Medicines & Healthcare products Regulatory Agency

Healthcare professionals consultation on improving how we communicate on medicines and medical devices' safety.

Executive summary of consultation and recommendations

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Foreword

I am exceptionally grateful to all the health care professionals who have contributed to this consultation. It is our shared endeavour to support the safe use of medicines and medical devices.

The results of our consultation confirm that our safety communications and ongoing engagement with health care professionals are vitally important in ensuring your practice is informed by the latest information on safety, that patients are informed about the benefits and risks associated with a medicine or device, and that safety concerns are reported and can be acted on quickly.

I am only too aware of the pressures that health care professionals are under and will ensure that the views and opinions that have been provided help to drive our safety communications strategy. This strategy aims to provide health care professionals with more relevant, actionable information to inform your practice and to enable you to provide up-to-date advice to your patients.

Maintaining patient safety is our top priority, and the launch of the MHRA's new reporting system 'SafetyConnect' has improved our surveillance capabilities by allowing better interaction with Yellow Card reporters and enhanced our ability to respond promptly to emerging safety signals.

Through the MHRA's corporate plan, we have set ourselves an ambitious path over the next three years, with clear, measurable aims that will allow us to respond to the evolving challenges. I look forward to continuing our engagement with healthcare professionals and organisations representing their interests to ensure we are providing the right information at the right time using the best possible communication channels.

Dr June Raine, MHRA Chief Executive

Executive Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) has a clear purpose, to put patient safety first, but cannot expect to achieve improvements in patient safety and safety communication alone. Healthcare professionals (HCPs) and healthcare organisations have a real commitment to improving patient safety which is shared with the MHRA. Yet, the demands on HCPs are greater than ever before. The MHRA is committed to doing more to support HCPs and external stakeholders in individual, organisational and system-wide efforts to improve patient safety. More details of this work can be found in the MHRA Corporate Plan 2023 to 2026.

As part of this commitment, the MHRA identified the need to review and refresh its approach to engagement with HCPs to improve the safety of medicines and medical devices. The need was also noted for improvements in information sharing and for more tailored engagement with the wider patient safety communication landscape. Therefore, the MHRA launched a public consultation to gather views from a wide range of individuals and organisations to inform its review of safety and risk communications and underpin the development of actions.

The aim of the consultation was to identify whether HCPs are receiving actionable information and guidance on the safe use of medicines and medical devices, and how that can be improved so that they can provide timely advice to patients.

The Consultation

The MHRA ran a 16-week consultation from 13 October 2022 to 31 January 2023, gathering insight and recommendations through an online survey, interviews and focus groups, and a number of organisations also submitted written responses. Responses were received from HCPs from all four nations of the UK, as well as patient safety leads, patient safety experts, representatives of professional bodies and patient safety organisations.

The feedback was remarkably consistent, and the MHRA values the clear and direct suggestions about what works and needs improvement. This addressed not only safety communications and websites, but also how the MHRA raises awareness of its own activities and engages with HCPs and organisations.

The consultation outcomes will underpin the MHRA's risk and safety three-year communications strategy, shaping the MHRA safety communication output and ongoing engagement with HCPs and ensuring that the MHRA supports HCPs and organisations across the medicines, devices, and patient safety landscape. Patients remain at the heart of the agency's focus, with plans to further embed meaningful patient involvement across the agency's regulatory pathways, and to develop efficacy and safety information that better meets the needs of all patients.

There are 13 key recommendations which fall into four main themes: communications, websites, awareness and education, and engagement. Though the remit for many actions lies with the MHRA, for others, there are many interdependencies at the organisational and system level whose support will affect how well the MHRA is able to respond.

Introduction

The MHRA improves and protects the health of millions of people every day by making sure healthcare products in the UK meet the highest standards and are safe to use. As the regulator of medicines, medical devices, and blood components for transfusion in the UK, the MHRA is responsible for ensuring these products meet safety, quality, and effectiveness standards.

The MHRA also plays a key role in educating the public and HCPs about the risks and benefits of medicines, medical devices, and blood components, leading to safer and more effective use.

The MHRA's provision of safety communications and ongoing engagement with HCPs is crucial in a number of ways. It helps get safe and effective medicines and medical devices to patients; it ensures that patients are adequately informed of the benefits and risks, and that safety concerns are reported and can be acted on quickly.

Safety communications are intended for and received by diverse audiences. An ever-increasing workload for HCPs and the volume of all types of communication creates an imperative to ensure HCPs are able to identify and prioritise information and guidance from the MHRA.

Today's public and patients have rightful expectations of safety and involvement in decisions about healthcare products, and the MHRA needs to support HCPs with the provision of suitable information and materials as part of meeting this need.

Aim of the consultation

The MHRA identified the need to review and refresh its approach to engagement with HCPs to improve the safety of medicines and medical devices. The need was also noted for information sharing improvements and more tailored engagement with the wider patient safety communication landscape.

The aim of the consultation was to gather views from a wide range of individuals and organisations, to inform its review of safety and risk communications, to identify whether HCPs are receiving actionable information and guidance on the safe use of medicines and medical devices, and how that can be improved so that they can provide timely advice to patients.

This report will underpin the development of actions and help set MHRA risk and safety communication priorities in the short, medium, and long term.

Design of the consultation

People across the healthcare landscape were consulted, including representatives from primary care, secondary care, and community care, the National Health Service (NHS) patient safety groups, and experts in patient safety and quality improvement.

An online survey was used to gather responses from HCPs. The survey was split into 50 questions, offering a mix of multiple-choice and open-box responses. Some questions were optional. The survey ran from 13 October 2022 to 31 January 2023.

Initial responses identified the need to explore some topics in greater detail, and to ensure contributions were representative of a range of demographics and specialities, especially within primary care. To achieve this, 20 individual interviews and six focus groups were held between 9 December 2022, and 7 March 2023.

The wide-ranging findings from the consultation reflect the diverse audiences that receive MHRA risk and safety communications. The consultation findings will be of interest to the wider health and care community, people working in patient safety, and those responsible for patient safety communications in other organisations.

Results: Online survey

The survey gathered 801 responses, 513 complete and 288 partial responses. Most survey responses were from individuals, but four responses were made on behalf of an organisation. The response rates for some questions do not add up to 100% because some closed questions allowed multiple responses, and open-ended questions were coded so a long answer could receive multiple codes.

