



Medicines & Healthcare products
Regulatory Agency

Putting patients first: A new era for our agency

Delivery Plan 2021-2023

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Introduction

A new era in regulation

Today's world calls for a new Medicines and Healthcare products Regulatory Agency driving forward a new era in enabling regulation, regulatory science and best evidence.

Today's public and patients have rightful expectations of safety and involvement in decisions about their healthcare products. Today's brilliant life sciences industry demands an agile and supportive regulator. Today's health service deserves safe and speedy access to the most transformative products.

The future agency starts today, and this plan is the roadmap to our future. It represents the beginning of a new era in the protection of patients, their closer involvement and the improvement of public health through innovative regulation based on excellence in science.

This time of change is a generational opportunity to deliver a new era and transform our organisation. As such, we are committed to delivering our new and ambitious two-year Delivery Plan 2021-2023 and building a new organisation that is fit for the future and underpinned by a robust long-term business model.

Successful delivery of our plan will ensure that we achieve our ambition: putting patients first, becoming a truly world-leading, enabling regulator and protecting public health through excellence in regulation and science.

- Putting patients first
- World-leading
- Innovative
- Scientific excellence



Our purpose

One agency, delivering for patients

Our purpose is clear: to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

We aspire to be a leading global example of delivering excellence in public health and patient safety, enabled through regulation and at the forefront of innovation. Delivering our vision relies on our ability to act as one agency and to relentlessly pursue the delivery of meaningful outcomes for the patients we serve.

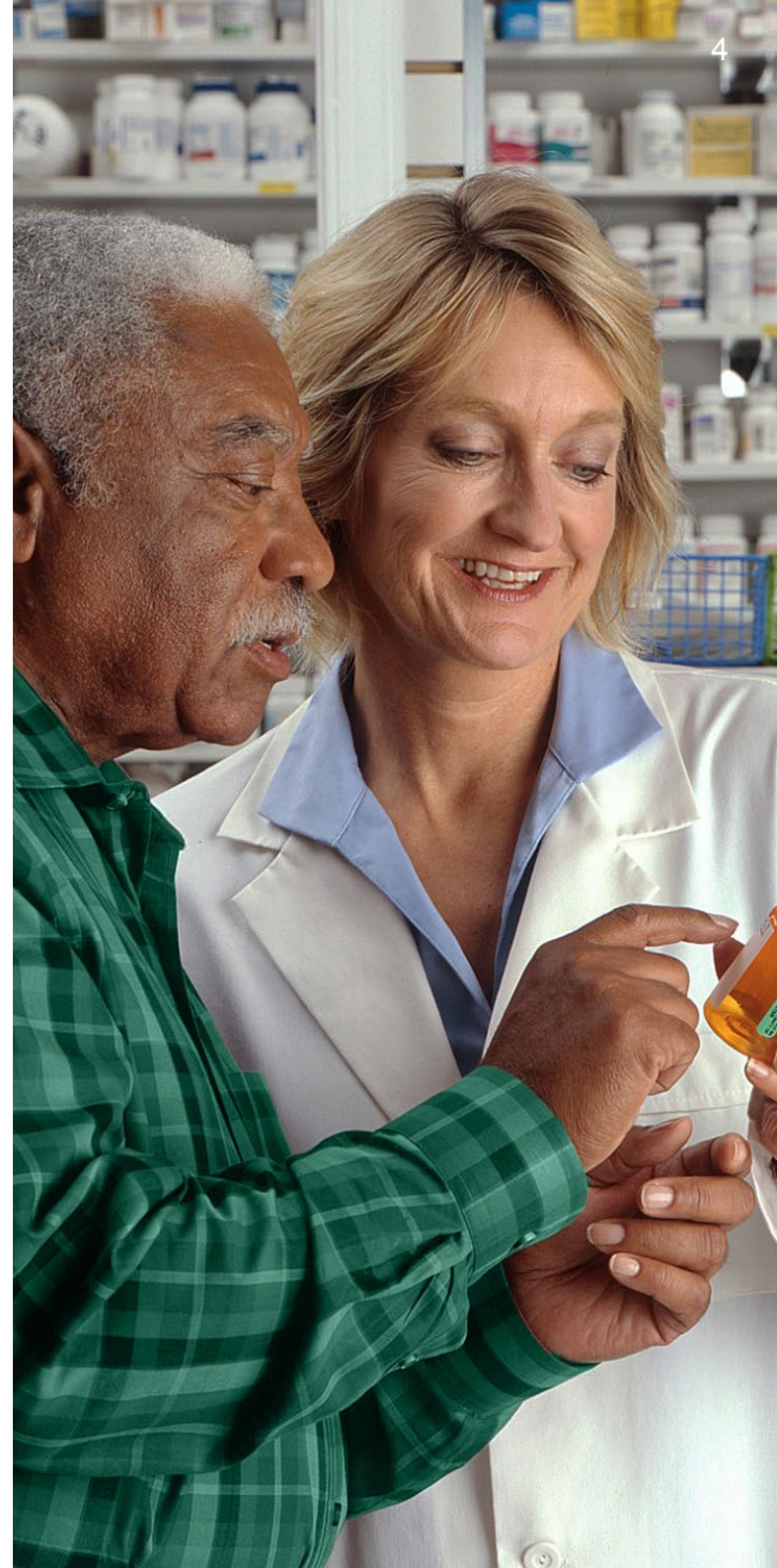
This means drawing together our scientific rigour and regulatory expertise to address the challenges faced by the life sciences sector and health service; how best to develop new regulatory frameworks and quickly realise the benefits that new therapies, artificial intelligence and innovative healthcare products can bring to patients, while still ensuring the right levels of safety, quality and efficacy. It also means more systematic engagement with patients and putting patient outcomes at the heart of what we do.

