Medicines & Healthcare products Regulatory Agency

Patient Involvement Strategy: An Assessment of Progress

Progress made in delivering the Patient Involvement Strategy, October 2021-Jan 2025

07 January 2025

Contents

Foreword

The public and patients must always be at the centre of everything we do. They rely on us to ensure that all medical products used in the UK meet the necessary standards of safety, effectiveness, and quality.

When we launched our Patient Involvement Strategy in 2021, I made a commitment to ensure the patient voice was heard and understood at every step of the regulatory process. Three years on this assessment of progress is very heartening. But there is no room for complacency.

I have heard the central messages voiced by the participants in this assessment, including the call for more outward communication from MHRA to the public and patients, and better feedback to patients after our engagement activities.

I offer my sincere thanks to members of the public, patients and carers who have given their unstinting help to us over the last few years, sharing their views and experiences, so that others may benefit. My commitment to continue this journey is as strong as it was at the beginning.

Dame June Raine

Chief Executive

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) published its first Patient Involvement Strategy in October 2021, covering the period to 2025. This defined how we would engage and involve the public and patients in our work.

The MHRA has regulatory responsibilities across the different stages of development of a medicine or device, referred to as the product lifecycle. In early 2023, a One-Year-On report was published outlining early changes we were making to engage more meaningfully with public and patients across this regulatory lifecycle. The report covered examples of activities between October 2021 to September 2022.

In mid-2023, two years into implementation of the strategy, we undertook an interim assessment of progress to gauge whether the changes being made were the right ones and to inform a refresh of the strategy from 2026 onwards. This report outlines what we have found.

Background

The MHRA published our Patient Involvement Strategy in October 2021, setting out our determination to put patients at the heart of the Agency's work. From the beginning of its development, the strategy was informed through consultation with patients and public to ensure that we understood what really mattered to them. It helped shape our approach to think about how we involve patients, how we respond to their different needs, how we work with partners across the system, how we demonstrate our progress, and how we drive the culture change required within the organisation.

The Independent Medicines and Medical Devices Safety Review also provided clear direction on where we could improve our engagement with patients. It recommended that the MHRA "needs to ensure that it engages more with patients and their outcomes" and "ensure that patients have an integral role in its work".

Our strategy set out five main workstreams to be developed:

- Involving patients and the public
- Responding to patients and the public
- Driving culture change
- Building partnerships
- Measuring outcomes

In mid-2023, two years into implementation of the strategy, we undertook an interim assessment of progress to gauge whether the changes being made were the right ones and to inform a refresh of the strategy from 2026 onwards. In thinking through how to approach the assessment, we noted that there were a large range of activities undertaken (summarised in Table 1**Error! Reference source not found.**). Inevitably some activities would be more successful than others. The question was how to evaluate the Agency's efforts as a whole?

Table 1 Examples of how patients input into our work

Formalised networks and Consortiums which include patients	Patient input into reclassification of medicines
Involvement of patients in our committees and groups	Patient input into safety reviews
One-off or longer-term tailored activities	Public Board meetings pre-submitted questions
Patient and Public Community (previously known as Patient Group Consultative Forum)	Public consultations
Patient experts at ad hoc stakeholder meetings and round tables	Public input into innovative license pathways
Patient input into pre-marketing pathway	Raising issues and concerns through correspondence

An article written by Gibson et al 'Evaluating patient and public involvement in health research' guided our thinking about key questions to pose when looking at the totality of the corporate effort.

- Are there multiple ways for patients to be involved?
- Who sets the agenda? Whose concerns?
- Does the patient have a strong or weak voice? Are they "heard"?

While desk research and case studies could contribute to answering some of these questions, we also considered it vital to explore public and patients' and MHRA staff's perspectives. An external agency was asked to conduct interviews independently to explore these perspectives. Table 2 sets out who was interviewed and the key areas of questioning.

