Medicines & Healthcare products
Regulatory Agency

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT PLAN

2026 - 2030

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01
Foreword

Patients and the public are at the heart of everything we do. People across the UK rely on the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure that medicines, medical devices, and emerging technologies meet the highest standards of safety, quality, and effectiveness. Listening to, involving and engaging people in our decisions is essential to fulfilling that responsibility.

Since the publication of our first Patient Involvement Strategy in October 2021, we have made significant progress in embedding patient and public involvement and engagement across our work. We made a clear commitment to ensure that patient and public perspectives are heard, understood, and meaningfully reflected throughout the regulatory lifecycle. That progress is encouraging, but we recognise there is more to do.

Our priority now is to build upon and develop our involvement and engagement activities further. We will broaden the range of voices we hear from, be more transparent and consistent in showing how involvement and engagement influence our thinking, decisions, and actions.

This Patient and Public Involvement and Engagement Plan sets out our ambitions for the next phase of that journey. It supports the MHRA's Strategy to 2030 and signals our commitment to continue working in partnership with patients and the public, treating their contributions with respect, and demonstrating the impact of their involvement. By embedding involvement and engagement in our work, we will continue to strengthen the quality of our decisions and build public trust. This includes modernising how we provide information to patients, ensuring it is clearer, more accessible and reflects how people access and use information today. We want to thank the patients and the public who have given their time, insight, and lived experience to support our work. We are fully committed to delivering this plan and expect all parts of the MHRA to play their role in doing so. Together, we will continue to ensure patients and the wider public are at the heart of our work.

Professor Anthony Harnden,
MHRA Chair



Lawrence Tallon,
MHRA Chief Executive



As Chair of the MHRA's People and Public Engagement Committee, I have seen first-hand the difference that meaningful involvement makes to the quality, credibility, and impact of our regulatory decisions.

This plan marks an important next step forward in the MHRA's journey. It builds on the strong foundations established through the 2021–2025 Patient Involvement Strategy, and the progress the Agency has made in embedding lived experience more consistently across its work. It also responds clearly to what we have heard from patients, the public and partners: that involvement must be broader, more inclusive, more transparent, and demonstrably influential.

The MHRA Board will continue to provide strong oversight of this agenda, including through the People and Public Engagement Committee. I am committed to ensuring that the principles set out in this plan are embedded consistently across the Agency's work and culture.

I would like to thank the patients, carers and members of the public who have contributed their time, insight, and expertise to shape this plan. Their contribution is invaluable to strengthen patient-centred regulation, enhance public confidence, and ensure that the MHRA delivers on its core mission to protect and improve public health.

Mercy Jeyasingham MBE -
MHRA Non-Executive Director
Chair, People and Public Engagement Committee





I welcome the MHRA Patient and Public Involvement and Engagement Plan 2026–2030, which demonstrates clear progress in placing patients' voices at the heart of regulation. A commitment to inclusivity, transparency and early partnership is essential to ensure lived experience informs not only individual decisions, but how the system evolves as a whole. It is encouraging to see a stronger focus on how patient input influences outcomes, reaching underrepresented communities, and embedding involvement across safety, innovation, and evidence. These are key to building trust and ensuring regulatory decisions reflect what matters most to patients.

I strongly support the emphasis on patient safety and the use of real world insight to identify risks, address inequalities, and improve communication. Meaningful involvement must go beyond engagement to genuine impact, where patients can see how their contributions shape action and drive improvement. I look forward to continued collaboration with the MHRA, with patient voices contributing to safer, more responsive, and more equitable healthcare for all.

Professor Henrietta Hughes OBE -
Patient Safety Commissioner for England





Meaningful patient and public involvement is not a courtesy; it is a cornerstone of safe regulation. When lived experience is embedded early and consistently across the regulatory lifecycle, it strengthens benefit-risk assessments, highlights inequalities that data alone may not reveal, and builds the public trust on which effective regulation depends.

I welcome the MHRA's commitment to moving beyond involvement as a tick-box exercise and towards an approach that is genuinely collaborative and transparent. For Scotland, and for patients across the UK, the priority is that this plan translates into practice.