We know that this means we need to change, right across the organisation, if we are to be successful in delivering our vision.

In the Independent Medicines and Medical Devices Safety Review, Baroness Cumberlege exposes areas of vigilance which need strengthening, gaps in the health system, but most important of all, a failure to listen to and respond to patients. Our plan addresses these with clear actions that will help us to embed the needs and expectations of patients throughout our organisation.

Following our departure from the European regulatory system, we will seize the opportunities to evolve our regulatory framework and keep pace with fast-moving life science developments, from novel personalised medicines to software and artificial intelligence, whilst ensuring our regulation provides the utmost protection of patients.

We continue to play a pivotal role in the health and social care system and a leading role internationally. We are committed to delivering our objectives in collaboration with others within and beyond the UK. Our remit is UK-wide, and we will continue to maintain strong relationships with the Devolved Administrations.



Our purpose

Rising to the challenge of COVID-19

Our continuing response to the challenges posed by the COVID-19 pandemic has demonstrated our outstanding contribution to public health. It has also revealed what sort of organisation we can be.

We have flexed our resources, demonstrated agility in our approach and worked more closely than ever with our partners in the UK and internationally, to support the NHS with the technologies and therapies it needed.

We have worked quickly and thoroughly to facilitate and approve clinical trials which have generated a sound evidence base for effective treatments for those infected, and for the approval of vaccines to prevent infection.

Our rolling reviews of the evidence have enabled us to rapidly approve licences for these products, while maintaining high standards of safety, efficacy and quality. Together, these actions have enabled a vaccine rollout that has directly saved lives.

Finally, our new approach to interrogating high volumes of safety data from those inoculated means we can provide public health advice in real-time about the benefit-risk of the vaccines across the UK population.



Image courtesy of the Press Association. ©PA 2021

Our purpose

How we operate

We are a government body that regulates medicines, medical devices and blood products for transfusion in the UK, underpinned by science and research.

We do this by making sure that the products we regulate — from painkillers to pacemakers — work properly and are acceptably safe; and by responding quickly and effectively when new concerns come to light.

No product is completely free of risk, but by using an array of evidence, we provide a critical appraisal of whether a healthcare product's benefits outweigh its risks and is suitable for use in the UK. Where some lower-risk medical devices are regulated by third party organisations, we set the regulatory requirements that define when those products can be approved for use in the UK.

To help the life sciences industry to develop effective and innovative healthcare products, we also engage proactively in the early stages of development.

We advise on the designs of clinical trials to ensure patient involvement and patient safety, and we advise on the evidence of safety and impact that developers will need to demonstrate for each product, to help products reach patients as quickly as possible while maintaining high levels of safety and quality.

Following our appraisal decision, we work with manufacturers to help them to comply with expectations of quality for their product to ensure they are safe to use.

We also monitor trends in data from a wide range of different sources, which enables us to quickly identify safety concerns.

Where these arise, we investigate and take a decision, using independent expertise, on the best course of action which could lead to products being removed from the UK market.

Right across our role in ensuring safe, impactful and quality medical products and technologies in the UK, we work with patients and healthcare professionals to deliver quick and easy-to-use advice and information about the products we regulate.

Our purpose

Our most valued asset is the expertise of our employees

Our highly skilled staff members, located in facilities in London, York and Hertfordshire, are among the best medical, regulatory and scientific experts in their fields, worldwide.

Using this expertise, we undertake a range of important services to protect public health:

- Acting quickly on patient safety issues and providing advice about the risks and benefits of medicines, medical devices and blood products, leading to safer and more effective use.
- Bringing innovation safely to patients as rapidly as possible.
- Enabling authorisation of established products promptly to support wider access to medicines.
- Carrying out the standardisation and control of biological medicines and promoting international standardisation and harmonisation.
- Ensuring that the UK's supply chain is safe and secure.
- Supporting innovation, research and development.
- Influencing UK and international regulatory frameworks so that they are risk-proportionate and effective.
- Enabling up-to-the-minute studies and trials by offering our anonymised GP clinical data service, which has data encompassing 60 million patients, including 16 million currently registered patients.



Our resources

We are an Executive Agency of the Department of Health and Social Care. We are funded mostly by income from fee-charging activities and sales from the products and services we offer, with the remainder of funds coming from the Department of Health and Social Care as grant-in-aid for specific activities mainly related to medical devices regulation and scientific research.

