



Medicines & Healthcare products
Regulatory Agency

MHRA Strategy for Improving Safety Communications

2024-2027

17 September 2024



Introduction

This is the MHRA's strategy for Improving Safety Communications. It sets out our ambition to transform the way we communicate about the risks and safety of medicines, medical devices and healthcare products in the UK to support effective implementation of new safety measures.

Our aim is that this 3-year strategy will deliver to healthcare professionals and patients more co-ordinated, targeted, and impactful safety communications, when they need it, using the best possible communication channels.

Healthcare professionals need the latest safety information to advise and support their patients, and we have listened to their feedback in bringing improvements to our communications and systems. Our plan is underpinned by the vital findings of our [recent consultation with healthcare professionals and healthcare organisations](#).

We will continue to listen to and shape our work in the light of feedback from patients, healthcare professionals and external experts to ensure that we continue to support all those with whom we work to improve patient safety.

Background

Our role

We are the regulator of medicines, medical devices and blood components for transfusion in the UK. We put patients first in everything we do, right across the lifecycle of the products we regulate, from supporting early-stage development to ensuring the safety of products throughout their time on the market. We rigorously use science and data to inform our decisions and enable medical innovation to make sure that medicines and medical devices available in the UK are safe and effective.

For all products we regulate, we protect public health by making sure that medical products in the UK are available and are of the right quality, applying appropriate standards of regulation.

Our safety communications

Medicines and medical devices available to UK patients must reach high standards of safety, quality and efficacy. However, no medical product is completely free of risk. We continually monitor the safety of products, balancing the population risks and benefits of each medical product and communicating transparently when we identify a new safety issue. We do

not hesitate to take action to protect the public, including by promptly issuing new advice to minimise these risks or remove products from use.

Effective communication is essential for patients to be informed of the benefits and risks of medical products, to assist healthcare professionals in best protecting their patients and to maintain confidence in medicines, medical devices and healthcare products, the broader health and care system and the MHRA.

Our safety communications:

- provide patients and healthcare professionals with timely information about newly identified risks and explain who needs to take action to protect safety
- help get safe and effective medicines, vaccines and medical devices to patients and support them to understand the risks, benefits and uncertainties in their treatment decisions
- reinforce the importance of reporting safety concerns so that we can act on new safety issues quickly
- protect patient safety and the public by transparently and clearly communicating regulatory decisions

We currently issue safety communications through a number of different routes and products, including:

- news, guidance and updates for the public, patients and all of our stakeholders on the [MHRA's website](#) and social media accounts
- [National Patient Safety Alerts](#) – safety critical alerts to healthcare providers to reduce the risk of death or disability
- [Medicines recalls and notifications](#) – messages to pharmacies and other settings to remove a product or batch of medicines due to a defect or safety issue
- [Drug Safety Update](#) – a monthly bulletin established in 2007 to provide updates on the safety of medicines to healthcare professionals
- [Device Safety Information](#) – advice and actions for healthcare professionals, patients and providers on identified risks for medical devices
- [product information about medicines](#), including Patient Information Leaflets (PILs), details on how the medicine can be used (SmPCs) and scientific reports linked to new authorisations and specific safety reviews (PARs)
- information and data on safety reporting through our [Yellow Card website](#)
- publication of communications from marketing authorisation holders of medicines ([Direct Healthcare Professional Communications](#)) and manufacturers of devices ([Field Safety Notices](#))

Our communications are published on the MHRA's website and are delivered through various routes such as direct email or subscriptions or through the [Central Alerting System](#). Many communications are also distributed or amplified further by provider organisations and employers, which is particularly the case in Scotland, Wales and Northern Ireland.

We work closely with stakeholders, patients, caregivers and healthcare professionals to inform our safety communications. We also work closely with professional organisations and charities to assist with delivering our messages to their members and networks.

Our systems for issuing safety communications are robust and well established. However, we know that there is more to do, and for the MHRA to transform how and what risk and safety information we provide, to better protect patients and support healthcare professionals.