Patients should be able to see clearly how their voices have shaped decisions, and the broadest range of experiences, including those from rural and underserved communities, should be actively sought rather than passively awaited. I look forward to seeing this ambition delivered, and I will continue to work collaboratively with the MHRA to advance safer patient care and amplify the voice of patients.

Karen Titchener MSc NP RN -
Patient Safety Commissioner Scotland





02
Introduction

This Patient and Public Involvement and Engagement (PPIE) Plan sets out the MHRA's approach to place meaningful involvement and engagement at the heart of the agency's work for the period 2026-2030. It builds on the good progress made through our Patient Involvement Strategy (2021–2025) and reflects feedback from patients, the public, internal staff, the changing context of the Agency and wider healthcare landscape. We have spoken to key stakeholders as we refined our approach throughout 2025, including our existing Patient and Public Community, internal staff, and partners across the healthcare system.

Aligned with the MHRA's Strategy to 2030, the PPIE Plan sets out our commitment to patient and public centred regulation, grounded in inclusive, transparent, and collaborative engagement. We will use a range of engagement and involvement methods to broaden who we involve in our work, actively reaching under-represented communities, including those affected by rare conditions and health inequalities. We recognise that medicines and medical devices can affect people differently depending on factors such as sex, ethnicity, genetics and lived experience. We will also use involvement to help identify where the evidence base does not yet reflect the diversity of the people we serve, to support more inclusive research from the outset.

This plan is intended for patients, members of the public, community, voluntary organisations, partners across the health system, and MHRA staff. It sets out our long-term ambitions whilst outlining the practical steps we will take to deliver them.

03
Background

In 2021, the MHRA published its first Patient Involvement Strategy, setting out how patients and the public would be engaged across the regulatory lifecycle. An assessment of progress, published in January 2025, reviewed delivery of the strategy between 2021 and 2025, alongside earlier "one-year-on" and interim reviews. This assessment showed clear progress in embedding patient involvement more systematically across the Agency and demonstrated the value of lived experience in informing regulatory thinking.

The assessment also highlighted areas for improvement, including clearer feedback on how involvement influences decisions. It presented a stronger focus on reaching a broader and more diverse range of voices, the importance of partnering early, lessons from feedback, and continued to strengthen internal culture and capability around involvement.

These findings have directly shaped this PPIE Plan, which focuses on inclusive opportunities, transparency about impact, collaborative working with partners to ensure patient and public involvement is meaningful, proportionate, and embedded in our work and decision making.



Why patient and public involvement and engagement matters

Patient and public involvement and engagement strengthen our regulatory decision-making by:

- Improving the relevance and clarity of regulatory advice and guidance
- Informing benefit-risk assessments with lived experience
- Identifying inequalities in access, participation, and safety
- Building transparency, legitimacy, and public trust; and
- Supporting innovation pathways that reflect patient priorities.

David Chuter – Patient and Public Community member

"Being part of the MHRA Patient and Public Community provides an important and crucial opportunity for Independent Cancer Patients' Voice (ICPV) and other organisations to add the expertise of their lived experiences, priorities and concerns to help shape the development, regulation and safe use of medicines and medical technologies. Meaningful and transparent patient involvement such as this will help build and strengthen public trust and helps to ensure that decisions are informed by those that are most affected by them."





Our PPIE Commitment

The PPIE Plan 2026-2030 sets out our commitment to patient-centred regulation in support of our vision **to ensure health and prosperity for all through scientific excellence.** The plan is a key enabler of that vision, building on the strong foundations we have established to embed patient and public perspectives into all of our work.

In delivering this commitment, we will focus our activity on alignment with the MHRA's strategy to 2030, particularly in relation to:

- Patient centred regulation
- Addressing evidence gaps and supporting proactive regulation
- Patient safety
- Supporting science and innovation

This plan also supports the ambitions set out in the NHS 10 Year Health Plan and aligns with Patient Safety Principles by ensuring patients and the public are engaged and involved in improving safety and shaping regulatory decisions that affect health outcomes.