As a government trading fund our finances have been separate from our sponsor department. Recently the Office for National Statistics assessed the economic status of the organisation and concluded we should be classified to the central government subsector. Once our Trading Fund status is ended, our finances will be consolidated within the department's accounting boundary.

We utilise the expert advice of the Commission on Human Medicines, the UK Government's independent advisory body on the safety, efficacy and quality of medicinal products.

The Devices Expert Advisory Committee is responsible for providing us with independent, external, expert clinical and scientific input and advice on a wide range of aspects relating to the introduction and safe use of medical devices.

**Our regulatory decisions
are impartial and based
solely on the extensive
evidence required for
each product**

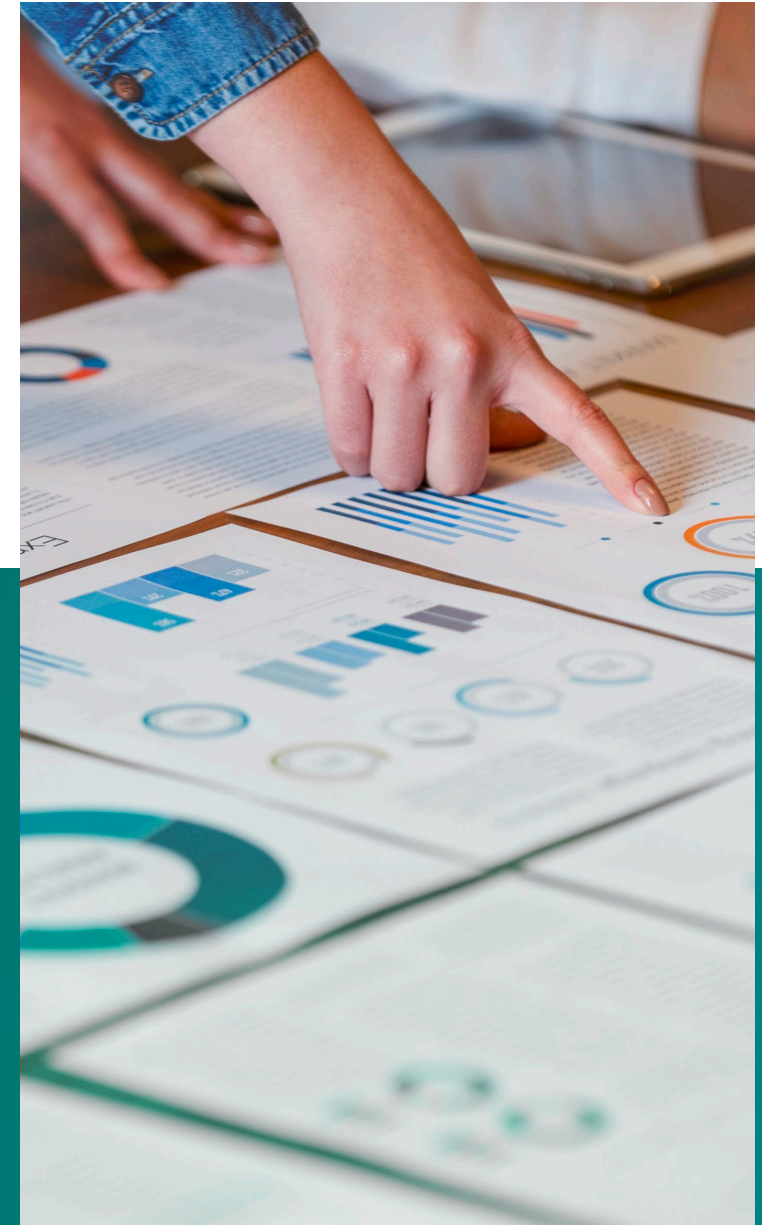
Our plan

A new plan for a new agency

Until now, every five years, we have published a corporate plan that outlines longer-term aims and objectives. Much has changed since we published our Corporate Plan (2018-2023), so we are seizing the opportunity to refresh it. We intend to deliver a new more focused plan to a shorter timeframe, reflecting the pace needed if we are to realise our aspiration to be a global leader in what we do.

It is vital that we respond to the opportunities we now face, and we must address several substantial and interconnected challenges, including:

- Evolving and strengthening our regulatory framework so that it looks to the future and keeps pace with fast-moving life science developments, from novel personalised medicines to software and artificial intelligence, whilst ensuring our regulation provides for the utmost protection of patients.
- Embedding changes into our everyday practices to deliver the recommendations of the Independent Medicines and Medical Devices Safety Review and ensure that we engage more systematically with patients and put patient outcomes at the heart of what we do.
- Creating a new business model that provides a financially sustainable future and preparing for the end of our operation as a Trading Fund and inclusion within the Department of Health and Social Care's accounting boundary. This will limit the use of our existing reserves to fund our Transformation Programme and investments to the 2021/22 financial year. After that date, we will no longer be able to carry forward reserves and will need a new financial model that balances our budget in-year.
- Capitalising on the creation of new international regulatory relationships, enabling collaboration in different ways now that we are no longer part of the European regulatory framework.



