Medicines & Healthcare products Regulatory Agency

Patient Involvement Strategy: One Year On

Progress made in delivering the Patient Involvement Strategy, October 2021-September 2022

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Foreword

It has been over a year since we published our Patient Involvement Strategy. Much has been achieved during the first year to engage and involve patients in our work. We recognise there is more to do to ensure we deliver on our commitment to put patients first, and this is just the start of a journey.

In the first year we have:

- involved patients in the early stages of medicinal product development, and encouraged the wider research landscape to do the same
- included the patient and public perspective in our work to widen access to medicines
- incorporated patient views and lived experience in our benefit-risk reviews of medical products
- integrated the views of over 2,400 members of the public into a new scheme which will help us understand and reduce the number of harmful side effects caused by medicines
- launched a training programme on patient involvement, specially designed for our staff

We are proud of the progress we have made, but we recognise we have more to do. We know that we need to continue to challenge and change how we do things to ensure the patient voice is embedded at every stage of the regulatory pathway. We need to make sure our staff and patient partners have the training, confidence and support needed to carry out this work. We need to act on what we've heard, and feedback to those involved. We must prioritise diversity and inclusion within our patient involvement, to support equity within health and care.

The progress so far gives us a solid base to build upon as we progress in this journey. Thank you to the members of the public, patients and patient groups who have contributed so far.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) published its Patient Involvement Strategy in October 2021. This defined how we will engage and involve the public and patients in our work.

The strategy was informed through extensive consultation with patients on what was important to them. 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".

The MHRA has regulatory responsibilities across the different stages of development of a medicine or device. We call these stages "the lifecycle". In this update, we discuss changes we are making to meaningfully engage and involve the public and patients across the regulatory lifecycle. It covers examples of activities between October 2021 to September 2022. It is not intended to detail all our progress against the Public Involvement Strategy, rather to highlight the range of activity which we have undertaken during the first year of our strategy.

How to read this document

The text contained in boxes provides additional context and information, for those who may be unfamiliar with the agency and our processes.

Progress made

Getting new medicines to market

Scientific research and clinical trials are an early stage of medicines development. During these stages, developers must collect evidence of the quality, safety, and efficacy of the medicine.

Developers of medicines can apply to access the Innovative Licensing and Access Pathway (ILAP). By giving enhanced regulatory and other expert input, this pathway aims to reduce the time it takes for a medicine to be brought to market. Reducing the time will give patients faster access to new medicines.

A pilot Patient and Public Reference Group was set up to ensure patient involvement is integral to how the ILAP operates. Made up of patients and patient representatives, the group provides valuable expertise and insight from their patient perspective. Members of the patient reference group sit on the ILAP Steering Group (part of the governance structure of the ILAP). This Steering Group reviews the applications from medicine developers to access the ILAP. Between October 2021-September 2022, patients have reviewed 57 applications, contributing to the decision as to whether to accept an application onto the pathway.

As well as actively involving patients and the public in our ILAP processes, we share the patient insights back with the developer. We encourage them to engage with a wider range of patient groups for diverse input, and to consider Patient Reported Outcomes and other measures to ensure the medicines in development offer the best outcomes for patients.

We know we have an important role and influence as a regulator. Together with other regulators, funders, and research organisations, we have signed the shared commitment to improve public involvement in research. Working together we will support the research community to carry out excellent public involvement.

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 conditions for which the medicine might be used.

What are the different legal classifications of medicines?

There are three legal classifications of medicines.

(i) Prescription-Only Medicines must be prescribed by a doctor or other authorised health professional and must be dispensed from a pharmacy or from another specifically licensed place.

(ii) Pharmacy medicines can be bought only from pharmacies and under a pharmacist's supervision.

(iii) General Sales List medicines may be bought from retail stores (e.g., a supermarket).

The underlying principle for classifying medicines is to maximise timely access to effective medicines while minimising the risk of harm from inappropriate use.