HCP professions

HCPs were asked to select their job role. Pharmacists had the largest professional role in responding to consultations (33% [Figure 1]). 19% of HCPs selected 'All other responses', and when prompted, the majority indicated they were secondary care physicians. General Practitioners (GPs) were under sampled, so they were prioritised for qualitative follow up. 68% of HCPs were in a patient-facing role, of which the majority had clinical roles. Respondents could select multiple roles, so responses do not total 100%.

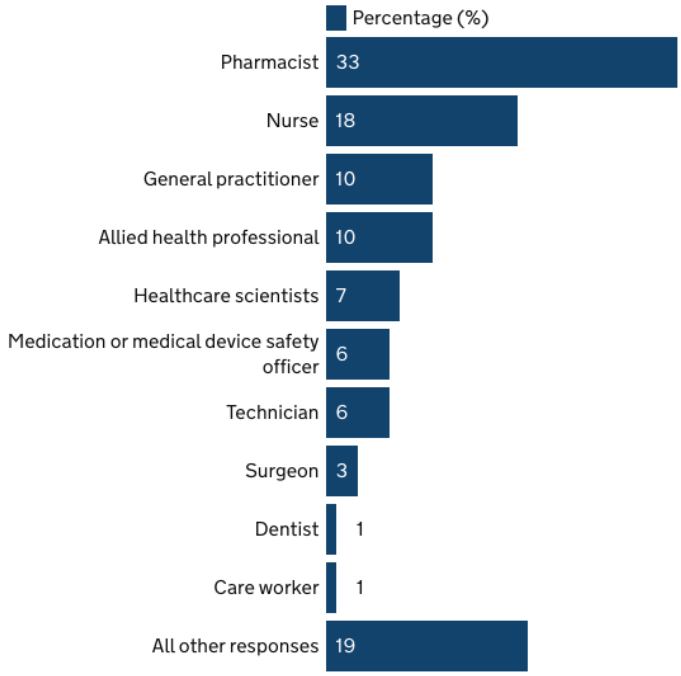

Figure 1. Professional roles selected by 513 HCPs completing the MHRA consultation online survey, UK, October 2022 to September 2023. Source: MHRA consultation online survey

HCP demographics

503 HCP supplied information on their location: 80% were currently working in England, 15% in Scotland, 6% in Wales, and 6% in Northern Ireland.

Channels for safety communication

The consultation asked HCPs how they currently received safety information related to medicines or medical devices. The 801 free-text responses gave a range of channels:

- Email (70%)

- Post (5%)
- Central Alerting System (CAS) or National Patient Safety Alert (NatPSA) (4%)
- Websites (3%)
- Newsletters (2%)
- Other channels (17%) including: journals, meetings, blogs, bulletins, social media, WhatsApp, National Institute for Health and Care Excellence (NICE), British National Formulary (BNF), intranet and suppliers.
- Notices or alerts in general (7%)
- No/don't know (6%)

Organisations mentioned:

- Personnel in healthcare organisations, including governance teams or Medical Device Safety Officer (MDSO) / Medicines Safety Officer (MSO) (12%)
- MHRA / gov.uk (11%)
- Manufacturers (2%)
- Pharmacy (2%)

The qualitative element of the consultation suggests these answers do not reflect the importance of internal cascades, as many HCPs were receiving MHRA communications via their own subscriptions and organisations. Effective actioning of the communication often required an organisational response, which was partially dependent on how the information was cascaded.

Quotes on how HCPs currently receive safety communications

> "Formal *Medical Device Alerts (*MDA*)*/NatPSA, etc*,* notices from the MHRA come via the *CAS* process into the Trust. Manufacturer *Field Safety Notices (FSNs)*/*Field Safety Corrective Actions (FSCA)* are very hit-and-miss and do not always go first directly to the *MDSO*/*MSO* or Trust Compliance Teams. They can go direct to users, to Accounts (as they were contact details on the initial order), or anywhere. This is a risk." *Healthcare scientist/Medication or medical device safety officer, England*

> "Via e-mail — I receive the NICE Awareness Daily e-mail directly, MHRA drug safety updates directly from the MHRA. I receive CAS alerts through my organisation - they are sent to my team (medicines optimisation team) directly via a generic e-mail and a team member then circulates the alert to the whole team." Pharmacist, England

Email was the messaging system HCPs interacted with the most time in a day (Figure 2).

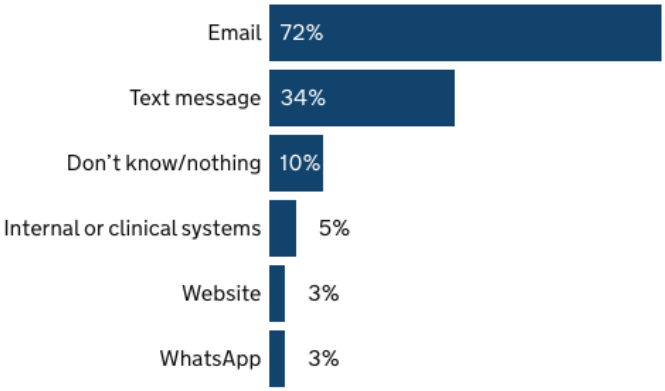

Figure 2. Messaging system with most frequently reported current interactions per day for 513 HCPs, UK, October 2022 to September 2023. Source: MHRA consultation online survey

When asked what the best way was to get benefit-risk information directly to you to inform your decision-making when treating patients, there were 801 free-text responses, with one clear preference:

- Email (72%)

There was a wide variety of additional suggestions which were grouped as follows:

- Internal or clinical systems (5%)
- Text messages (34%)
- Website (3%)
- WhatsApp (3%)
- Don't know/nothing (10%)

Quotes on how HCPs would prefer to receive safety communications

> "Email unless very urgent or severe, then I suggest this is flagged up via pharmacy who will email all the appropriate professionals." *Physician, England*
>
> "A simple, regularly updated web page, that clearly states the risk, recall status, and necessary actions for all safety notices. This should be complemented with a weekly email listing all changes and updates." Healthcare scientist, Scotland
>
> "Via clinical IT systems Vision, EMIS etc on prescription of the drug" *Medication or medical device safety officer, England*

Communication from the MHRA

When asked if they had received a communication from the MHRA in the last 12 months, 513 HCPs responded:

- 81% said yes
- 10% no
- 9% were unsure

HCPs were asked how they mainly received communication from the MHRA. The majority, 70%, said they received directly from the Agency (Figure 3). Qualitative responses indicated that many received communications both from organisational cascades and through individual subscription to notices.