Table 2 Respondents contributing to the interview element of the assessment

Perspective	Further detail	Key questions
Patients familiar with the Agency	Ten semi-structured interviews were conducted with members of the public familiar with MHRA work.	Are there multiple ways for patients to be involved? Who sets the agenda? Whose concerns? Does the patient have a strong or weak voice? Are they “heard”.
General public	Three focus groups were conducted with members of the public with a health condition but no previous contact with the MHRA.	Awareness of MHRA Views on balancing risk against benefit? Views on patient involvement
MHRA staff	Ten semi-structured depth interviews were conducted with MHRA staff.	How important is patient involvement seen within MHRA? Are there multiple ways for patients to be involved? Who sets the agenda? Whose concerns? What support is needed?

Considering the findings

No assessment approach is without limitations, and it is important to recognise these when considering the findings. This is a relatively small-scale assessment. Findings are based on desk research and a small number of semi-structured interviews and group discussions. It is almost a year since the examples of patient engagement and involvement were collated for inclusion in this report and the overview of MHRA activity will not be current.

The report does not provide an assessment of overall impact. The focus is on what we have heard from patients, public and staff to provide insight on what is going well, what isn't and how we can improve the Agency’s efforts to listen.

We used external consultants to conduct the interviews to ensure that the voices we heard were undiluted. However, the work was coordinated by an internal MHRA team.

Findings

Earlier we described how there are five main strands to the MHRA Patient Involvement Strategy. In this section we summarise key activities in each workstream and share feedback received from patients, public and staff.

Workstream 1 - Involving patients and public

This workstream focuses on developing new processes to safely and ethically expand our patient engagement. We have regulatory responsibilities across the different stages of development of a medicine or device, and we are committed to finding ways of listening to the public and patients across this lifecycle.

Getting new medicines and medical devices to market

Scientific research and clinical trials are an early stage of medicines in development. During these stages, developers must collect evidence about the quality, safety and efficiency of the medicine. This evidence is then used to determine whether a marketing authorisation (or licence) can be granted for a medicine. We have been gaining greater experience of involving the views of patients and carers in the assessment of applications for new marketing authorisations, plus the renewal of existing licences.

For example, in response to a request for involvement, we assisted the Commission for Human Medicines (which advises ministers on the safety, efficacy and quality of medicinal products) in identifying patients and their families to present their views at a meeting to inform the decision on whether the conditional licence for a treatment for Duchenne Muscular Dystrophy should be renewed. In another case, an expert dementia patient carer provided input to the Commission on Human Medicines' discussion on a finely balanced risk-benefit decision, as part of the assessment of a marketing authorisation application for a drug to slow the onset of dementia.

A Wellcome Trust funded project, delivered in partnership with NICE, has helped us to consider public perceptions of digital mental health technologies. These products are used for many purposes, including mental health wellbeing promotion and prevention, to software that supports the assessment and treatment of mental health conditions. Some products qualify as medical devices and are referred to as Software as a Medical Device (SaMD). These are regulated by the MHRA to ensure they are safe and effective. This project looks at the challenges of regulating and evaluating these products. Topics covered through the

course of public and patient involvement included: expectations of how these devices would be used, ideas for how such SaMD should be regulated, and how information about SaMD should be disseminated to stakeholders. Lived experience adviser representatives are on the project board and working group and have contributed extensively to the project discussions and outputs to date.

Patient Experts with lived experience of cancer and representatives of rare disease patient groups have been participating in the Highly Personalised Medicines Expert Working Group. This helps ensure patient views are considered as we have developed our approach to the regulation of these innovative new products.

Patient and public experts took part in the selection of the eight products for the Innovative Device Access Pathway pilot. The pilot recruited eight Patient Experts who were key in selecting and scoring 8 products from a field of 30, to go forward to the next stage.