Where we are now

We ran a 16-week consultation with healthcare professionals, from 13 October 2022 to 31 January 2023, gathering insight and recommendations from an online survey, interviews and focus groups. A number of organisations also submitted written responses. We heard from healthcare professionals across England, Scotland, Wales and Northern Ireland, as well as from patient safety leads, patient safety experts and representatives of professional bodies and patient safety organisations.

We published [the Executive summary of the consultation and its recommendations](#).

The feedback was remarkably consistent, and the MHRA values the clear and direct suggestions about what currently works and needs improvement. This consultation report underpins our strategy to transform the MHRA's safety communications over the next 3 years.

In addition to the findings of the consultation, this strategy aims to build on our previous strategic lessons, the clear direction for proactive and transparent communication set by the [MHRA Corporate Plan 2023 to 2026](#) and the continued feedback we receive every day from healthcare professionals, patients and healthcare organisations.

Today's public and patients have rightful expectations of efficacy and safety of the medicines and medical devices they are using and of involvement in decisions about these healthcare products. We aim for this strategy to complement and build on the success of the [MHRA's Patient Involvement Strategy 2021 to 2025](#), embedding our patient-focus into our system of safety communications. We must also look ahead to new areas that the MHRA will need to communicate about, such as [new medical technology including AI and diagnostics](#).

What we want to achieve

Our ambition is that:

- our trusted advice reaches those who need it, in a timely fashion to keep patients safe
- every healthcare professional is able to understand how the latest information from the MHRA affects their patients and their care
- patients and caregivers can easily find accessible and understandable information to inform their decisions on medical products
- the UK public recognise the MHRA as a respected and trusted voice for the latest safety information related to medical products used in the UK; and our safety information helps support the agency in its efforts to combat mis- and dis-information
- our approach to safety communications continues to be informed by the needs of providers, healthcare professionals and patients and for everything we do to be evaluated with defined routes for feedback and opportunities for further improvements

We will work with partners and external experts in safety communication and behavioural science to inform delivery of the strategy. We will also introduce a training and speaker programme to MHRA staff, assisting all areas of the agency to better deliver safety advice that is accessible and has impact.

Our over-riding principles for the strategy are that by 2027:

- 1. Healthcare professionals and healthcare organisations across the UK consistently receive and read our safety communications, understand the basis for our recommendations and can take effective and timely actions.**
 - 2. Patients have access to more relevant, accessible and timely advice about risk and safety of medicines, medical devices and healthcare products and that this is informed by their needs.**
 - 3. We build and maintain trust in MHRA safety communications through transparency and ongoing engagement, so that the MHRA continues to be seen as a respected source of truth and evidence and can effectively combat misinformation, reach seldom heard audiences and support improved public health across the UK.**
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Strategic changes and objectives

The [healthcare professional consultation made recommendations](#) under key themes and these underpin our strategy to transform our safety communications. Recommendations from the consultation that are not relevant to this area will be considered and brought forward separately.

Communicating and our websites

The [consultation feedback regarding communications](#) showed high levels of awareness of our safety communications, but feedback showed that we need to do more to assist busy healthcare professionals and healthcare organisations to extract, signpost and action information and turn it into meaningful actions.

Many healthcare professionals and healthcare organisations who responded to the consultation asked for better targeting of our safety communications so they can choose to receive what is relevant for them, at a frequency and through a channel that meets their needs. The consultation also identified the need for more partnership work with other organisations who cascade and amplify our communications to our key audiences and with digital systems.

Patients are a key audience for our safety advice, and we know we must continue to consider the diverse information needs of the UK population and develop channels and materials to meet the needs of this audience, including for younger people and people who are less digitally enabled.

The [consultation feedback for the MHRA websites](#) showed that healthcare professionals struggle to find the information they need across our websites, which means that greater optimisation is needed. There was also low awareness on what we publish to support the wider safety profile of healthcare products and the resources we provide.

The consultation feedback also showed that we need to help healthcare professionals in finding information on the MHRA on our website by providing more resources and information on what we do, making these resources easier to find and use and providing more resources on how to use our website and our safety communication products.