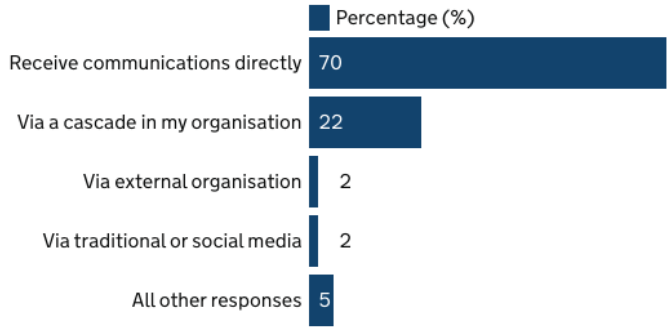

Figure 3. The main ways 417 HCPs report receiving MHRA communications, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

Of the HCPs that said they mainly receive communications directly from the MHRA, 290 HCPs provided more information and the majority reported receiving drug safety update bulletin or product recalls and alerts (Figure 4).

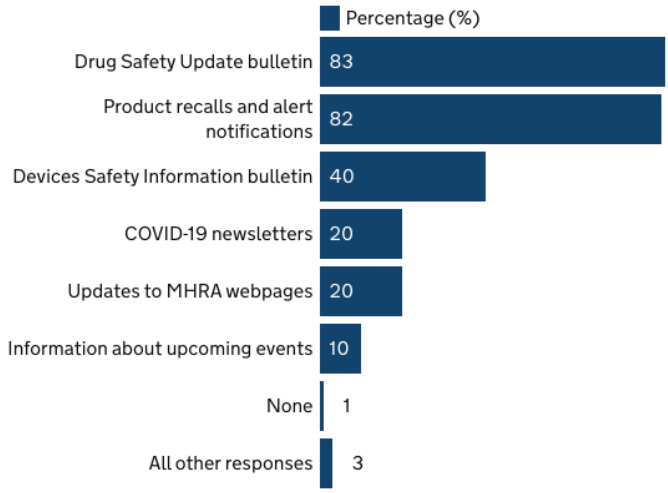

Figure 4. The main types of MHRA communications 290 HCPs report receiving directly from the MHRA, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

Of the HCPs that said they mainly received MHRA communications via a person in their organisation, 91 answered the follow-up question; of these, 31% said that person added additional context.

Product recalls and alerts

The 236 HCPs who said they received MHRA product recalls and alerts were asked how frequently they acted on them (Figure 5).

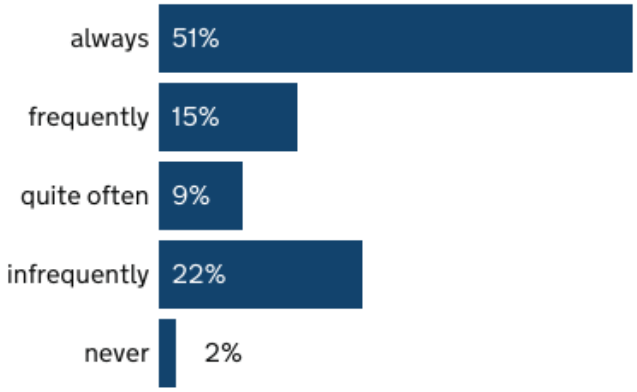

Figure 5. The frequency in which 236 HCPs report acting on MHRA product recalls and alerts, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

The main reasons for not always acting on MHRA communication were grouped (Figure 6). Lack of relevance to their role was the main reason action was not taken.

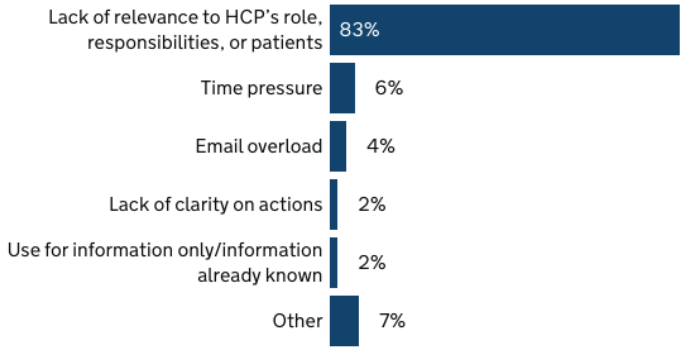

Figure 6. The frequency in which 236 HCPs report acting on MHRA product recalls and alerts, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

Quotes on actioning safety communications

> "If I work in a GP *practice,* I don't see why I should see info about meds that are only used in hospital or those that are only relevant to community pharmacy. It seems like everything is just sent to everyone without any level of filtering which means busy clinicians ignore it." *Pharmacist, England.*

> "Do act on medicines, not devices. Often class 1 and 2 are issued on Friday where there is already heightened pressure on staff. If *possible,* can processes be quickened to get notice to sites earlier?" *Allied HCP, Scotland*

> "Too time consuming to check every alert by downloading PDF files to see if it relates to what I'm interested in." *Allied HCP, England*

> "Sometimes the information does not require action, for example about a known side effect of a drug commonly in use. What was the point of that MHRA update?" *Critical Care Clinician, England*

315 supplied free-form suggestions for improvements to product recalls and alert notifications, of which the main suggestions were:

- More targeted or relevant (13%)
- Better summaries or highlighting key information (10%)
- More clarity on actions that should be taken (7%)
- Changing timing or frequency (3%)
- Channel suggestions in line with previous questions (7%)
- Existing system works well (7%)
- No suggestions (40%)

Quotes on improving safety communications

> "Info should detail what type of provider this effect i.e Primary or Secondary care. This would help in streamlining information to disseminate further within the organisations." *Governance and Compliance Manager, England*

> "Make a table each month that we can distribute to other healthcare professionals, this is half the battle in primary care." *Clinical technician, England*

> "Lists of affected products for all recalls and alerts to be provided along with the alert, in the form of a spreadsheet, in order to cross-reference with local asset management database." *Healthcare scientist, England*