Improving access to medicines

Every medicine has a legal classification. The legal classification of a pack of medicine determines the level of control over its supply. In part, classification rests on how much health professional input is needed to diagnose and treat the condition. We are committed to widening access to medicines by reclassifying a medicine, for the benefit of public health, when it is safe to do so. In addition to safety consideration, a key factor in the reclassification process is focussing on issues that matter to patients. For example, members of the public informed our decision to reclassify Gina 10 microgram vaginal tablets. These tablets are a form of low-dose local hormone replacement therapy (often known as HRT). It was previously licensed as a Prescription Only Medicine. It is now available from pharmacies.

The MHRA has also been working to involve patients in decision-making in pre-marketing authorisation for medicines. For example, staff met with sickle cell and thalassemia patients to understand the experience of individuals living with these conditions as part of the process of authorising Casgevy, the world-first gene therapy authorised to treat sickle cell disease and transfusion-dependent β-thalassemia.

Balancing the benefits and risks

No medical product is completely free of risk. We use many sources of evidence to provide a critical appraisal of whether a product's benefits outweigh its risks. The examples below describe how patients and carers have been involved in benefit-risk evaluations.

Staff worked with patients on the risk-benefit review of the cystic fibrosis drug Kaftrio. A recording of group discussions with patients and parents of children taking Kaftrio was shown to the Neurology Pain and Psychiatry Expert Advisory Group of the Commission on Human Medicines. Members of the charity who ran the discussion, together with patient experts, were present to answer any questions after the recording was viewed.

Other examples of involving patients and carers in safety reviews and benefit-risk evaluations include:

- *Montelukast* – two parents of children who have experienced changes in behaviour and mental health challenges following treatment with Montelukast, shared their experiences with the Pharmacovigilance Expert Advisory Group

- *Valproate* – the Commission on Human Medicines heard directly from patients, carers and those who support them to understand patient views and experiences on the safety of prescribing sodium valproate

- *Fluoroquinolones* – we supported patients to present their experiences at the Commission on Human Medicines

- *Isotretinoin* – patients and other stakeholders presented to the Isotretinoin Expert Working Group

- *Pulse Oximeters* - we met with patients and patient groups to gain their personal experience and input to help shape a review of the existing guidelines for healthcare professionals on pulse oximeters and inaccuracies with darker skin pigmentation

- *Topiramate* – working in collaboration with relevant epilepsy, migraine and mental health charities, patients contributed their experiences of the drug through one-to-one conversations and a survey

What we heard from patients familiar with the Agency

The following summarises feedback from the interviews with patients familiar with our work. The feedback relates to MHRA performance on patient involvement more generally rather than to specific engagement exercises.

1. **Question: Does the organisation offer different opportunities for public and patients to engage?**

Participants did not think that the MHRA offered different opportunities for engagement. Forums and Committees were valued but there was confusion over structure and

responsibilities. There was a feeling that consultations were a ritual and that they indicated the decision had already been made.

While outward communication from the MHRA was welcome, communication was felt to be sporadic. It was felt that more use could be made of patient networks.

> *"They should have public conferences on medicine safety. At the moment, these kinds of get-togethers are always industry-led."*

> *"The website is not engaging. Partly it's language."*

2. Question: To what extent are public and patients being listened to?

Most participants thought that patient involvement meant active listening. This was further defined as *hearing* as well as listening. There were mixed views on whether the MHRA really listened. Some felt that listening was poor, others that messages were lost as decision-making progressed.

It was felt important that feedback be offered to participants in engagement events to complete the communication loop. Failure to do so meant that patient contributors could not see the impact they have. For this reason, there was some frustration about the opportunities there were to contribute. It is time consuming for the public and they felt it was not always clear that it is worth their time. This also applied to initiatives such as Yellow Card. Feedback might include what the MHRA has done, is planning to do, or an explanation of why patient views cannot be taken forward.

> *"They do listen and take it on board – but how far into the organization does it go?"*

In committees and meetings, challenging experts was seen as intimidating, and it was made clear that patients need support.