Our plan

Our new Delivery Plan 2021-2023 is designed to bring together and prioritise our existing efforts in one place, and to outline a programme that focuses on delivering over the two-year period.

The new priorities and objectives are being supported by our Transformation Programme which will deliver structural changes to the organisation and a new operating model within the same timeframe.

We have also redesigned internal governance from the top of the organisation via a refreshed unitary Board and Executive Committee, led by our Chair and Chief Executive. The creation of a new committee structure will support more efficient decision-making and operation.

We have put the lifecycle of the products we regulate at the core of our new structure. This will break down silos and group our staff and expertise in a way that focuses our resources where they add most value. This will ensure we deliver what our customers want, as well as public health outcomes that benefit patients.

Our plan is the result of an extensive process of development. Our unitary Board and Executive Committee, led by our Chair and Chief Executive, have worked together to agree the strategy that underpins the future of our organisation and the priorities that will shape how we deliver that future.

We have developed this alongside an assessment of core activities that must be delivered by the business, and worked to identify interdependencies and trade-offs, which has culminated in the critical objectives that form this plan.

The priorities and objectives of our plan have been informed by our ongoing dialogue with our stakeholders. Partnership working is central to successful delivery and we intend to use the plan to engage our partners and strengthen relationships via detailed work programmes.



Our plan

The impact of COVID-19

For as long as it is necessary, we will continue to prioritise efforts to combat COVID-19. As the regulator, we are responsible for continuously monitoring the safety of all medicines, including vaccines, and medical devices once they are approved for use.

Vaccines are the most effective way to prevent infectious diseases and they save millions of lives worldwide. At the time of writing, over 37 million doses of vaccines against COVID-19 have been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in the UK.

Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them. We continually monitor safety during widespread use of any vaccine. This is to ensure vaccines are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.

This work will remain a priority while we deliver the wider objectives in the Delivery Plan 2021-2023. We will continue to authorise the development of vaccines, facilitate clinical trials of new medicines, support the supply of safe medicines and healthcare products, and ensure prompt, clear public health communication to the UK population.

All of our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks

Our goals

Ensuring we deliver our promises to patients

This plan focuses our efforts on six strategic goals and 14 underpinning objectives. Scientific innovation, healthcare access and patient safety are our three key business outcomes. These are enabled by ensuring we have a dynamic organisation, that we make the most of collaborative partnerships and that we are financially sustainable.

Our Delivery Plan 2021-2023 has one overarching goal – delivering for patients and the public is at the heart of our plan and is a priority for all staff.

Our goals



Scientific innovation

2. Deliver public health impact, world-leading research innovation and a unique proposition
3. Overhaul the clinical trials system to support innovation and reduce time to approval



Healthcare access

4. Develop and deliver our future strategy and approach for access to medicines and devices
5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products



Patient safety

6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe
7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products



Priority for all staff

1. Deliver better patient and public involvement to ensure we put patients first



Dynamic organisation

8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator
9. Deliver a programme to enhance our leadership capability and to attract, retain and develop talent so that we can fuel innovation and drive change



Collaborative partnerships

10. Leverage international partnerships to drive better outcomes
11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes.
12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications



Financial sustainability

13. Establish a new business model for the future that increases income, reduces costs and improves productivity
14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies

Our deliverables

A priority for all staff



1. Deliver better patient and public involvement to ensure we put patients first

Our vision for a new agency puts patients at the heart of what we do.

The Independent Medicines and Medical Devices Safety Review clearly outlined the importance of more engagement with patients and their outcomes. This is why we have put patient and public involvement at the heart of our Delivery Plan 2021-2023.

This is a cross-cutting priority: the majority of the objectives below have been developed with the needs of patients in mind, and many of the planned changes will involve consultation with patients. This will ensure we put patients first across the full range of things we do and lifecycle of the products that we regulate, for example:

- Develop our use of Patient Reported Outcome Measures to make patient outcomes more central to clinical trials (objective 3).
- Making patient involvement more prominent following the implementation of the Medicines and Medical Devices Act (2021) and a new innovative licensing and access pathway that aims to ensure that patients are involved meaningfully at every stage of the process (objective 4).
- Develop and publicly consult on a new regime for medical devices that makes patient safety and engagement, and transparency more prominent (objective 5).
- Implement an enhanced and more responsive safety reporting system (objective 6).
- Continue prompt public health action to protect patients (objective 6 and 7).
- Roll out patient engagement activities, deliver communication campaigns and an enhanced Customer Service Centre (objective 12).
- Deliver a new digital self-service platform that will improve the service patients and customers receive (objective 14).

Scientific innovation



2. Deliver public health impact, world-leading research innovation and a unique proposition

We are recognised as a global leader in science and we will build on this reputation.

Our new ambitious science strategy will draw from our deep expertise to ensure we capitalise on the unique selling points and differentiation of our science, research and data. It will allow us to keep pace with the changing needs of patients in the UK and global trends in medicine and medical device innovation, and help us to prioritise and focus our efforts accordingly.