To respond to the recommendations of the consultation we will:

- redesign our safety communications to ensure the audience and scope of each communication is clearly displayed and that they effectively set out the information needed for action

- review and optimise our channels for safety communications, strengthen our ability to reach health and care professionals through improvements to cross-system digital systems such as the Central Alerting System and bring in new innovative digitally enabled approaches to communicate directly with our audiences, including by broadening our reach to all groups of patients
- change the frequency that we issue safety communications so that we deliver new safety messages promptly and targeted to key audiences, as well as a monthly round up of all our safety advice, whether for medicines or medical devices
- support greater flexibility in direct subscribing to suit the needs of different healthcare professionals; allowing individual tailoring by frequency and by clinical speciality to ensure healthcare professionals receive the communications that are important for their practice
- provide greater clarity on who should be receiving and actioning our different safety communications, at an individual and organisational level, in our guidance
- continue to build and improve our reach to patients, including through use of innovative mechanisms to bring our safety advice directly to patients affected, through communication methods that are tailored to their needs
- establish closer ways of working with organisations who support and distribute MHRA safety communications to support and amplify our safety messages
- review how we evaluate the effectiveness of our safety communications and collect feedback to ensure our communications lead to meaningful and positive changes for patient safety
- review our website design and user journeys to understand where problems are affecting use of our safety communications and where improvements can be made
- optimise the design and accessibility of the MHRA website to help healthcare professionals find information about our role, our safety initiatives and safety issues
- produce and promote materials and guidance to support healthcare professionals to use our websites and portals
- review our subscription functions to ensure healthcare professionals can subscribe to all of our safety communications through one centralised easy to use portal
- create a new centralised page with all of our safety communications, with filtering tools for audience, clinical speciality, urgency and dates

We aim to start delivering on these strategic changes by or before September 2025. However, we will continue to work with and listen to healthcare professionals and partners throughout the entire strategy to evaluate success and ensure our changes have had a positive impact.

Informing and awareness

The [consultation feedback](#) has shown that further work is needed to raise the profile of the MHRA with healthcare professionals. It recommended more resources and guidance is provided to support awareness of our role, how we reach decisions and on the different types of safety communications that are available. It also showed the need to provide this guidance to organisations acting on our safety advice, which for the MHRA includes hospitals, pharmacies and GP practices, as well as dental services, residential care and private providers.

The consultation also recommended that the MHRA work to establish more formal relationships with key organisations and professional bodies that support the learning and professional validation of healthcare professionals to raise awareness in partnership with them.

The consultation identified the need to raise awareness in healthcare professionals about the materials we provide to support them in counselling patients on the risks and benefits of medical products they are using.

To respond to the recommendations of the consultation we will:

- raise healthcare professionals' awareness of MHRA roles, remit and safety communications through continued engagement and communication campaigns
- produce new guidance, resource and supporting materials to ensure healthcare professionals, patients and the public can use and understand our safety communications more easily
- create and promote informative materials and guidance to increase understanding of our safety communications, the Yellow Card scheme and the MHRA
- improve the materials we provide to support healthcare professionals to communicate with patients about safety, piloting approaches to deliver these directly to patients in innovative formats

- increase the transparency behind our safety decisions and assessments by supporting the publication of more information about the MHRA's assessment of safety issues and linking this information with the resulting safety communications
- work across the safety system with professional regulators to increase the profile of safety communications during accreditation and qualification stages, embedding action on these as a professional responsibility
- work across the safety system to provide more consistent and updated information to medical schools and training programmes about safety communications to embed action on these as a responsibility of healthcare professionals

These are long-term ambitious objectives that we intend to deliver by or before September 2027. However, our work on many of these objectives will begin early in our strategy. We will do this by working with partners, building and formalising relationships with new organisations and by supporting initiatives to promote our role and safety communications.

Engaging and consulting

The [consultation feedback for our engagement](#) showed our engagement with healthcare professionals, professional bodies and patient safety groups must increase and that we must take a central leadership role in supporting patient safety across the UK.

