



Medicines & Healthcare products
Regulatory Agency

Patient Involvement Strategy 2021-25



Introduction

This, our first Patient Involvement Strategy, sets out how we will engage and involve the public and patients at every step of the regulatory journey.

In developing the strategy, we have started as we mean to continue. Our approach was informed at the very outset through consultation with patients on what was important to them. The Independent Medicines and Medical Devices Safety Review also provided us with clear direction on where we could improve our engagement with patients, and the resulting strategy was then approved by our Patient Safety and Engagement Committee and agency Board.

We wanted to be sure that the strategy resonated with patients too, conducting a final public consultation on the strategy to identify any areas that we needed to adapt, or that we had overlooked. This step allowed us to make some further additions to our approach and we will continue to listen to patients throughout as we deliver it.

We recognise that these are the first steps on an ambitious journey, and that its successful delivery lies in the engagement and involvement of the public, patients and other health sector organisations as partners, with us on the journey.

Strategic Objectives

1. Patient and public involvement

Objective

We will develop and introduce clear processes for engagement and involvement, to ensure teams have a systematic means of engaging and involving patients and the public in their work and that we publish how we do that.

We intend to deliver and have these processes embedded across the agency by December 2022.

Supporting objectives

We will define and measure the type of outcomes that might be expected from that engagement and involvement.

With health inequalities in mind, we will identify stakeholders who are not active members of patient groups and create opportunities for them, as well as under-represented groups and diverse communities, to interact with us (e.g. minorities, older people, those with learning disabilities, those who do not have English as their first language).

We will explore collaborations with other health regulators to provide a collective training/resources offer to patient groups.

We will look for ways to reflect the views of children and young people in our work, who may have different perceptions of their medical issue and how it is treated.

We will learn from the National Standards for Public Involvement and other examples and models of good practice that we might seek to adopt for the agency.

Examples of how we will achieve this:

- Identify ways to ensure that patients and the public can be better informed about the specific products used in their healthcare to enable them to make more informed decisions
- Commission research on post-COVID-19 public understanding of risk (visa-vis medicines, devices and vaccines), and how risk is best communicated
- Develop a process to involve patients and the public more systematically in our regulatory decision-making processes, committees and governance. To include:
 - » Through our Innovative Licensing and Access Pathway, incorporating patient and public views on the benefits and risks of medical products and the overall development programme, ensuring that medicines and devices are developed in a way that considers their needs

- » Piloting new approaches to 'design-in' patient and public engagement and involvement to our processes, including patient and public input in the regular review of patient safety 'signals' and new sections in assessment report templates that act as a prompt to check that patient and public engagement has been considered
- » Developing the use of Patient-Reported Outcomes so that it is built into all of our licensing decisions
- » Formalising the work of our Patient Group Consultative Forum, including regular attendance from members of the agency's Executive Committee, so that it becomes truly representative of the whole healthcare landscape and the central route through which the 'patient and public voice' is communicated to the agency
- » Recognise the importance of online and digital channels in the delivery of our services to patients and the public, ensuring that their design is informed with input from patients at every step.
- Build transparency into our regulatory systems, decision-making processes, committees and governance, and report on what impact the involvement of patients and the public has had. This will include:
 - » The Board's sub-committee on Patient Safety and Engagement will provide oversight of and challenge to the agency on how well we are achieving these aims.
- Increased involvement of patients and the public in drafting public-facing information material including on GOV.UK and in the development of our digital products and services e.g.
 - » When producing guidance for patients, public or healthcare professionals on medicines or medical devices that will be published on GOV.UK, wherever possible we will share the draft guidance with the target audience for comment before publication and seek to incorporate that feedback in the final version where possible, practicable and appropriate
 - » Seek patient and public views on concepts and material for communications at the appropriate time in the decision-making process to ensure as far as possible that they are shaped around patient needs and preferences
 - » When developing digital products and services for patients, we will involve patients, ensuring government standards are adhered to.
- To supplement a new programme of Board meetings in public, introduce a schedule of regular (e.g. twice yearly) public meetings where we will explain our work and ask patients and the public proactively for their views on medicines, medical devices and other issues being considered by the agency or which patients and the public wish to raise with us, as well as seeking their help in deciding our priorities:
 - » We will seek initial views from our Patient Group Consultative Forum on potential topics.

- We will improve our engagement with patients and the public, considering their journey through the health system and the key points at which we can add value and deliver meaningful engagement. This will include considering the awareness of the Yellow Card Scheme, as well as other important safety connection opportunities such as the Patient Information Leaflet
- We will improve our understanding of patients' and the public's attitude to risk/benefit in relation to the use of medicines and devices and use this understanding to improve how we engage and involve patients so that they can make informed choices.

2. Responsiveness

Objective

In designing and delivering our services, we will embed the patient and public voice to ensure that those services meet the needs of the patients and other members of the public who use them. We will implement a process allowing for more agile and regular review of high-risk safety issues, with a system that flags when more in-depth involvement of patient groups is needed.

We intend to deliver this by December 2022.

Examples of how we will achieve this:

- As we design and build our new operating model, we will introduce systems and standards of service delivery that focus on the importance of regularly updating those who have raised a concern and informing them about any other relevant issues and ongoing work, in order to build confidence and trust
 - » Develop a cross-agency protocol on responding to patients when they raise concerns, including thresholds to ensure urgent response when appropriate
 - » Improving user experience of the Yellow Card scheme
 - » Develop and continue to build the Customer Service Centre as the single point of contact for patients and public.
- We will ensure that we design, deliver and maintain our online channels and websites, in a way that enables us to respond and continually improve our services for patients.