This will ensure we deliver world-leading research innovation that focuses on protecting and improving patient health; and ensures we retain our global prominence.

- Develop and publish our laboratory strategy and long-term plan, including a standards sub-strategy, by Q4 2021/22 and implemented from Q1 2022/23.
- Upgrade our observational research infrastructure to enable timely and secure delivery of research data services: map out requirements by Q4, 2021/22; commence implementation of new systems by Q2, 2022/23.
- Scale up two pilot primary care common data models to facilitate pharmacovigilance across different data sources: the 'Observational Medical Outcomes Partnership' model by Q1, 2022/23; the 'Sentinel' model by Q2, 2022/2023.
- Draft guidelines for independent laboratory testing to support UK certification of batches of biological medicines by Q3, 2021/22; implement independent testing based on risk-based strategy by Q4, 2022/23.



Our deliverables

3. Overhaul the clinical trials system to support innovation and reduce time to approval

Overhauling the clinical trials system will ensure we continue to have a world-leading regulatory system that supports both UK and global trials.

We will drive the uptake of innovative trial designs, patient focused outcome measures, data enabled recruitment, and real-world evidence collection and analysis. We will put the patient voice, and active patient participation, at the heart of the regulation of trials. We will keep up with international standards and emerging innovative therapies to ensure that those engaged in trials will continue to develop safe, innovative treatments, both benefitting patients and boosting growth.

This will ensure we encourage more trials; greatly improve the time it takes for trials to be approved, started, and delivered; and ensure that outcomes are more patient focused.

- Encourage a more innovative and pragmatic approach to UK clinical trials via an initiative to facilitate the uptake of novel trial designs and a communication effort to tackle the misperceptions that “traditional” clinical trials are always required for a licence by Q4, 2021/22.
- Launch a new service that assists in the rapid recruitment of patients into commercial clinical trials, with the first contract in place by Q3, 2021/22; and offer this service to companies as standard by Q2, 2022/23; and by Q4, 2021/22 achieve 1 in every 4 UK GP practices signed-up to our clinical practice research data service.
- Consult on options for changing UK legislation to make conduct of trials generating real-world data easier by Q4, 2021/22.
- Publish guidance on points to consider when using trial designs with a real-world data element to support a licence application by Q4, 2021/22.
- Deliver NHSX funded synthetic data research project by Q4, 2021/22 and launch prototype synthetic data generation service by Q2, 2022/23.
- Finalise and promote the Innovative Licensing and Access Pathway Novel Trial Design Tool in partnership with the wider health ecosystem by Q2, 2022/23.
- Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by Q4, 2022/23.
- Develop our use of Patient Reported Outcome Measures via involvement in the “Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data” international initiative from Q1 through to Q4, 2021/22; work up deliverables in 2022/23.
- Deliver two NIHR funded, real world pragmatic clinical trials through our innovative data-enabled clinical trials platform, with the first patients randomised in both trials by Q3, 2021/22.

Healthcare access



4. Develop and deliver our future strategy and approach for access to medicines and devices

Following the UK's exit from the EU, we intend to ensure the UK becomes an even greater place to develop, manufacture and supply products; and that we have continued access to safe new medical products.

The passing of the Medicines and Medical Devices Act (2021) brings with it the opportunity to evolve the UK's regulatory regime.

We will develop our strategy for the products we regulate and ensure we encourage and enable developers to bring products to the UK market.

- Put in place new legislation to ensure safe access to innovative products and to protect public health: timings agreed and public consultations begin from Q1, 2021/22; consult on a national scheme to replace the falsified medicines directive's safety features regulation by Q4, 2021/22 and formulation of final post-standstill policy during 2022; resolution of any live regulatory issues following EU transition by Q1, 2022/23. Together, this builds towards a new underpinning legal regime that delivers for patients and supports the UK's Life Sciences industry.
- Integrate with the Health Research Authority and National Institute for Health Research Clinical Research Network to provide a fast track approval for defined clinical trials - criteria for approval agreed by end Q2, 2021/22; expand pilot process providing a single decision on research using both a medicine and device to a wider cohort of applicants and develop a process for the combined review of a product by Q1, 2022/23.
- Reduce regulatory burden by working with stakeholders to identify which flexibilities introduced in response to COVID-19 are safe to embed by Q3, 2021/22.

We intend to ensure the UK becomes an even greater place to develop, manufacture and supply products; and that we have continued access to safe new medical products

- Support access to generics and biosimilars via more global harmonisation in approval standards; seek membership of International Pharmaceutical Regulators Programme from Q3, 2021/22; take forward discussion of UK Biosimilar guidance in the Access Consortium, a medium-sized coalition of regulatory authorities, from Q3, 2021/22.
- Develop a mechanism to pilot joint clinical trial approval and clinical trial and licensing scientific and compliance advice via Access Consortium by Q4, 2021/22.
- Further develop the Innovative Licensing and Access Pathway concepts and tools, in collaboration with the National Institute for Health and Care Excellence and the Scottish Medicines Consortium to create a world-class first port of call for medicines development and access by Q3, 2021/22.
- Ensure integrated UK regulatory pathways for products that combine medicinal products and medical devices; consultation by Q3, 2022/23.
- Work closely with the Northern Ireland Executive to ensure effective regulation and timely access to life-saving medicines and medical devices.