> "A Database/pool for us NHS professionals in Governance to access to review trends would be helpful in being proactive in patient-safety improvement, patient immediate care when something goes wrong, and when looking to procure new devices." Healthcare scientist/MDSO, England

Drug safety updates

241 HCPs who indicated they received drug safety updates were asked to rate their value:

- 59% selected very valuable
- 30% quite valuable
- 10% neutral
- 1% not of value

When these HCPs were prompted if they had used patient information sheets provided with some drug safety updates, (not limited to Drug Safety Update [DSU]), 241 responded:

- 57% had not used
- 34% had used
- 9% were unsure

Communications about medicines and medical devices

When asked to suggest improvements to MHRA communications on medicines and medical advice safety, the 689 free-form responses were very wide-ranging and included:

- Targeted, filterable, or reduced communications (12%)
- Clearer and more concise information (9%)
- More advice and guidance (4%)
- A summary section (3%)
- An indication of urgency (3%)
- More openness and transparency (2%)
- Channel suggestions in line with previous responses (17%)
- Continue as it is now (5%)
- Centrally issued (3%)
- More open/transparent (2%)
- Searchable (1.5%)
- Other (19%)

- Don’t know or no suggestions (36%)

Quotes on improving design of safety communications

> “We suggest that it might be worth sending those who are subscribed to MHRA alerts an annual summary of their subscriptions so that these can be updated in line with any new areas of interest or responsibility.*”*
> *Professional organisation (pharmacists), NI*

> “Add a summary so all understand 3 things quickly; what issue is, what consequences are for patients, what action individuals need to take.” *Nurse, Scotland*

> “Colour coding or re labelling the email headers to make it easier to know what it is about. More emphasis on unit managers communicating the information to the team, so easy to print, poster style summary information that can be shared with other staff.” *Nurse, England*

> “Utilising a range of platforms and channels to ensure prompt communications.” *Midwife, England*

MHRA webpages

57 HCPs indicated they received updates to the MHRA webpages:

- 53% said these were very valuable
- 32% quite valuable
- 14% were neutral
- 2% selected not of value

When asked which MHRA websites HCPs were aware of and which they had interacted with, a similar proportion of HCPs reported accessing the main MHRA website (gov.uk) (37%, Figure 7a) and the MHRA products website (31%, Figure 7b) more than once a month. In contrast, only 7% reported accessing the Yellow Card site at the same frequency (Figure 7c). This may reflect the lower need for adverse event reporting compared to general safety information. A higher proportion of HCPs, however, said they were unaware of the MHRA products website (29%) compared to the MHRA main site (5%) or Yellow Card site (5%).

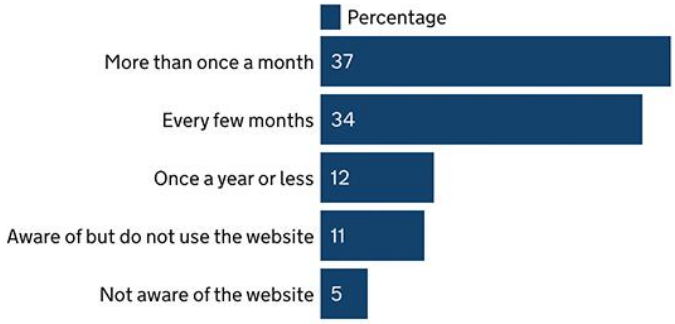

Figure 7a. Frequency 513 HCPs report accessing the main MHRA website, UK, October 2022 to September 2023, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

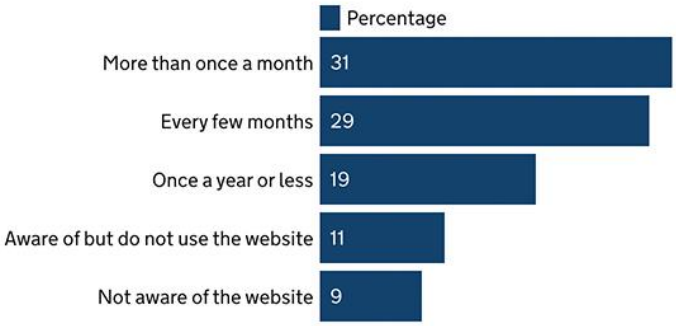

Figure 7b. Frequency 513 HCPs reported accessing the MHRA Products website, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

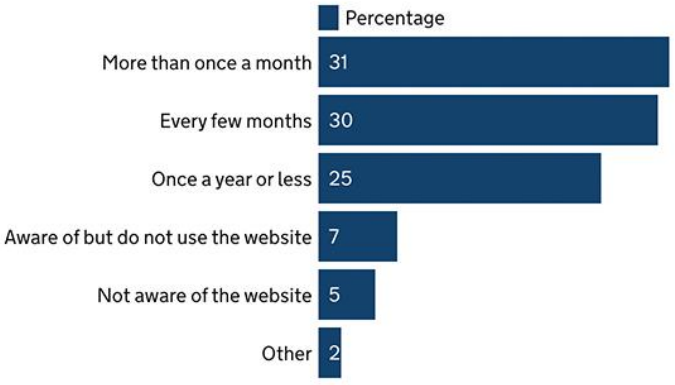

Figure 7c. Frequency 513 HCPs reported accessing the MHRA Yellow Card side effects reporting website, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

Suggestions for improvements to the MHRA websites came from 42 free-form responses with the following main themes:

- Improved search functions (12%)
- Improved site navigation (7%)
- More guidance and clarity on actions (7%)
- Relevant/filtered information (7%)
- Faster updates (5%)
- Highlighting important information better (2%)
- Easier to access (2%)
- Provision of contact details (2%)
- 'No' (31%)

Quotes on MHRA websites

> "The MHRA product site is not as good as medicines.org.uk (the electronic medicines compendium [eMC]) so I use this instead. The way the alerts are listed on your sites can be very confusing particularly those coming via CAS / NatPSA." *Pharmacist, England*

> "The MHRA Product website: Summary of Product Characteristics (SmPC)/Patient Information Leaflet (PIL) – it's not easy to identify license holder or brand from the outset and its time-consuming opening each SmPC/PiL one by one to find the one needed." *Pharmacist, England*