> *"I was given a limited time to make my case. Thirty others in the room and me. It was intimidating and distressing"*

3. Question: Whose agenda is the focus of engagement?

Overall, respondents felt that patient impact on agenda-setting needed to be improved. Currently, agenda-setting was seen as weighted towards the Agency. There was no understanding of where public and patient views had influenced the agenda and no sense of

there being the opportunity to influence it in the future. Examples of what patients wanted to talk about included continuity of supply, orphan drugs and rare diseases, and American and European drugs on the UK market.

> *“They are very secretive – I don’t know what they’re discussing.”*
> *“I’m worried that they don’t get it.”*
>
> *“How can you look after patients, if you don’t know what they want?”*

Workstream 2 - Responding to Patients and public

The Customer Experience Centre (CEC) was established in March 2020 to put customers at the centre of what we do and improve the customer experience for anyone who contacts the MHRA. Today, the CEC is the front door to the agency driving cultural change from the front line which includes standardising processes and accelerating query response times.

What we heard from members of the public

The following summarises feedback from the interviews with members of the public who have not interacted with the MHRA.

1. **Question: Are you aware of the MHRA and how to report a concern?**

Among those in the three group discussions, while there was some knowledge of previous medicine recalls, there was little knowledge of how to raise a concern. When the MHRA role was explained, interviewees asked why the regulator was not better known. There was low awareness of Yellow Card.

> *"I've never seen them advertised in a GP surgery, but I've seen loads of posters telling me to wash my hands."*

In terms of future reporting, interviewees preferred:

- Online reporting
- Through health professionals as part of a medicine review or consultation
- Through other routes such as Patient Advice and Liaison Services

2. **Question: What are your views on balancing risk against benefit?**

Interviewees understood that there were different roles.

- Doctor or prescriber "they can determine the risk for individual patients."
- Manufacturers "they have done the trials and have the data"
- The NHS "would look at side effects"

Within this system, there was a mix of trust and competence.

> *"Sometimes it's really hard to trust people who are in charge, especially when you are injecting something into your blood."*
>
> *"An independent regulator should be doing this, not pharma companies."*

3. Question: Your views on patient involvement?

There was a strong appetite for involvement and interviewees saw that this could be achieved through a range of channels: surveys, online comments, advertising, discussion boards, panels and forums.

> *"Patients should be given the opportunity to take part in forums to discuss their concerns."*

Interviewees felt comfortable about the regulator reviewing this anonymised data.

Workstream 3 – Driving Culture change

A key element of the MHRA Patient Involvement Strategy is to embed a culture of putting patients first across the agency.

An online training course was implemented in 2022-23. Almost 90 per cent of staff completed the course. A new training offer is currently under development, and our induction programme now includes a section on patient involvement for all new Agency staff.

The Patient, Public and Stakeholder Engagement Team has produced tailored guidelines to support staff in patient involvement activity. The guidelines cover issues such as safeguarding patients, data protection and designing consultations. The team liaises with other health system agencies to align policy on issues such as the payment of patients for their contributions.

Meanwhile, Board Meetings in Public provide opportunities for members of the public to observe the Board conducting its business via an online broadcast. When time allows, the Chair provides an opportunity for the public to ask questions aligned to the agenda.

An external contractor was commissioned to review how we currently recruit, and support Committee members drawn from the wider population (often referred to as lay members). The aim was to understand how to strengthen these processes, with a view to improve the number and diversity of lay representatives across committees supporting our work. Recommendations from the work included the need to:

- Clarify purpose and role of lay members
- Forward plan and consolidate recruitment and selection activity, standardising materials where possible.
- Strengthen and standardise onboarding, including induction.
- Provide opportunities for ongoing and peer-to-peer support

What we heard from staff

1. **Question: How important is patient involvement seen within MHRA? Are there multiple ways for patients to be involved?**

Staff felt positively about the increased focus on listening to public and patients, recognising that the issue had come to the fore in the last two to three years. Some mentioned the MHRA Board as a major factor in promoting patient involvement and that leadership were receptive to change.

