including making use of developments in AI	Q4
Establish the operating model for a Yellow Card biobank	End Q4
Develop and publish guidance on a new innovative UK licensing procedure for biosimilar products to operate from 1 January 2021 to reduce the burden on clinical trial data generation.	By end Q3
Develop practical proposals and publish guidance on the use of Real-World Evidence in supporting clinical trial data and regulatory approvals to support innovation	Q3
Working with patient representatives, improve new information and guidance on products	from Q2
Utilise strategic partnerships to ensure health sector bodies understand and act on information and guidance	By Q3
Review current and future regulatory process to create a streamlined approach to lifecycle management	Q2
Develop standards to support a risk-based proportionate approach	Q3

4. Data and Analytics:

We will enhance access to data, data services, and evidence-based data analysis to underpin our regulatory and science processes so as to improve patient safety and health outcomes. We will achieve this through three strategic objectives:

- To improve further our unique data assets to strengthen how we regulate medicines and medical devices
- To maximise the impact of our analytical capabilities to enhance risk evaluation and safety management
- To develop the infrastructure to support data and analytics

In 2020-21 we will:	By
Translate CPRD data into common data models	Q3
Increase CPRD data coverage to 25% of the UK population	Q4
Standardise analyses and outputs across different datasets to facilitate the assessment of regulatory submissions	Q3
Develop tools to automate routine processes to expedite regulator decisions	Q4
Implement a high-performance computing network	By end Q3
Analyse current data structures held in new and legacy systems and deliver a road map to manage data going forward	Q1/Q2
Create an integrated centralised data analytics team for medicines and devices vigilance	Q2
Review current and future regulatory process to develop a regulatory model fit for future products and methodologies	Q3
Create a sandpit infrastructure to support experimentation of innovative analytical techniques and test innovative methodologies, eg AI, in a secure environment	Q2
Manage transition of infrastructure to new providers, move legacy systems to the cloud, and upgrade applications and hardware to retain resilience	By Q4

5. Governance and partnerships: reinforced governance, delivery capacity, and external partnership working

We will review and transform leadership and develop improved governance processes and structures to drive and support change and to manage key programmes across the Agency. Aligned to that we will have impactful and strategic engagement and work jointly with strategic partners including across the health and care sector. We will achieve this through three strategic objectives:

- To revise structures and governance to drive change
- To improve Agency-level programme management
- To enhance strong active partnerships

In 2020-21 we will:	By
Review and reshape the Agency's governance structures to ensure top-level Executive governance is aligned with and drives Agency Change, including an appropriately structured Agency Executive Committee and a refreshed unitary Board	End Q1

Establish robust structures for Agency-wide management of key delivery and change programmes, with aligned planning and financial reporting to Board and DHSC	Q1
Develop a new model for setting fees in future years in the context of strategic finance planning	Q2
Define in Q1 and drive forward through the year the Agency's efficiency programme	Q1
Focus engagement with key strategic partners to support innovation and influence clinical practice to encourage manufacturers to bring innovative products to the UK	End Q2
Prioritise engagement so that we get the right information and messages to patients through the wider healthcare system	Q1