> "The .gov website is less user-friendly and I find it difficult to find historic information on there at times, with the exception of the DSU bulletins. Having an area which summarises what the different types of alerts are, and then a list of those alerts that can then be searched (similar to the CAS page) would be really helpful." *Pharmacist, England*

> "I was not aware of the MHRA Products website. To make it easier to remember to access information on medicines and medical devices safety, one common website would be easier for busy healthcare professionals." *Medication or medical device safety officer, England*

> "There is limited information on MHRA web pages. After Brexit especially. We need to work on getting more information for MHRA webpages regarding UK-approved medicines so that we should not have to refer to the European

> Medicines Evaluation Agency (EMEA) website. Definitely, more expertise and resources are required and more budget." *Pharmacovigilance, England*

MHRA engagement with HCPs

When asked for examples of where the MHRA had engaged with respondents in a way that was valuable, the 313 free-form responses covered a range of topics and many HCPs provided very detailed individual responses. Overall, 45% responded no or nothing, and of the remaining responses, the following elements were most often mentioned as valuable:

- Drug safety updates (not limited to DSU) (11%)
- Email communication (5%)
- Yellow Card scheme (4%)
- Covid-19 updates (4%)
- A response to a query (4%)

Quotes on engagement with HCPs

> "The MHRA has been an excellent communicator in regard to covid vaccination in pregnancy and provided timely and helpful advice." *Midwife, England*

> "When first registering our product with the MHRA, we sought advice on registration and classification. Subsequently when adding a product to our repertoire, we clarified with the MHRA whether this would fall under our existing registration. Responses were most helpful." *Healthcare scientist, Scotland*

> "The MSO forum could potentially be very valuable, but it is a "clunky" platform with insufficient engagement to make it of meaningful use." *Pharmacist, England*

> "[An MHRA representative] attended the Faculty of Pharmaceutical Medicine's annual symposium in Nov '22 - wonderful. It's good that the Agency has 'a face'!" *GP, Rep. Ireland*

> "Have seen some useful talks specific to my practice from MHRA members at seminars in the past." *Healthcare scientist, England*

When asked what source HCPs generally preferred to received information and/or updates relevant to their profession, the responses had a fairly even split (Figure 8):

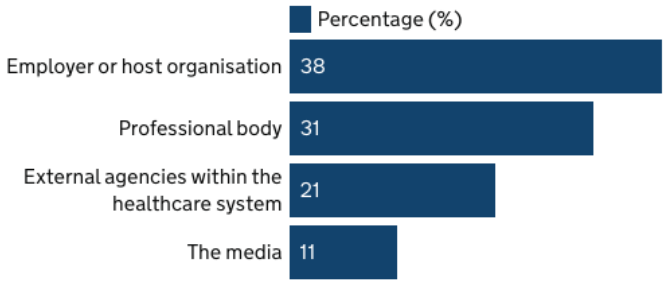

Figure 8. Preferred source for information or updates with professional relevance reported by 502 healthcare professionals, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

HCPs were asked, when they received information from an organisation, whether they prefer to receive one communication that has updates on many different topics or each communication to focus on a different topic. In the free-from responses to this question, the responses were grouped into the following themes:

- Separate topics (8%)
- Multiple topics (8%)
- Depends on subject matter (7%)
- Depend on urgency (5%)
- Depends on amount of information (3%)
- Summary page required (3%)
- Don’t mind as long as targeted (2%)
- Don’t mind as long as concise (1%)

Reasons for preferring separate topics included that this is better for urgent communications (6%), makes it more concise (1%), means HCPs are less likely to miss things (1%), are easier to focus on (1%), and are easier to share (1%).

Reasons for preferring multiple topics included this is better for more general communication (3%), it reduces the amount of communication (2%), help with checking that nothing has been missed (1%).

Quotes on topics for safety communications

> “Depends how much detail there is! If lots of info on one topic, single topic is better. If several smaller pieces of info, then multi-topic is fine.” *Pharmacist, England*

"Themed communications can be useful but too many different topics in one communication can be hard to digest / forward for action." *Pharmacist, England*

"Depends on how important the update is - if very important send as one but if general then all in one update." *Psychiatrist, Scotland*

"Would like some topics to be more focused, especially relevant ones to my area of practice, sometimes general multiple topics are fine." *Nurse, Scotland*

"General news, SmPC changes etc. OK all together but specific warnings requiring action then individually." *Surgeon, England*

HCPs were asked to rate their agreement with a set of statements about MHRA communication. The top two box agreement was above 50% for all questions, and the bottom two box scores were highest for relevance of information and clarity of actions (Figure 9).

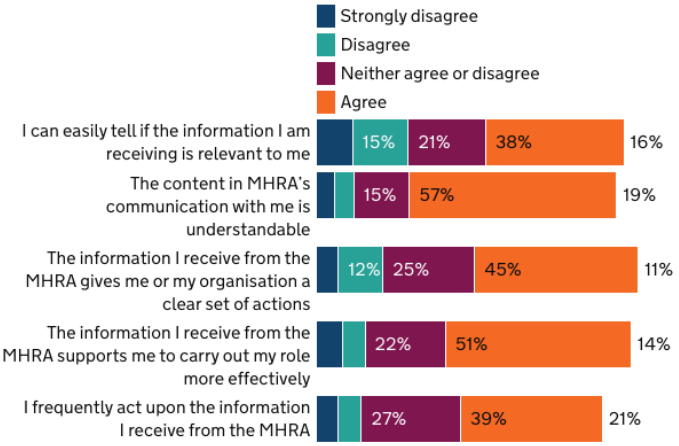

Figure 9. Strength of agreement with statements about MHRA communications with healthcare professionals, UK, October 2022 to September 2023. Source: MHRA consultation online survey, n=513.

