Medicines & Healthcare products Regulatory Agency

Putting patients first - Delivering our priorities

Delivery Plan 2021-2023
Updates for year two

Contents

Focusing on our priorities, maintaining our momentum

Last summer we published our two-year Delivery Plan 2021-2023 'Putting patients first – A new era for our agency'.

In it, we set out an ambitious roadmap for change: ensuring that we put patients first, become a truly world-leading, enabling regulator and that we continue to protect public health through excellence in regulation and science.

At this point in our delivery, we have updated some timescales and sharpened our focus on the following areas of activity:

- Patient and public involvement
- Equity in healthcare – our role
- Embedding innovative ways of working

These new themes allow us to focus on important areas that require greater clarity and prioritisation.

One year on, we are proud of what we have achieved, particularly our continued response to the pandemic and our wider transformation into a sovereign regulator that is trusted, proactive and proportionate.

Patient and public involvement

Delivering our commitment to putting patients first

Following the publication of our first Patient Involvement Strategy on 1 October 2021, we defined how we will engage and involve the public and patients at every step in our work.

This was informed at the outset through the consultation with patients on what was important to them. Moreover, the Independent Medicines and Medical Devices Safety Review also provided us with clear direction on where we could improve upon our engagement with patients.

Here we list the actions planned for the coming year that will deliver the step-change needed in patient involvement in our work.

- Develop new processes to safely and ethically expand patient engagement in our work. For example, developing training and support for patients and members of the public in contributing to our work by Q3.
- Tailor patient engagement guidelines to ensure the needs of different parts of the population can be included; for example, those who are already engaged with us and those who are not, by Q4.
- Pilot these new guidelines through two patient "listening sessions" as a method of seeking patient input in an ethical, respectful and consistent manner, by Q4.
- Define deliverables on Patient Reported Outcome Measures to better understand the impact of regulation on patients and deliver these by end Q4.
- Develop our understanding of patient perceptions of benefit-risk to enhance regulatory decision-making and deliver these by end Q4.
- Incorporate patients' views and lived experience in at least 50% of our substantial benefit-risk reviews by Q4.
- Deliver staff training and support via new "Patient Champion Network", to improve staff understanding and ability to deliver patient engagement by end Q3.
- Develop plans to support patient contributions to committees and groups to improve patient representation and contributions by end Q4.
- Develop a more consistent and effective approach to public consultations by end Q3.

Equity in healthcare – our role

Regulatory frameworks that deliver for everyone

Diversity, representation and inclusivity are critical factors in the evolution of healthcare and, specifically, in how healthcare is regulated in the UK.

To ensure we – and our regulatory frameworks – deliver for all patients, we have strengthened our focus on activities that will improve equity in healthcare.

- Reform UK clinical trials legislation to encourage the inclusion of underserved populations and increase the diversity in clinical research; lay statutory instrument by end Q4. (Also supports our Scientific Innovation theme.)
- Improve UK medical devices legislation by requiring more representative clinical data to increase assurance of reduced bias and appropriateness for different populations; lay statutory instrument and publish guidance and best practice phased over mid-to-late 2023. (Also supports our Healthcare Access theme).
- Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3. (Also supports our Patient Safety theme.)
- Review teratogen use during pregnancy, seek independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4. (Also supports our Patient Safety theme.)
- Review women's health regulatory inequities by end Q4.
- Improve diversity of our patient group consultative forum to enhance its contribution to regulatory decision-making by end Q3.
- Improve our ethnicity data by using a new algorithm and integrating a more accurate and updated ethnicity record into the anonymised patient records within our databases by end Q4.
- Develop a prototype web-based tool that detects and correct biases due to underrepresented populations for Artificial Intelligence applications by end Q4.
- Define deliverables for integrating our suspected side effect data with NHS healthcare records to deepen our understanding of the representativeness of our data and the impact of demographics in patient adverse drug reactions by end Q3.
- Improve UK regional representativeness of our clinical practice research data service to include at least 10% of GP practices across all UK regions by end Q4.
- Provide translated webpages on how to engage with our Yellow Card scheme in languages other than English commonly spoken in the UK to improve inclusion and accessibility by end Q4.

Embedding innovative ways of working

Implementing activities essential to embedding important changes and improvements

An important priority for us over the last year was to implement wide-ranging and impactful organisational change that transformed us into an agile and sovereign regulator, able to respond readily to new opportunities and challenges.

Now that step-change has been delivered, the following new actions focus on embedding the changes and improvements we want to see, while building upon the remaining deliverables in our plan.

- Launch key redesigned services and supporting process and systems, including design of a refreshed underpinning quality management system, by end Q3.
- Embed operation of new risk-proportionate established medicines pathway by end Q3.
- Implement innovative devices pathway in conjunction with innovative medicines and build foundations for collaborative approach with the Access Consortium by end Q4.
- Refresh our culture action plan and continue driving the culture change needed for our new operating model, Q1 to Q4.
- Publish new people strategy by end Q3 to support the implementation of our Delivery Plan and retain our status as a world-leading regulator and employer.
- Continue delivery of our leadership development plan from Q1 to Q4.
- Update talent management model by end Q3 to ensure we attract, develop and retain world-class scientific and regulatory capability.
- Engage with staff to ensure their contribution to the development of the future vision statement, values and behaviours framework, to align with the new operating model by end Q3.
- Deliver a refreshed health and safety system, including high hazard assurance monitoring, by end Q3.
- Implement new inclusive hybrid working policy by end Q3 to ensure an effective working approach that balances business and staff needs.