Our deliverables

5. Establish a new medical devices legislative framework to support safe innovation and ongoing access to products

Levelling up the UK's medical devices regime will ensure changes in clinical needs, technologies and patient views are integrated into modern and effective legislation.

We will design, consult on and implement a new legislative framework for medical devices.

This will support ongoing access to products with the aim of providing an environment in which to support safe innovation. It will build on the existing framework, taking into account international best practice.

To address the recommendations of the Independent Medicines and Medical Devices Safety Review, patient safety and engagement, transparency, and our pre-market role will also be key considerations. In the design and implementation of the new framework, we will work with partners across the healthcare system, including the National Institute for Health and Care Excellence, the Health Research Authority, clinicians, NHSX and NHS Digital.

Our efforts will ensure an ongoing supply of safe medical devices to patients, the public and the healthcare system.

- Publish public consultation covering all key aspects of proposed new market access framework by end Q2, 2021/22.
- Publish a consultation response with finalised policy positions by end Q4, 2021/22.
- Lay relevant statutory instruments by end Q1, 2022/23
- Publish key guidance documents by end Q3, 2022/23 with ongoing engagement with stakeholders over the course of 22/23 to prepare them for the new framework.

Patient safety



6. Deliver a more responsive safety surveillance and risk management system, for all medical products, to keep patients safe

Continually improving our systems for identifying and acting on public health risk is essential to ensure we respond swiftly, effectively and appropriately to any emerging issues of safety.

The need for an updated adverse event reporting and medical device safety surveillance were areas identified by the Independent Medicines and Medical Devices Safety Review. We will deliver a more responsive system that detects and responds to signals of issues more quickly and enables greater interaction with reporters. We will move towards better risk assessment and more impactful safety messaging.

In addition to our own deliverables, we will work closely with NHS colleagues to support the development of the Medical Devices Information System. Our efforts will ensure we keep patients safe and improve our service to patients and healthcare professionals.

- Complete review on new medical devices signals and risk management process, embed risk assessment template and identify opportunities for patient involvement by end Q1, 2021/22.
- Improve the model of the Devices Expert Advisory Committee and its Expert Advisory Groups by Q3, 2021/22, to ensure greater involvement of independent, scientific, technical, lay and clinical experts in regulatory decision making.
- Deliver enhanced signal detection process for medicines and medical devices by Q4, 2021/22; service enhancement and international opportunities to defined in Q4, 2021/22 and delivered in 2022/23.
- Agreed policy for a significantly enhanced transparency regime for medical device regulation by Q4, 2021/22 with key elements being delivered over 2022/23.
- Further action on sodium valproate to drive compliance with the Pregnancy Prevention Programme. Enhance the valproate registry by extending the established England registry to include all antiepileptics by end of Q2, 2021/22 and to make available a UK-wide digitalised annual risk acknowledgment form alongside defining the extension of the registry to the whole of the UK by end of Q4, 2021/22.
- Review of teratogen use during pregnancy, and consideration of the strategies of other regulators by Q3, 2021/22, with independent patient and stakeholder input and expert advice by Q4, 2021/22; and, if required, updated action and guidance by Q2, 2022/23.
- Deliver an options appraisal for our project to investigate the role of genetics in the development of adverse drug and vaccine reactions by Q3, 2021/22.

Our deliverables

7. Deliver innovative interventions to ensure the UK has a secure supply chain providing high quality products

Delivering a secure supply chain for medical products, and to the highest internationally accepted standards, will help keep patients and the public safe.

We will protect the UK's supply chain via proactive management of poor compliance, a proportionate risk-based inspection programme and innovative interventions to disrupt serious criminal threats.

Building on and learning from our ongoing response to the COVID-19 pandemic, we will also look for ways to reduce any unnecessary regulatory burdens and increase the efficiency of our processes.

This will help ensure that patients get safe access to medical products and that we protect public health.

- Pilot voluntary 'pre-inspection' checks to fast track new applications for manufacturing licences and piloting the use of consultants as 'compliance monitors' in remediation cases by Q3, 2021/22; roll out of automated inspection reports and identify new risk-proportionate approaches with our international partners by Q4, 2021/22; embed file-sharing platforms for remote inspections and visual technology capabilities as a standard part of inspections in 2022/23.
- Deliver the Great Britain Medicines Verification System, to replace the EU system and enable medicines to be tracked through the supply chain – delivery in partnership with the Department of Health and Social Care and to their timescales when finalised.
- Deliver a world-leading approach to inspections and enforcement with assurance that products are developed and manufactured to the highest standards and prompt action to reduce criminal threats throughout 2021/22 and 2022/23.