When asked if there was anything the MHRA already does to communicate updates to HCPs that they would like the MHRA to increase or improve, the 582 free-form responses provided a mix of new ideas and improvements, many of which were reiterations of previous responses, these were grouped into the following themes:

- More or more regular or consistent communication, updates, or information (10%)
- Improved design (6%) including colour coding, accessibility, summaries, actions, standardised layouts

- Improved relevance (5%)
- Direct communication preferred (5%)
- Emails are useful (4%)
- Channel suggestions (3%) including integration with clinical systems, texts, WhatsApp, paper, social media, newsletters
- Improved clarity (3%)
- Improved website or search or user experience (2%)
- Improved response (2%) including access to representatives, speed and more consultations
- Openness/transparency/sharing (2%)
- Fewer emails (1%)
- Website improvements (1%)
- Other (19%)
- Don't know (12%)
- No/nothing (46%)

Quotes on subscribing to safety communications

> "Drug Safety Update is very helpful and cold be improved for better use with mobile devices." *Pharmacist, UK*

> "… kindly use human factor specialists to review the design of the communications. This ensures the end user has an easy task reading it. In turn this increases the chance of the message being read." *GP, England*

> "I want to receive different topics only in one email. It would be better if the MHRA communicated changes about technologies for medical devices and had a few workshops to discuss changes, improvements, and the future of MHRA after Brexit." *Allied health professional, England*

> "Publicise how to sign up for alerts and make this process a little easier to navigate." *Pharmacist, England*

When respondents were asked how they liked to receive the MHRA's urgent safety information and product warnings, the 573 free-from responses mentioned the following channels:

- Email (65%)
- Directly (6%)

- Through employer (4%) including MDSO/MSO or governance team
- Channel suggestions: text message (4%), website (2%), app (2%), CAS (2%), clinical system (1%), WhatsApp (1%), social media (1%), other (1%).
- Via professional body (2%)
- As currently (1%)
- Yes, non-specific (2%)
- No (9%)

97% of 513 HCPs were aware of the Yellow Card scheme, and 70% of 493 HCPs said they had ever used the Yellow Card scheme to make a report. HCPs said they had reported the following concerns to the scheme (Figure 10):

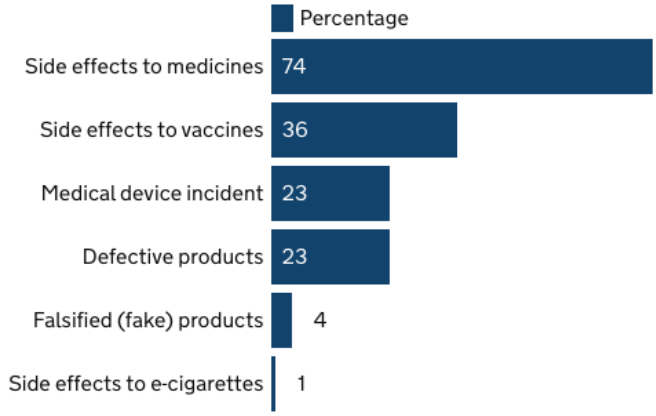

Figure 10. Concerns 364 healthcare professionals reported ever submitting to the Yellow Card scheme, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

There were 552 free-from responses to a question asking HCPs what route they would like to have available to inform the MHRA about the concerns of medicines, medical devices, or other matters within the MHRA regulatory remit. The channel suggestions were varied:

- Email (28%)
- Yellow Card scheme / improvements to Yellow Card (15%)
- App / Mobile / Phone (non-specific) (15%)
- Online (non-specific) (14%)
- Online form (8%)
- Current system (4%)
- Clinical system (including Systm1, EMIS) or within patient records (4%)
- Text message (2%)
- WhatsApp (1%)
- Letter / Paper (1%)
- Forum (1%)
- A variety of routes (1%)
- A single route or platform (1%)

- N/A (11%)
- Other (8%)

When asked how they thought the MHRA should engage with HCPs who have raised a concern, the 551 free-form responses covered both channel suggestions, including forums, Teams, and in-person meetings, and the manner of the interaction:

- Give feedback / respond to concern / keep updated (29%)
- Channel suggestions (including email, online form, Teams, text, letter, forum) (18%)
- Clearly or directly (13%)
- Manner of response (professionally / openly / honestly / supportively / without bias) (6%)
- Provide information / guidance (5%)
- Engage in discussion (2%)
- Show evidence of investigation / share number of complaints per issue (2%)
- Yes (single-word response) (5%)
- Don't know/no preference (13%)
- Other (7%)

HCPs were asked if there was anything else they would like to tell the MHRA regarding how it engages and involves HCPs in the agency's safety work. 328 free-form responses:

- Provide more feedback / respond faster / regular updates (7%)
- Improve communication / clarity of communication (5%)
- Provide training / increase awareness (4%)
- Greater transparency / honesty (4%)
- Improve Yellow Card scheme (4%)
- Engage with HCPs more visibly / engage with stakeholders / seek feedback from HCPs (3%)
- More diverse channel usage / more digital (2%)
- Improve website / centralised comms (2%)
- Have local / named contacts (1%)
- Attend more meetings / events (1%)
- Other (10%)
- No / nothing (58%)

Quotes on improving safety communications

> "It would be good to engage more with HCPs as regards packaging and labelling of medicines." *Pharmacist, England*

"It would be useful to understand what the MHRA does. This area is highly relevant to oncologists in practice and in trials and most have little understanding. E.g., a 1-day course or a section on your website." *Oncologist, England*

"I work as a prescribing advisor, and we are trying very hard to get GPs to complete more Yellow Cards. The feedback consistently is that the process is difficult, and they don't see the value. Information about how Yellow Card reporting has resulted in real changes to improve patient safety would help to improve engagement. Perhaps include a news story/success story with the monthly drug safety updates?" *Pharmacist, Wales*

"CAS alert system is good but clearly is not being used as main source of information, why is this? We feel information should be held in one place with a priority indication, so it is clear which things are most important." *Pharmacist, England*

"More people should be aware of the Yellow Card reporting system. I found out via a non-care sector friend, who'd been told by her beautician! I've asked numerous care sector colleagues/managers of services etc - I'd estimate less than 5% have known about it." *Care worker, England*

More detail on whom/ what roles make these decisions on safety, and how those decisions are made. This will provide a sense of transparency that could foster trust in your work. *GP, Rep. Ireland*

Awareness of the MHRA

HCPs had high awareness of MHRA responsibilities, though awareness of the MHRA role in educating HCPs and the public was lower (Figure 11).