Continuing to put patients first, in everything we do

We remain committed to the delivery of our remaining goals - they are essential to us realising our ambition: putting patients first, becoming a truly world-leading, enabling regulator and protecting public health through excellence in regulation and science.

On the following pages, we present our prioritised goals for the coming year against our existing themes:

- Scientific Innovation
- Healthcare Access
- Patient Safety
- Dynamic Organisation
- Collaborative Partnerships
- Financial Sustainability

Where we have amended original deliverables they are indicated with an asterisk (*)

Significant progress, change and impact have been delivered, and we continue to pursue the delivery of meaningful outcomes for the patients we serve.

Progressing our priorities

Quarterly deliverables for Scientific Innovation, Healthcare Access, and Patient Safety

Scientific Innovation

- Work with the HRA and the NIHR Clinical Research Network to provide regulatory support for expediting delivery of defined clinical trials; support a pilot to improve set-up of phase 1 oncology trials by end Q4*.
- Improve UK clinical trials legislation, including encouraging the inclusion of underserved populations and increasing diversity in clinical research; lay statutory instrument by end Q4*. (Also aligns with our Equity in Healthcare theme).
- Publish new regulatory science strategy by end Q3*.
- Risk-based approach to batch release: guidelines drafted by end Q3; implement independent testing based on risk-based strategy by end Q4.
- Work with our Access consortium partners to deliver a clinical trial work and information sharing mechanism, put forward proposals for a common assessment template, and associated guidance to ensure a more harmonised approach by Q4.
- Improve our IT platforms to support delivery of an enhanced clinical trials service by end of Q4.
- Deliver expanded scope of NHSX-funded synthetic data research project and launch the synthetic data service by end Q4.

Healthcare Access

- Establish new devices framework to support safe innovation and ongoing access to products: lay statutory instrument and publish guidance and best practice phased over mid-to-late 2023*. (Also supports our Equity in Healthcare theme.)
- Deliver a set of work packages to ensure that AI as a medical device is underpinned by robust evidence to enable safer innovation by end Q4.
- Ensure integrated UK regulatory pathways for products that combine medicinal products and devices; consultation by end Q4*.
- Embed visual technology capabilities as a standard part of inspections by end Q3.
- Finalise Compliance Strategy through consultation with external stakeholders by end Q3*.
- Lay the statutory instrument for remaining elements of the first tranche of legislative change proposals by end Q4.
- Agree policy for an enhanced devices transparency regime by end Q3, with key elements delivered over 2022/23 and 2023/24*.

Patient Safety

- Deliver enhanced signal detection process; roll out from Q3, 2022/23 to end of Q4*.
- Launch a project to define a sustainable business model and commence pilot set-up activities for a service to investigate the role of genetics in the development of adverse drug and vaccine reactions by end Q3. (Also supports our Equity in Healthcare theme.)
- Improve model of the Devices Expert Advisory Committee: launch consultation by end Q3; and establish statutory committee by July 2023.
- Review teratogen use during pregnancy, seek independent patient and stakeholder input in Q3 and updated guidance and action to protect public health by end Q4*. (Also supports our Equity in Healthcare theme.)
- Work with others in the healthcare system to implement new, strengthened safety measures for sodium valproate by end Q3, and to continue to drive down the number of exposed pregnancies.
- Develop risk communication strategy to ensure more coordinated, pro-active communications by end Q4.
- Review the available evidence on pelvic mesh benefit-risk by end Q4.

Progressing our priorities

Quarterly deliverables for Dynamic Organisation, Collaborative Partnerships, and Financial Sustainability

Dynamic Organisation

- Deliver our Transformation Programme including plan for optimised services benefits realisation and implement restructuring; operationalise the future operating model and redefine and optimise prioritised core services by end of Q3*.
- Review workforce, identify actions to ensure we embed workforce planning by Q4.
- Deliver HR support and guidance to staff during restructuring throughout Q1-Q4, 2021/22.
- Complete main elements of our rebranding to ensure consistency and raise our profile by end Q3.
- Deliver our data strategy, including a data sharing strategy, underpinned with robust security standards and privacy by design by end Q3*.
- Support revised medical devices regulations, deliver the digital self-service, automation and data platforms required by early-to mid-2024.
- Fully scope what self-service functionality can be delivered via the regulatory management system and deliver the core system by end Q1, 2023/24*.
- Review our use of expert and advisory committees to ensure best use of expertise, the application of consistent, high-quality standards of operation and safeguard their important independent advisory role, by Q4.

Collaborative Partnerships

- Publish a partnerships strategy by end Q4: setting out our long-term partnerships approach and the impact that partnerships can achieve.
- Improve our ability to exchange data with partners by adopting international standards; new system full implementation by end Q1, 2023/24*.
- Identify key policy areas for the second tranche of legislative change and define timescales for putting legislation before Parliament over 2022/23 and beyond by end Q3.
- Identify which flexibilities introduced in response to COVID-19 are safe to embed by end Q3*.
- Consult on a national GB scheme to replace Falsified Medicines Directive safety features regulation; put legislation before Parliament as per departmental timescales; and agree position on Falsified Medicines Directive for Northern Ireland post 3-year EU derogation, by end 2023.
- Agree policy on reliance and recognition, for global implementation by Q4 2023/24.

Financial Sustainability

- Implement organisational design, creating a new, leaner organisational structure and balancing costs by end Q4, 2023/24*.
- Develop and implement a new fee structure from Q1, 2023/24
- Reduce corporate costs including technology costs by 15% by the end of 2024/25.

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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