Dynamic organisation



8. Deliver our Transformation Programme to make us a truly world-leading, innovative regulator

We have reached a pivotal point in our development and have the opportunity to become a global exemplar in public health and patient safety, enabled through regulation and at the forefront of innovation.

Our Transformation Programme will drive change across the organisation, support the Delivery Plan 2021-2023 and ensure we deliver our objectives with greater accountability, focus on benefits and a systematic prioritisation of activities that add value and deliver better outcomes for patients.

This will ensure we adapt successfully and become a truly world-leading innovative regulator.

- Embed the Delivery Plan 2021-2023 in staff objectives by Q1, 2021/22; monitor performance from Q2, 2021/22 with an updated reporting approach; and fully review progress in delivering the plan and agree any changes with the Department of Health and Social Care in Q1, 2022/23, as part of our annual business planning cycle.
- Deliver accompanying Transformation Programme and organisational redesign (staffing, governance, structures, processes) by Q4, 2021/22 and post implementation support including benefits realisation from April 2022 onwards.

Our deliverables

9. Deliver a programme to enhance our leadership capability to attract, retain and develop talent so that we can fuel innovation and drive change

Leadership and workforce planning are vital to supporting organisational change, maintaining high performance and attracting the expertise we need to remain a first-class regulator.

We will deliver a programme alongside wider organisational change to identify workforce and talent requirements, and the training our staff need. We will work to attract, retain and develop our talented staff.

This will ensure we have the right workforce and we empower our staff to put patients first and deliver the change needed to make our Delivery Plan 2021-2023 a success.

- Develop an organisational culture action plan by Q1, 2021/22 and deliver associated actions; refresh plan in Q1, 2022/23.
- Launch staff leadership action plan from Q2, 2021/22.
- Deliver Human Resources support and guidance to staff during organisational restructuring throughout Q1-Q4, 2021/22.
- Identify future workforce and talent needs and deliver action to ensure we embed workforce planning by Q2, 2021/22; and review workforce in Q1, 2022/23 to identify follow up actions.



Collaborative partnerships



10. Leverage international partnerships to drive better outcomes

We are committed to excellent international relationships that deliver high standards of patient protection, prompt access to innovative products and that keep the UK an attractive market for developers and manufacturers of medical products.

We will work with international partners to scope and deliver priority work programmes, with a particular focus on the interoperability of data and systems; strengthening the outputs of the Access Consortium, helping to make it competitive as a global regulatory pathway for companies; and helping to maintain and establish new relationships globally, following our exit from the EU.

This will ensure we make the most of new opportunities since leaving the EU and continue to secure our leading international role.

- Development of an international strategy underpinning and aligned to the wider objectives in the Delivery Plan 2021-23 by Q2, 2021/22.
- Continuing our collaboration with the EU, through the establishment of the Medicinal Products Working Group, established under the Trade and Cooperation Agreement as a forum for bilateral cooperation that can be built on in future. Q2, 2021/22.
- Collaborating with other country regulators to provide quicker access to the next generation of cutting-edge treatments, while maintaining the highest safety standards by Q4, 2022/2023.
- Full assessment of the linkages needed with the World Health Organisation, including in the context of our biological and control standards work by Q2, 2021/22.
- Improve our ability to capture and exchange data with partners by adopting international standards including “Identification of Medicinal Products” regulations by Q2, 2022/23.
- Establish greater international regulatory collaboration and alignment with the Access Consortium so patients benefit from timely access to high quality, safe and effective medicines from Q3 2021/22.
- Deliver a refreshed inspection network that adds strengths and international standing to the work of our inspectorate by Q4, 2021/22.
- Actively engage in ongoing negotiations (with the USA, Australia, New Zealand and others), putting forward a positive regulatory agenda and enhancing areas of regulatory cooperation throughout 2021-23 as per the Department for International Trade timescales.

Our deliverables

11. Leverage UK healthcare system partnerships to integrate processes and drive better outcomes

The complex cross-cutting nature of issues facing a modern health and social care system means effective partnerships are vital to ensuring we deliver our objectives.

We will enhance our relationships with key partners, with defined work programmes and impacts, and with a particular focus on NHS organisations, including the All Wales Therapeutics and Toxicology Centre, Health Research Authority, National Institute for Health and Care Excellence, and the Scottish Medicines Consortium.

We will continue to deliver our commitments to the Department for Health and Social Care, UK Ministers and the Devolved Administrations.

This will ensure we protect public health, maximise our impact and reach across clinical networks and more effectively share information to empower patients and the public to make informed decisions.

- Agree a revised Partnership Agreement and a detailed package of work programmes with the National Institute for Health and Care Excellence, focused on safety and standards, improving timely access to medicines and healthcare products for patients, and the promotion of innovation and growth by Q1, 2021/22.
- Run partnerships meetings with the Devolved Administrations and wider stakeholder groups to inform and involve them about the delivery of their priorities, quarterly throughout 2021/22 and 2021/22.
- Deliver our data sharing strategy across the health sector, underpinned with robust security standards and privacy by design by Q3, 2021/22.
- Map and identify the most important partnerships for delivery of our 2021-23 objectives and refresh strategic relationships with detailed work programmes developed to maximise reach and impact across the system from Q2 and in place by Q4, 2021/22.
- Continue delivery of our commitments to the Department of Health and Social Care and ministers throughout 2021/22 and 2021/22.