The MHRA's Patient, Public Involvement and Engagement (PPIE) team leads and coordinates delivery of this plan and is the MHRA centre of expertise for involvement and engagement. They advise and support teams to plan, design and deliver high-quality patient and public involvement and engagement. Providing expert advice on inclusive and proportionate approaches, and directly delivering or commissioning PPIE activity to support major corporate priorities and strategic programmes.

Our Principles[1]

Our approach to patient, public involvement and engagement is guided by the following principles:



Creating inclusive opportunities

- We will create opportunities to ensure regulatory decisions are informed by the experiences of people who may otherwise be underserved or disproportionately affected.
- We will use a range of involvement and engagement methods to reach diverse audiences, including communities affected by rare conditions and health inequalities.
- We will use what we hear to help address gaps where research has not adequately reflected the diversity of people who use medicines and devices, supporting fairer and more representative regulatory decisions.



Transparency

- We will be clear about the purpose, scope, and limits of involvement, and communicate how contributions influence regulatory thinking, guidance, policy, and decisions.



Working together

- We will collaborate with partners to involve people early, ensuring lived experience informs decisions alongside clinical and scientific evidence.
- We will adapt and improve our approach based on feedback and learning.

1. These principles have been informed by the UK Standards for Public Involvement and insights from the assessment of progress against the MHRA's Patient Involvement Strategy.

04
How patients and the public are involved and engaged in our work

We involve patients and the public at multiple points across the lifecycle of medicines and medical devices. The approach and timing of involvement will vary according to the stage of development, the scope for influence, potential impact on patients, and the level of public interest. To ensure involvement is proportionate, meaningful, and effective, we tailor our approach to suit diverse groups. This plan recognises a spectrum of engagement and involvement:

Public and citizens	Most people are not actively engaged with the MHRA and may be unaware of our role. Reaching them requires accessible and innovative approaches.
Reporting patients	Some patients and carers contact us to report concerns or seek information. Even one-off interactions can provide valuable real-world evidence.
Engaged patients	Some patients, carers and organisations collaborate with us regularly. Their lived experience helps shape our work.
Patient experts	Some individuals are highly involved with the MHRA and the wider health system, helping to ensure patient and public perspectives inform strategic decisions.

Asmina Remtulla – Patient and Public Community Member

"Being involved with the MHRA has been a really positive and fruitful experience for me. As a patient and member of the public, I have always been treated with respect, and my voice has genuinely been heard. Every session allows ample time for patient and public contributions, and questions are always welcomed. Members are also encouraged to write in afterwards if they want to add ideas or suggestions, which makes the process feel open and collaborative."



Public and Citizens

For many people, the MHRA is not part of their everyday experience, and awareness of our role varies. Engagement with the wider public will therefore focus on accessible, inclusive, and considered approaches. Where appropriate we deliver in partnership with others across the health and care system.

We use a range of methods, including citizens' assemblies, workshops, focus groups, online dialogue. Allowing us to explore public values, expectations, and concerns on complex or emerging regulatory issues. This ensures approaches are high quality and responsive across the UK and devolved administrations. We use the insights gathered through these activities to inform future regulatory approaches, guidance, communications, and policy development.



Silvia Cerolini – Rare Disease Parent and Patient Advocate

"The science for many rare diseases already exists, yet it is still not reaching patients like my daughter, Vicky, quickly enough. The new MHRA Rare Disease Framework is an important step in recognising the need for new approaches to development, evidence generation and regulation and it has the potential to accelerate life-changing treatments for rare disease patients while also paving the way for the future of precision medicine."



Engaging the public on AI regulation in healthcare

The National Commission into the Regulation of AI in Healthcare delivered one of the UK's most comprehensive public research and engagement programmes to inform future regulation of AI in healthcare. The programme combined open, targeted, and deliberative approaches to capture both breadth and depth of insight. A key priority was ensuring underrepresented voices were heard. Working with National Voices and The Health Foundation, the Commission engaged carers, young people, people with learning disabilities and other communities through accessible and inclusive participation methods.