There was a strong desire to listen to public and patients, however it was recognised that engagement activity is resource intensive and takes time. Staff needed support in connecting with relevant patient groups. There was discussion of how far the Agency heard what patients said. Listening was only as good as the follow up.

> *"We're still doing more talking at patients than listening – let alone hearing."*
>
> *"We don't do as much listening as we used to. Our systems are less patient-centric."*

Staff were aware that there were several channels for patient engagement but thought these were “tried and tested” rather than leading-edge. The potential lack of diversity in the patient pool was recognised as was the need to integrate with the rest of the healthcare system.

> *“We have good channels.”*
>
> *“We talk to patient groups, but how much directly with people?”*

2. Question: Whose agenda is the focus of engagement?

There was a recognition that patient involvement was being implemented through a variety of different workstreams and at different levels of engagement. However, some thought patient agenda setting was a weakness. Patient involvement could be crowded out by other priorities.

> *“We take patient input seriously. We’re not dismissive. But how good are we at playing that back to patients?”*
>
> *“I do have a sense there’s a strategy. It’s fundamentally about being a trusted voice. Trust has to be earned. We have to show we’re independent and prove it through outcomes.”*

Others felt that sometimes a more research-based approach might be needed, to ensure all voices were represented.

> *“For me, the key is how to make patient involvement more representative.”*

3. Question: What support is needed?

Resourcing was an issue for many but not all. Some wanted more support from the MHRA Patient Public and Stakeholder Engagement team while others recognized that the central team was small. Others thought the answer was to mainstream rather than build up one team.

> *“The will is there but it’s a big resourcing challenge.”*
>
> *“Cumberlege [Independent Medicines and Medical Devices Safety Review] shone a light on MHRA. We have been forced to focus a bit more, which is right. But we’ve lost some people who had experience.”*

"It is hard with our resources. I feel frustrated. We have too many other issues. But it's bad for patients and needs to be improved."

"It needs a lot of preparation to allow patients to contribute."

Looking to the future staff were positive about change, the question was one of pace and progress.

"We have to have a sustainable model for inclusion in all our processes."

Workstream 4 – Building Partnerships

Many of the examples given earlier in the report could only have been achieved with the help of the third sector. We are grateful for the help and co-operation we receive from the large number of patient organisations who support us.

Some of these organisations come together to form the MHRA Patient Group Consultative Forum. Membership of the group has recently been refreshed and updated, forming the new MHRA Patient and Public Community. This new group will offer improved outward communication to interested groups.

Together with other regulators, funders, and research organisations, we have signed the shared commitment to improve public involvement in research. The commitment is to drive up standards of public involvement in health and social care research.

Partnerships have also informed decisions on in-house training. Our Patient, Public and Stakeholder Engagement Team worked with the University of Oxford to produce a series of videos of patients talking about their experiences of medicines and devices. These "*Patient Stories"* are released for internal viewing every other month.

Workstream 5 – Measuring outcomes

We wanted to develop an evaluation approach to assess progress. This report is the first step in setting out a range of activities in the patient involvement arena. The contributions of public, patients and staff allow us to embark on the journey to towards greater public and patient involvement.

We have heard from patients that there is a greater need for patient focused communications. For example:

- Improved active listening on the Agency's part; feeding back what we have heard; explaining how patient contributions have been used in decision-making
- Patient contributors would appreciate more outward communication about our activities
- From the perspective of the public, there could be more explanation about our role

From the perspective of Agency staff, there is a recognition of how resource intensive patient involvement can be and they are aware of the need to attend to the ethics of engagement on sensitive topics. Staff will need ongoing support in making decisions on proportionate and meaningful engagement.

Next Steps

Assessing progress has provided a valuable sense check of where we are on the journey to becoming a more patient focused regulator. We will now take on board these insights into our performance to guide our approach to the next five years. We will of course return to patients and staff to check direction. We will continue to monitor and evaluate our progress.

Acknowledgements

Interviews with public, patients and staff were conducted by Woodnewton Associates Limited.

With thanks to members of the public and MHRA staff who contributed their views.