Our deliverables

12. Build public and stakeholder trust in our organisation through a programme of proactive and innovative communications

In our role as a regulator, it is vital that we maintain trust in our approach, expertise, products and services.

We will deliver a programme of proactive and innovative communications to support all relevant Delivery Plan 2021-2023 objectives. This will have a particular focus on ensuring we put patients first, ongoing COVID-19 communications, prompt communication of safety issues and enhancing the operation of our Customer Service Centre.

This will help build public and stakeholder trust and support the delivery of wider objectives.

- Develop and deliver communications to support the launch of new and ongoing activities (products, services, campaigns and issues) throughout 2021/22 and 2022/23 (covers all communication deliverables in the plan).
- Publish our Public Engagement and Involvement Strategy, which sets out how we can best include patients in our work by Q1, 2021/22.
- Issue ongoing, prompt and responsive safety communications, including COVID-19, falsified medicines and medical devices, safer medicines and devices for women, drug safety issues, reclassifications, product alerts and notifications; deliver communications to improve the understanding of and engagement with current and new medicine and medical device safety reporting services among patients and healthcare professionals, throughout 2021/22 and 2022/23. Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from Q2, 2021/22.
- Develop and deliver further communications to support the evolution of our COVID-19 vaccines strategy from Q2, 2021/22.
- Enhance our Customer Service Centre to support effective engagement with patients and customers, enabling them to access the information they need when they need it from Q4, 2021/22.

Financial sustainability



13. Establish a new business model for the future that increases income, reduces costs and improves productivity

We must create a new business model that ensures the organisation has a financially sustainable future given the changing circumstances.

We will conduct a full review across our sources of income and costs, adjusting fees and defining a new business model. This will ensure the organisation is put on a robust footing for the future.

- Develop, consult on (Q3, 2021/22) and implement a new fee structure by Q2, 2022/23.
- Implement organisational design, creating a new, leaner structure for the organisation and balancing our costs by Q3, 2021/22.
- Use available cash reserves to fund necessary systems investments, operational deficits and restructuring costs until the end of our Trading Fund status at the end of 2021/22.
- Reduce corporate costs by 15% by the end of 2022/23.
- Reduce non-pay costs of £60m by £6m per year through contract renegotiation and contract management by the end of 2022/23.



Our deliverables

14. Deliver an optimised IT infrastructure to improve our service and reduce our costs with fewer digital technologies

Modern digital, data and technology solutions are central to our new organisation and the services we provide.

We will deliver simple, smart solutions using automation, artificial intelligence and digital self-service. We will build on established technology platforms so they support multiple services, improve interoperability across the UK health system and internationally, and optimise costs.

This will ensure we focus on meeting the needs of patients and our stakeholders more completely and quickly than ever before. It will also improve our ability to share data and collaborate across the UK health system and internationally; provide opportunities to reduce costs and ultimately enhance our ability to protect public health.

- Finalise our plan to overhaul costly legacy systems by Q3, 2021/22 and start to deliver improved service and savings from Q4, 2021/22, and to have a new regulatory management core system in place by Q3, 2022/23.
- Deliver a new digital self-service platform in beta by Q4, 2021/22 and live in Q1, 2022/23 that will improve the service patients and customers receive.
- Support the revised regulations around medical devices, deliver the digital self-service, automation and data platforms required by Q3, 2022/23.
- Work with the Health Research Authority to deliver an enhanced clinical trials service by Q4, 2022/23.

Our reporting

Monitoring our progress

Each year, as part of the Department of Health and Social Care's annual planning process, our strategy, targets and plans are summarised and reported to the Department for scrutiny and review.

Before the start of each financial year, we prepare, for endorsement by our Board and agreement with the Department, a plan that demonstrates how we will deliver our objectives and the regulatory functions that the Secretary of State has instructed us to carry out on his/her behalf. Each plan sets out the intended activity for the following financial year and includes specific objectives and deliverables. Once approved by our Board and the Department, we publish a summary of the plan.

Progress against delivery will be reviewed as part of our quarterly and annual accountability meetings with the Department. Progress will be monitored internally by our new unitary Board and Executive Committee, supported by our new cross-agency Management Committees and a balanced scorecard with performance measures for our strategic objectives.



Contact us

We are an Executive Agency of the Department of Health and Social Care. The Department holds us to account for our performance, and we work in partnership to serve ministers and Parliament. Details on our relationship with the Department can be found in our Framework Agreement.

As UK civil servants, all our staff are committed to the Civil Service core values of integrity, honesty, objectivity and impartiality. Additionally, our staff are not allowed to have any personal financial ties to pharmaceutical companies or medical device manufacturers.

If you are a patient, member of the public, healthcare professional, or work for a pharmaceutical company or medical device manufacturer and would like more information on our work, please contact us.

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