We are committed to widening access to medicines 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. We seek input from patients in the reclassification process. We do this through stakeholder meetings and through public consultations.

One example is when members of the public informed our decision to reclassify Gina 10 microgram vaginal tablets (estradiol). It was previously licensed as a Prescription Only Medicine. It is now available from pharmacies. Gina 10 microgram vaginal tablets contain the female hormone estradiol. They are a form of low-dose local hormone replacement therapy (often known as HRT).

Four members of the public were part of a stakeholder meeting to discuss this reclassification, alongside eight health care professionals and two representatives of professional bodies. Patients and the public also responded to the public consultation.

When we run consultations, we provide information about a topic and then ask for views through a series of questions. As well as seeking views on reclassifications of a particular

medicine, we also run consultations when developing policy and legislation. We have made changes to how we run all our consultations to support more people to respond.

Since we made these changes, we have seen in an increase in the responses to our consultations. We received 1,042 public responses for the Gina 10 reclassification. This is a higher number of public responses than we have received in our previous consultations. The greatest response before the changes was 251. The increase in responses gives us more information and public insights to inform our regulatory decision.

The improvements we made to consultations include:

- structure - people giving views can navigate more easily. This includes the ability to jump to sections that are of interest rather than having to comment on everything
- clarity – using language that makes it easier for people who are not experts in the topic to understand what is being discussed
- focus - promoting our consultations to relevant audiences, so the right people know about it
- scope – providing additional information about the background to, and scope of a consultation, and how to respond

We will continue to work with our patient partners to identify other changes which will make it easier for the public to inform our decisions. Small changes, such as offering one-to-one support sessions to public members in advance of an ad hoc meeting, are having an important impact.

Balancing the benefits and risks

No medical product is completely free of risk. We use an array of evidence to provide a critical appraisal of whether a product's benefits outweigh its risks.

The Independent Medicines and Medical Devices Safety Review highlights the need for us to engage more with patients and their outcomes. We are committed to incorporating patient views and lived experience in our benefit-risk reviews. This is an important focus for the agency moving forward.

The examples below demonstrate some of our progress so far. The insights we have heard inform our continued benefit-risk assessment of medicines and devices and shape our approaches to reducing harm. We know we have much more to do.

- We held a patient and public engagement session focused on medical devices. Patients shared their thoughts and experiences on important safety issues
- During a safety review of a medicine, patients shared their experience of the drug and what aspect of treatment has had the greatest impact. They shared insights into how the risks associated with the medicine should be managed
- The Commission on Human Medicines heard directly from patients, carers and those who support them (e.g., charities) to understand patient views and experiences on the safety of a medicine being discussed.

The Commission on Human Medicines is an example of a committee. The MHRA has statutory (required by law) and non-statutory committees and expert groups which provide impartial advice about the regulation of medicines and medical devices.

Why do we have committees?

In the public interest, we need the advice we receive on matters relating to the regulation of medicines and medical devices to be impartial. We also need to be able to get advice from a wide range of highly-skilled professionals who are senior and well regarded in their respective fields and from a range of appointed lay members.

Independent advisory committees have been established to provide this advice. These committees can also establish working groups to address specific problems.

We have lay members on our committees. Their role is to promote the viewpoint of the public and the patient. Our working groups draw membership from a wide cross-section of stakeholders including patient support groups, patients, carers, and public members.

We have committed to develop plans to support patient representation and contributions to our committees and groups. We need new and improved ways to incorporate the patient voice into our committees and groups.

Monitoring and reducing side effects of medicines

We are responsible for monitoring the safety of all marketed medicines and devices.

Our Yellow Card scheme allows healthcare professionals and members of the public to report suspected side effects of any medicinal product. Yellow Card reporting makes medicines and medical devices safer by helping the MHRA collect and monitor information on possible safety concerns.