Key activities included:

- A national Call for Evidence that generated more than 750 responses from individuals and organisations, demonstrating strong interest and engagement from across the health and care system.
- Three deliberative engagement sessions held across the UK brought together 72 members of the public, selected to reflect the demographics of the UK, enabling informed discussion on complex issues around AI, safety, and trust.
- Three targeted focus groups with seldom-heard groups (young people, unpaid carers, and people with learning difficulties) ensured perspectives often missing from policy discussions were actively included.
- An open access "Ask Me Anything" webinar engaged 360 participants, generating 180 public questions and providing a transparent forum for direct dialogue with Commission leadership, helping surface real-time public concerns and priorities around AI in healthcare.

The engagement identified broad support for the use of AI in healthcare, provided robust safeguards are in place. Across all audiences, participants consistently highlighted the importance of trust, transparency, accountability, and meaningful human oversight. There was strong support for proportionate regulation and ongoing monitoring of AI systems throughout their lifecycle, alongside a clear expectation that innovation should not come at the expense of safety, fairness, or inclusion.[2]

The programme demonstrates how meaningful patient and public involvement can strengthen policy development, build public confidence, and support trusted innovation in healthcare.

2. MHRA landmark report reveals public views on AI in healthcare - GOV.UK

Reporting Patients

Some patients or carers contact the MHRA to report suspected side effects, device problems, or safety concerns. Although this engagement is often one-off or time-limited, it provides critical real world insight into how medicines and medical devices are experienced in practice and can result in important safety changes.

The PPIE team works closely with internal colleagues to ensure patient reports and feedback are captured, shared, and used to inform safety monitoring, communications, and regulatory action.

Counterfeit GLP-1s

The MHRA was notified of fake GLP-1 15mg pre-filled pens identified within the UK supply chain. The manufacturing process was unknown, meaning sterility could not be assured, and use posed a potential risk of infection or allergic reaction. We contacted patients who may have received the affected pens to provide advice and ensured appropriate follow up. Safety communications were issued to healthcare professionals advising the immediate quarantine and return of affected stock and public communications were issued to ensure clear advice for patients. Enforcement action was taken in partnership with professional regulators to recover the affected products.



Engaged patients



Some patients, carers and organisations engage with the MHRA on an ongoing basis, contributing informed lived experience that helps shape our work. They bring insight into how medicines and medical devices are used in practice and how regulatory decisions affect people's lives, complementing clinical and scientific evidence.

Engaged patients often develop a deep understanding of the MHRA's regulatory role and processes. This enables them to engage with complex issues, consider impacts beyond their own circumstances, and contribute population level insight on patient safety, access, and communication. Their ongoing involvement helps ensure patient perspectives are embedded consistently across our work, rather than captured through one-off engagement.

Harriet Carroll – Patient and Public Community member

"For UKCV Family, being part of the Patient and Public Community (PPC) means that our members, who are often left with significant and life-changing symptoms without proper medical support, feel like they finally have a voice. It is also great to connect with other groups who have many shared experiences and unique perspectives."



Patient and public community

The MHRA Patient and Public Community (PPC), established in October 2024, provides regular opportunities to engage with patients, patient organisations, and charities to inform our work and policy development.

Through regular engagement, the PPC helps embed patient and public perspectives across the MHRA's work. The PPC has contributed to discussions spanning clinical trials, MedTech, patient information, and medicines safety, as well as key strategic work including the Patient and Public Involvement and Engagement Plan, the MHRA Strategy to 2030 and the Women's Health Programme.



David Chandler – Patient and Public Community member

"Being part of the MHRA Patient and Public Community enables the Psoriasis and Psoriatic Arthritis Alliance (PAPAA) to ensure that the lived experience of people with psoriasis and psoriatic arthritis directly informs regulatory thinking and strengthens patient safety. It creates a vital bridge between patients, clinicians, and regulators, helping to shape safer, more effective, and truly patient-centred approaches to treatment and care."



Patient experts

Patient experts contribute at a strategic level across the MHRA combining lived experience with sustained engagement in complex regulatory issues, complementing clinical, scientific and professional expertise.