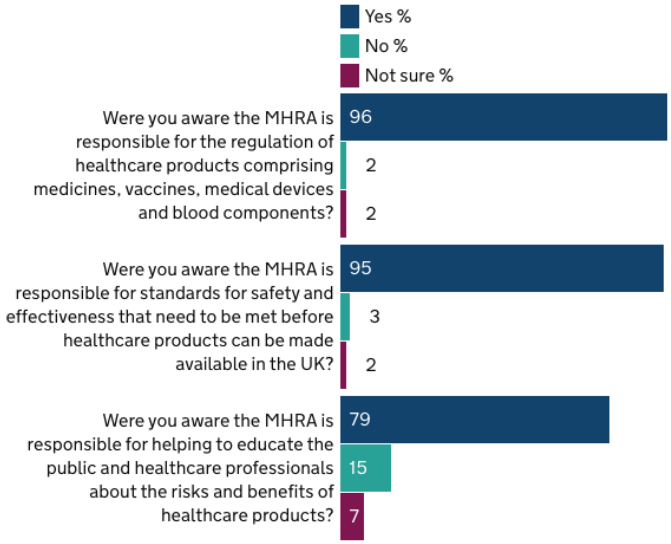

Figure 11. Claimed awareness of MHRA responsibilities among 513 healthcare professionals, UK, October 2022 to September 2023. Source: MHRA consultation online survey.

There was 72% top to box agreement by HCPs with the statement that the MHRA supports them as a professional to use medicines and medical devices safely (Figure 12).

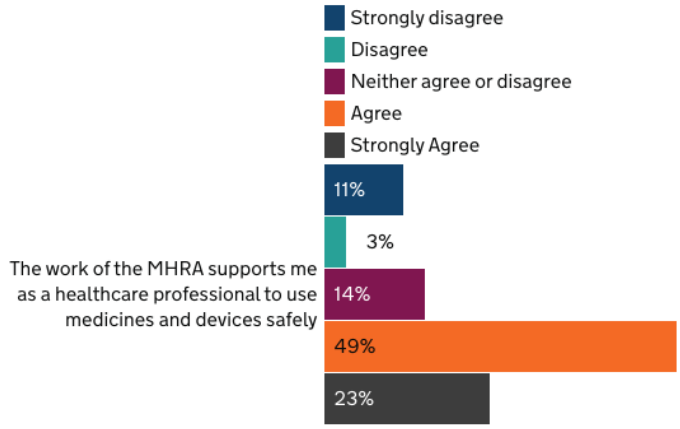

Figure 12. Healthcare professional agreement on a 5-point scale with 'The work of the MHRA supports me as a healthcare professional to use medicines and devices safely', UK, October 2022 to September 2023. Source: MHRA consultation online survey, n=513

Quotes on the MHRA roles

> "A number of areas don't have clear supporting guidance so can be left open to individual interpretation. Clear guidance to support interpretation of regulations would be useful. More support with manufacturers is required to address issues of look-alike / sound-alike drugs and poorly worded SmPC/PIL to improve medicines safety." *Pharmacist, England*

> “Being up to date with the latest medicines safety information is very important to reduce harm for patients. The alerts also provide a framework for our Integrated Care Board (ICB) to address medicines safety priorities and issues.” *MSO/MDSO, England*

> “Despite using medical devices regularly and prescribing these to patient I feel I do not know enough about the MHRA and what it does. I do not feel throughout my education or carer anyone has explained who they are or why they are relevant. I understand that they approve devices but do not feel enough is explained about the rest of their role or how we should interact.” Allied health professional, England

Results: Qualitative interviews and focus groups

Twenty supplemental one-on-one interviews were conducted with nine GPs, four secondary care physicians or surgeons, two pharmacists, two nurses, one dental practice manager, and two people with safety roles in the pharmaceutical industry.

Virtual focus groups were undertaken with six organisations, including three national healthcare safety teams, two Integrated Care System (ICS) teams, and one professional body. Respondents had a wide variety of roles including MDSO/MSOs, patient safety leads, hospital and community pharmacists, GPs, physicians, and educators.

Interviews summary

The GPs interviewed were a mix of partners, salaried GPs, and locums from both urban and rural practices. The points made by GPs were broadly consistent, with no regional variations. Suggestions were primarily focused on making communication more targeted and concise, and Yellow Card reporting shorter and more integrated with existing clinical systems. GPs from larger, urban practices were more likely to express an interest in materials and activities that would help raise awareness of the MHRA or educate about the different types of communication.

All secondary care clinicians interviewed were at the consultant level. Responses were more variable than other HCPs and tended to be focused on systems-level safety issues and access to data for research or monitoring. The difficulties in engaging the MHRA, identifying named contacts and building relationships were also concerns, though these may reflect the additional professional roles and organisational patient safety responsibilities of the consultants that responded to the consultation qualitative outreach.

Pharmacists had the highest frequency of regular interaction with MHRA communications and, as such, were the group most comfortable with the existing layout and contents.

Focus groups summary

Focus group discussions were mainly at the system-level, and there was an acknowledgement that many issues would require inter-organisational cooperation to solve. Suggestions for design and content improvements to existing communications were in line with other HCPs, with more focus on the potential benefits of additional clinical context or information that would help organisations cascade and action communications. Website improvement suggestions focused on increasing access to historical data and improving search functionality. Sharing of Yellow Card data was an area the MHRA should improve for the benefit of patient safety. MHRA engagement with other healthcare organisations, including professional bodies and healthcare system organisations, could be improved, especially through provision of MHRA contacts and relationship building.

Safety communications

Key concerns from all HCPs were the workload and time pressures that they were under and the volume of all emails received, so external safety communications needed to be relevant and brief. Organisations noted that click-through rates on their own safety newsletters or updates were low.

All GPs requested the ability to easily filter or subscribe to communications that were relevant to primary care. Most consultants and secondary care staff also requested MHRA communications be targeted by speciality.

All organisations and over half the GPs noted that part of the reason for the high volume of irrelevant alerts was the lack of a standard process for receipt, triage, and dissemination of safety communications. Organisational suggestions include the creation of standardised guidelines for safety communication distribution, or the provision of a centralised safety communication channel. Some of the challenges with organisational distribution included identifying off-license usage to ensure all relevant parties received updates, and easily identifying and reaching some groups of staff including locums. Additional risk information, including, for example, the number of patients, number of affected medicines or number of affected devices in the system, or the risk ratio for adverse reactions, would help organisations with prioritisation and reduce the need for each organisation to do a risk assessment to quantify the issue.