We are always looking to improve the Yellow Card scheme. We use feedback from patients and healthcare professionals to help us do this. In February 2022 we launched a new Yellow Card website. The digital technology supporting the website makes reporting more accessible. As part of the new design, we changed how a member of the public reports. In the old design, the person completing the form had to know whether a product was classified as a medicine or a device. Patient feedback highlighted that this was confusing. People no longer need to know how their medical product is classified to submit a report.

In May 2022 we introduced further improvements to benefit people completing reports. People are now able to update reports for medicines and vaccines, and include additional information in the form of attachments (e.g., photographs). The forms that capture the reports now have smart form functionality, meaning that questions are based on the responses already provided by individuals. This gives a more tailored experience.

The agency is considering expanding the Yellow Card scheme. We propose to create a Yellow Card Biobank to research how an individual's genetic makeup influences how they react to a medicine.

What is a Biobank?

A Biobank is a collection of bodily fluid or tissue collected for research use to improve our understanding of health and disease. Demographic information (e.g., age, gender), information about the person's medical history and/or information about their lifestyle may also be reported to provide a deeper understanding of how individuals experience disease.

What would a Yellow Card Biobank be for?

People who have completed a Yellow Card report relating to specific medicines would be invited to give a sample of their DNA for analysis. DNA is an individual's genetic makeup and can change how the person reacts to a medicine. Researchers could use this data to develop better treatments and reduce the number and severity of side effects in the future.

There are a lot of practical and ethical issues to consider in this proposal. We wanted to understand the general public's perceptions on our proposal. This included how people would want the scheme to work (if at all) and what would motivate or discourage them from providing a DNA sample and becoming a Yellow Card Biobank participant.

Over 2,400 members of the public gave their views through a combination of surveys, focus groups and four Citizens' Juries. Citizens' Juries bring members of the public together to carefully consider and debate an issue. This helped us better understand the public needs and concerns and design the set-up of the Biobank around what we have learnt. We will continue to engage and involve the public in all future stages of the project.

Building a patient-focused agency

We want to embed a culture of putting patients first across our agency.

All our staff now have a goal focused on putting patients first as part of their annual review. These are tailored to each person's roles and responsibilities. Staff will be supported to deliver on these objectives through a new training programme focused on patient and public involvement.

This content is tailored to our role as a regulator and covers 8 themes. It will help staff understand:

- what it means to be a public-facing agency
- how we involve and engage patients as partners
- what our role is and our responsibility to the public and health care professionals
- what it means to treat patients, the public, and healthcare professionals as partners from best practice and shared case studies
- how to clearly articulate the agency's responsibility and accountability to patients, the public, and healthcare professionals
- practical tools and skills to help proactively engage patients, the public, and healthcare professionals
- how to build trust with patients and gather their insights effectively
- how to demonstrate that patient insights have been incorporated into practice and decision making.

The training programme was designed and piloted over the last year. It has now launched, and all staff have been asked to complete the training by March 2023.

We will continuously monitor and evaluate the impact of the training. We will provide tailored training and support to address gaps in staff skills.

Next steps

The MHRA Patient Involvement Strategy sets out our wider ambition over the next three years, 2022-2025. In addition to the Patient Involvement Strategy, our Delivery Plan 2021-2023 updates for year two outlines our actions in relation to patient involvement up until March 2023.

A priority is to develop the underlying guidelines and processes to expand patient engagement safely and ethically in our work. This includes developing training and support for patients and members of the public in contributing to our work. We will tailor the guidelines to ensure the needs of different parts of the population can be included; for example, those who are already engaged with the MHRA and those who are not.

We will continue to work with and learn from others, listen to our patient partners, and reflect on what we are doing well, and where we can improve.

Be part of our journey

You can find out more about opportunities for the public to be involved in our work on our website. If you would like to hear about opportunities to be involved in our work, or share your reflections on our progress so far, please email engagement@mhra.gov.uk.