They may sit on formal advisory committees, contribute to the development of regulatory guidance and policy, or engage with senior leadership on matters of strategic direction. They are often well connected within patient communities and the wider health and care system, enabling them to represent perspectives beyond their own experience and consider system wide impact.

Their involvement brings continuity, informed challenge, and an understanding of how regulatory decisions land in practice over time, helping ensure the MHRA's commitment to patient centred regulation is embedded in strategic decision making.

Patient insight also plays a key role in our licensing decisions. We are taking a structured approach to understanding where patient input adds the most value to regulatory assessment.



We are undertaking a retrospective review of a licensed product, examining the patient involvement and patient experience evidence submitted as part of the application and how this has informed our assessment.

Alongside this, we are working with NICE to align what each organisation looks for in patient involvement evidence, so that companies and patient organisations can prepare submissions that serve both regulatory and health technology assessment purposes, reducing duplication and burden across the system.

We will use the learning from this work to identify how patient involvement in licensing can be strengthened, made more consistent, and better embedded in future.

Linda Galbraith – Rare Disease Parent and Patient Advocate

"I am a member of the Rare Disease Consortium - I have an ultra-rare cancer - apparently the only one in the UK. The tumour - a bone cancer - was in my sinus, and I have had a number of major ops to rebuild my face over the years. It is difficult to make plans, as there is no likely prognosis. Luckily, I've lived beyond the predictions so far! Being on the Rare Disease Consortium gives hope - for all those in this situation, particularly for those with young children in this position."





Involving patients in the rare disease consortium

The MHRA has established a Rare Disease Consortium to develop and implement a patient-focused regulatory framework for rare diseases. The programme has combined sustained advisory involvement with targeted workshops and meetings to capture both breadth and depth of insight from the rare disease community, exploring the challenges patients face and how the framework can support timely access to innovative therapies.

Key activities included:

- A dedicated rare disease patient involvement advisory group of 23 patient representatives, spanning a range of rare conditions, providing sustained input into the development of the framework.
- Two all-day in-person workshops bringing patients and patient representatives together to shape the key challenges and opportunities for the work.
- A series of online meetings enabling continued dialogue and detailed input into the draft guidance.
- Patient-led dissemination of the consultation, with representatives instrumental in extending its reach across the wider rare disease community.

A key priority was ensuring the breadth of the rare disease community was represented. Patient umbrella organisations sit on the Consortium alongside individual patient representatives, bringing perspectives from across a wide range of rare conditions into the work.

Patient involvement has directly shaped the programme. Representatives have defined the key challenges and opportunities the framework must address, contributed their expertise to the draft guidance, and put the issue of medicines repurposing on the agenda.

The programme demonstrates how sustained patient involvement can strengthen regulatory policy development, and continued involvement will be crucial to creating a framework that best meets the needs of the rare disease community.

05
Involvement and engagement methodologies

We use a range of involvement and engagement methods across the regulatory lifecycle, selected to reflect the regulatory question, wider societal context stage of development and potential impact on patients and the public. These include patient expert panels and advisory committees, one-to-one, and small-group discussions, lived experience input into benefit–risk assessments, involvement in safety reviews and post market surveillance, pre authorisation engagement, and targeted outreach to under represented or less heard groups.

Where appropriate, we will collaborate with partners to use deliberative engagement methods, such as citizens' assemblies or structured public dialogue, to explore complex or emerging regulatory and societal issues that are relevant to our work and build deeper understanding of public values and expectations over time.



06
Our focus areas

Our focus areas align with the MHRA Strategy to 2030 and patient and public involvement in these areas will be prioritised.

- **Addressing evidence gaps and supporting proactive regulation –** We will use patient and public involvement to identify and help address evidence gaps where lived experience has historically been under weighted. This includes involving patients early in areas of unmet need, such as women's health, and where regulatory frameworks may need to evolve.