3. Internal culture

Objective

We will introduce new systems, processes and training to support a change in our culture, so that every member of staff considers the patient and public perspective in their decisions, and that all staff are well supported and involved in delivering that change.

We aim to deliver this by December 2022.

Examples of how we will achieve this:

- Introduce new ways of working as outlined in sections 1 and 2 above, with patients and the public central in how we develop our new operating model for the agency
- Regular patient speaker programme, with patient advocates giving presentations to staff about how we can engage patients and the public and involve them in our work
- Introduce a programme of training for our staff to support them in engaging more effectively with patients and the public
- Incorporate into the work, thinking and behaviours of all staff by ensuring 'Patients and Public' is a common thread within our Delivery Plan 2021/23. 'Our core focus will be on patients and the public, placing them at the heart of our thinking'
- Develop and share examples from across the agency of staff bringing to life our value 'We focus outwards on patients and the public', highlighting indicative behaviours to help staff know if they are performing well in this area or if they need to change
- Build patient and public engagement into the corporate induction for all new starters, including patients and others talking about the importance of the agency engaging with patients and the public
- Embed a focus on patients as customers of our services within the agency's new performance development scheme so it is reflected in goal plans for staff.

4. Measuring outcomes

Objective

We will develop, build and embed a clear patient outcome evaluation framework that ensures we consider all patient groups and which enables us to demonstrate our progress in delivering our vision of being a patient-focused regulator.

We intend to deliver this by June 2022.

In measuring patient engagement outcomes, it is important that we consider patient engagement in its broadest sense, and beyond the scope of many of the actions contained in the strategy. Our model comprises three patient groups that we engage with to considerably varying degrees. Successful delivery of this approach will rely on our ability to align all activity and measures of patient engagement and involvement with our high level framework of outcomes.

Our engagement outcomes are an important driver of our overall reputational measure of trust in the MHRA and in public confidence in medicines and medical devices. We will create a patient engagement index for each group, and we will explore the validity and appropriateness of creating an overall patient engagement index.

The outcome framework will provide us with a robust understanding of patient engagement and experience across the three main groups, but we also require far greater depth in our approach to evaluation and this would include:

- Evidence of increased speed with which we involve patients in signal management (i.e. the process by which data or information that may suggest a new causal association, or may contribute new information about a known association, between a medicine and a side-effect with a medicine or a problem with a medical device, that justifies further investigation)
- Evidence of increased number of clinical trial protocols for which the agency recommended that patient-reported outcome measures should be built into their design
- Tangible and an increasing volume of evidence that the agency is demonstrating that it is taking into account what patients and the public have told the agency and that it is acting on that input
- Immediate feedback from patients and the public via a set of standard questions for the interactions a patient has with the agency (e.g. based on 1-5 star rating and the reason for giving that rating), with a procedure in place to proactively act on feedback received
- Commission an independent provider to conduct focus groups or interviews with patients and the public who have been involved in activities to identify strengths and areas for improvement as we continue to develop in this area. To include representation from under-represented groups and communities

- Six-monthly survey, targeted at those who have engaged with the agency (where known) and published on GOV.UK, to gather feedback from patients, the public and other stakeholders on overall progress against our objectives and actions towards achievement of our outcomes - to include both quantitative and qualitative feedback
- We will use the Government Service Standard to guide the development of our new digital services, and assess our performance against those standards
- Quarterly pulse check (asking the question: 'how are we doing?') with patient groups via the Patient Group Consultative Forum
- Annual tracking study on broader public understanding of risk to help us amend how we deliver
- Benchmark against other regulators including in other sectors and outside the UK.

Internal Culture Change Measures

- Patient and public engagement-specific questions in the annual Civil Service People Survey
- Surveys of staff pre/post-training
- Develop and monitor an employee index as part of the existing quarterly pulse survey of staff and linked to the One agency change programme
- Analysis of other metrics including the proportion of staff attending monthly patient speaker presentations, the proportion of staff undertaking patient and public engagement and involvement training as part of induction or continuing professional development, and the number of patient/public partners involved in activities and diversity of those participants.

5. Partnerships

Objective

We will develop a cross-sector partnership plan that builds and delivers collaborations with partners across the health sector to improve the effectiveness of engagement and share patient insight.

We intend to deliver this by December 2022.

Our partners across the health sector have an important role to play and we will continue to build ever closer relationships that enable us all to deliver the best outcomes for public and patients. There are three core areas where this can add significant value and where we will focus our effort.

- **Insight Exchange**

Our increasing patient engagement through consultations, workshops and forums provides us with a rich source of research and data which needs to be consolidated into one point. This could provide us with a rich source of patient insight that could be shared across the agency to inform new projects and maximise the benefit from the investment. We can be sure that other health partners also manage similar insight resources and we need to explore whether it is possible to build a more co-ordinated approach, removing duplication, and making better use of the information we hold to the benefit of patients.

- **Patient Engagement Mechanisms**

We intend to overhaul the membership of our Patient Group Consultative Forum to make it far more representative of the patient population and improve its diversity. Again, we know that other health partners have built similar pools and we would be keen to look at whether a syndicated collaboration were possible.

It is essential that our patient forum pool is more diverse and representative of the wider patient population to ensure that we incorporate the views of the broadest possible spectrum of patients into our regulatory processes. We will explore the different options available to us that recognise the time that patients give up, and we will undertake a review of similar practices across the health sector to determine the most effective solution for the agency.

In the absence of this, or until we can realise that ambition, we will also engage health partners to access existing patient population pools held by others, and where it makes no sense for us to duplicate an already effective approach.

- Delivering improved patient journeys through Cross Partnership working.

We will use our cross-sector partnership engagement opportunities to explore how we can collectively deliver an improved and co-ordinated experience for patients.



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