Engagement will be key to the success of this strategy and the consultation report identified the need for us to continually strengthen our relationships with professional bodies and patient safety organisations as outlined in our [Patient Involvement Strategy 2021 to 2025](#).

The consultation recommended that we should provide avenues for continual engagement with healthcare professionals by continually listening to and taking direction from on-the-ground professionals. There was clear feedback that the MHRA considers how its safety updates and alerts should be more integrated into national systems and available at point of care.

To respond to the recommendations of the consultation we will:

- build upon the MHRA's Patient Involvement Strategy and strengthen our relationships within organisations and individuals within the healthcare sector across England, Scotland, Wales and Northern Ireland to improve safety at a system-level and ensure we receive intelligence on what they need from us to deliver our safety communications to improve patient safety

- increase our direct contact with healthcare professionals by systematically engaging with key networks of healthcare professionals for advice and active feedback on our strategic changes and future directions, as well as direct feedback on our safety communications
- strengthen our relationships with professional bodies, regulators and patient safety organisations, as well as individuals such as Medication and Medical Device Safety Officers, Patient Safety Specialists and Safety Officers working in health boards, to amplify reach of MHRA safety communications and our strategic initiatives
- work with system partners to integrate our messages more consistently with health and care digital systems to amplify our reach to healthcare professionals and patients and have a greater impact of our safety actions
- hold a dedicated online consultation with patients and the public on how the MHRA communicates safety information to them

These are long-term ambitious objectives that we intend to deliver by or before September 2027. However, work on many of these objectives will begin early in our strategy through working with partners across all 4 nations of the UK, building and formalising relationships with new organisations and supporting initiatives to promote our role and safety communications.

Monitoring and evaluation

Our safety communications are an essential part of our safety system in the UK. The changes we wish to make must be evaluated comprehensively to show positive changes and to avoid unintended harmful consequences.

We will work extremely closely with our expanded networks of healthcare professionals to ensure that this work is informed by direct on-the-ground feedback, so it has a positive impact on how we deliver safety communications.

We will assign key performance indicators aligned with our overarching goals. Our methods to assess performance will include surveys, focus groups and workshops, direct feedback, audience growth analytics, media monitoring and tracking and engagement metrics.

We will also utilise our real-world data tools to evaluate the impact of key safety initiatives for real and meaningful change in behaviour and safety indicators. We will be transparent in publicising where we have seen or not seen impact, and our next steps.

Our aim is that this evaluation will show positive improvements in our reach and indicators showing our communications have positively impacted patient safety. We will also continue to examine our outcomes to help identify areas of success and areas that may require adjustments.

Conclusion and future considerations

The MHRA has been issuing advice about the safety of medical products for more than 50 years. As these products evolve, so must our communications and our systems of issuing these messages. We must also reflect the opportunities and challenges of modern healthcare, as well as societal and technological changes, to ensure clear and accessible messages are reached by all those who need to see them, at the best time to take action.

Our recent consultation with healthcare professionals gives us clear direction to improve our communications, websites, awareness and engagement with this vital audience who are our key focus in bringing greater patient safety.

The MHRA must also continue to work with other organisations representing all parts of the health and care system in the UK. Without this partnership work we are unable to ensure effective collaborative communications and safety efforts that lead to meaningful change. We will continue to build on our existing strong relationships, formalising these partnerships in the best interest of patients and their safety.

We understand that we also need to reach more patients directly with accessible and helpful safety communications. Our strategy aims to broaden our reach with patients and the public, building on the strategic priority in the [MHRA's Corporate Plan for 2023 to 2026](#) to maintain public trust through transparency and proactive communication. To build on this, we also plan to launch a new consultation in 2025 to ask patients and the public directly their views about how the MHRA communicates with them about safety. This will inform both our work within the later years of this strategy, as well as our future strategic directions.

The way we issue safety communications is an evolving continuous process. This strategy aims to set out our ambitions and approach to be further built upon, informed by the views of healthcare professionals, organisations and patients.

We plan to run a second healthcare professional consultation at the end of the 3-year period and will publish our findings so that we can transparently measure the success and impact of this strategy and set our next direction.

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