- **Patient centred regulation –** We will involve patients and the public in shaping and testing approaches to patient centred, proportionate regulation, including how benefits and risks are understood and weighed. This will ensure regulatory decisions better reflect what matters most to people affected. For example, our Improving Patient Information project will enhance how patients access and understand information about medicines. We will modernise patient information, so it is clearer, more accessible, and easier to understand. By 2030, we aim to have structured digital content that can be accessed through a range of tools and services, while ensuring alternative formats remain available for those who need them.

- **Patient safety –** Patient and public involvement will remain central to our safety and surveillance work. We will continue to test medicines in our laboratories to ensure they are always of the highest possible quality for patients. We will also continue to develop the key testing materials needed to ensure accurate measurements when clinicians assess patients' health. Lived experience will inform safety reviews, risk assessment, patient information leaflets, and the development of clear, proportionate safety communications, helping us identify emerging issues and understand real world impact.

- **Supporting science and innovation –** We will involve patients and the public early in the development of new regulatory pathways and areas of innovation, particularly where science, technology or data raise complex questions. This will help ensure emerging frameworks are shaped by lived experience as well as scientific evidence, including through our NIHR-funded Regulatory Science Research Unit (RSRU), which incorporates a strong Patient and Public Involvement and Engagement (PPIE) component to ensure our work reflects patient perspectives and priorities.

07
How we will support these priorities

We will support delivery of these priorities through a phased approach that strengthens consistency, capability, and governance for patient and public involvement across the MHRA.



Year 1

In Year 1 we will deliver a step change in patient and public involvement, so it is visible, inclusive, and routinely shaping MHRA priorities, decisions, and ways of working. We will:

- Use deliberative engagement to shape patient and public centred approaches to assessing medicine benefits and risks
- Ensure lived experience informs patient safety activity, including safety reviews, risk assessment, patient information leaflets, and communications

- Expand the Patient and Public Community to better reflect the diversity of the UK population
- Embed diversity and inclusion at the design stage of all PPIE activity to support equitable outcomes and help address inequalities in health experiences and outcomes

- Sustain engagement with the rare disease community to inform delivery of the Rare Diseases Framework
- Involve patient and public representatives in phase two of the Improving Patient Information project
- Support the implementation of patient and public involvement and engagement recommendations arising from the National Commission into the Regulation of AI in Healthcare

- Map patient involvement across the regulatory system to address gaps, reduce duplication, and improve alignment with key partners (e.g. NICE/MHRA alignment)

- Strengthen feedback and learning by enabling MHRA teams to evidence influence and share impact
- Build MHRA capability by supporting staff to work confidently and effectively with patients and the public
- Develop a proposed measurement and monitoring framework to track participation, diversity, and evidence of influence on decision making



Year 2

In year 2 we will embed consistent, high impact involvement across priority programmes and pathways. We will:

- Expand deliberative and partnership-based engagement to support complex or emerging regulatory areas
- Support ongoing engagement within priority programmes (e.g. rare diseases, devices, AI/software as a medical device, innovation pathways, Improving Patient Information project) as they mature

- Apply learning from partner alignment work (e.g. NICE/MHRA) to reduce duplication and improve coherence for patients and organisations

- Establish baseline measures, and continue routine monitoring and reporting of participation, diversity, inclusion, and evidence of influence on decision making
- Regular monitoring and reporting will assess progress against Year 1 baselines, identify areas for improvement, and provide assurance to the People and Public Engagement Committee on implementation, reach, diversity, and impact

Year 3

In year 3 we will demonstrate impact and accountability, using robust insight and evaluation to adapt approaches and shape future regulatory frameworks. We will:

- Evaluate the impact and outcomes of our involvement and engagement activity on patient outcomes, using learning to refine approaches
- Use insight and evaluation, including PPIE good practice from other health systems to inform the next phase of PPIE planning, ensuring continuous improvement
- Continue to adapt approaches in response to emerging science, technologies, and regulatory priorities, ensuring patient perspectives inform new frameworks from the outset

Together, these actions will enable us to deliver a meaningful and ambitious programme of involvement and engagement to improve patient outcomes. The MHRA's People and Public Engagement Committee (a Board assurance committee) will review the PPIE plan and its progress.



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