For pharmacies, similar to other healthcare organisations, protocols for receipt, cascade and actioning communications were not standardised. This was especially true for independent

pharmacies, whereas NHS community pharmacies were more likely to be considered as part of an Integrated Care System cascade process. In general, however, the process for actioning notices was more formal in pharmacies than in general practice, which reflected the role of pharmacies in recalling stock.

Some noted that the main issue was that most HCPs would not remember a notice from many months previously, so that some information would be better integrated with clinical systems or software so it was available at the point of use. This was considered especially important for patients in a cross-sector situation, or non-specialist sector. The challenge would be to ensure such systems were not overloaded by the high volume of information that did not aid clinical decision making.

Most HCPs were familiar with product recall notices and medicines/device safety updates. Pharmacists and MSO/MDSO were most comfortable with the existing formats, which reflects their regular engagement with MHRA communications. There was lower awareness of the other types of communication, and few HCPs were aware of patient information sheets produced by the MHRA.

Some HCPs were not aware that MHRA communications were available at different frequencies. Some GPs felt the frequency of alerts to be irrelevant, whereas others wanted much more control over their subscription preferences and alert frequencies. Organisations were more concerned about ensuring priority information reached them promptly and that actions were clear. There were requests that the MHRA be more realistic about response times due to current pressures on NHS services.

In general, for primary care, the in-practice pharmacist was identified as the most appropriate individual to have responsibility for cascading safety information. Still, guidance from the MHRA would be welcome. Particular groups, such as locums, were at risk of missing communications. Some GPs noted that having an effective monitoring and measuring system for notices was difficult due to the high frequency of communications (not just from the MHRA), and this would need to be balanced against the overall workload. A few GPs suggested that ICS prescribing teams could play more of a role in filtering and tailoring safety communication for primary care, and one GP observed that NICE and Care Quality Commission (CQC) were able to produce and distribute communication targeted at primary care.

Suggested improvements to MHRA safety communications were consistent across all HCP roles and are summarised in Box 2. For primary and secondary care HCPs, this included making sure key information, such as drug name, was in the email subject line, that actions were clear, communications had a simple message of no more than a few lines or concise bullets. The overall preference was a link out for further information, though some preferred supplemental information to be supplied at the end of the same document. Pharmacists

noted that consistency in communication format was important, and the drug name, action required, batch numbers and expiration dates were the most useful information for them. As with other HCPs, the need for brevity was important; large amounts of additional information were not necessary to action most notices. There was a mixed response from all HCPs to the potential implementation of a traffic light system for urgency; some felt it would be helpful and others felt it meant all, but the most urgent, would be left unread.

Some doctors wanted simple population or risk-benefit statistics, and a few suggested these would support patient communication. Organisations also considered that additional clinical context would be beneficial but acknowledged the challenges in selecting the appropriate information.

Quotes on safety communication

> "You look at the paperwork and then you go to your shelf, and you see whether you have those expiry dates or stock numbers. And then you just pull them out. That's pretty much it." *Pharmacist, Wales*

> "It's really difficult because GP's get huge amounts of e-mail and information. And it doesn't seem to be tailored or relevant particularly. I'd really rather like not receive it if it wasn't relevant for primary care …because it's a bit like the boy who cries wolf. If you get lots and lots of stuff that's not useful, you just stop opening them." *GP, London*

> "I think the better way is integrating [MHRA safety information] into something that already exists, like the BNF. And the reason for that is it's an existing thing that everyone uses and it's not like, oh, not another app that we've got to download." *GP, N.E. England*

> *"In* community pharmacy *[in an ICS region] there are lots of locums, small pharmacy teams, changing shift patterns, locations open 100 hours a week, and to get one email cascaded to everyone covering in a week is impossible." Lead pharmacist, S.E. England*

> *"I try to get alerts down to a 50–60-word summary for onward distribution and to get attention, including the must do action. In a big organisation you may be trying to reach only 4-5 people it's relevant to. This summary and action in the first bullet or line is especially important when it's drugs in general use."* Operational pharmacist, S.E. England

MHRA websites

The user experience of MHRA websites was mixed, with information signposting and the search facility generally considered as areas for improvement. Websites like NHS Futures or the eMC were held up as good examples of user experience.

Yellow Card

The majority of GPs' comments on MHRA websites related to Yellow Card reporting. Reporting was considered onerous. Suggestions for improvement consistently included integration with existing clinical systems (EMIS, SystmOne) so patient data could be auto-populated, that the form take no longer than one minute to complete, submission acknowledgement should be standard, and the progress or outcome of a report should be provided. GPs also commented on how the move by the BNF to digital platforms reduced their exposure to the Yellow Card reporting form.

The slow response or lack of feedback on Yellow Card reports was a common frustration among individual HCPs and organisations. HCPs requested acknowledgement of submission and regular progress updates.

Gov.uk

The MHRA gov.uk site was noted by HCPs across a variety of roles to have potential as a safety resource or database, but the limited search functionality was a notable area for improvement. A few noted that the MHRA homepage could be optimised to provide clearer signposting to information. There were requests that the main website includes an organisational overview or navigation on who to contact for what.

Some organisations and a few individual respondents suggested setting up testing panels to review both the user experience and clinical content.

National organisations felt Brexit-related information and information relating to individual nations was felt to be a weakness, especially in relation to Northern Ireland protocols. Device regulation was also an area where additional information should be provided or be easier to find.

MHRA products

Consistent with the online survey, there was overall lower awareness of the MHRA product website. Many HCPs used eMC as they felt it had a better user experience.

Quotes on MHRA websites

> “If I had a vague memory that there was an MRI safety alert about a particular bit of kit, or I wanted to know whether there were safety alerts about a particular category of kit, I would find it incredibly difficult to go back and search and find [on the MHRA website].” *Physician, N.E. England*

> “It would be nice to have a really good clear search engine so you can access retrospective documentation.” *GP, S.W. England*

> “It would be really nice if the Yellow Card functionality would be integrated with our clinical systems, you'll tend to find most people use either system one or EMIS. [A similar] example would be for a notifiable disease, so things are auto populated so we don't have to waste time …filling in demographics.” *GP, E. Midlands*

> “[With Yellow Card] you're got to go back through the notes and find the start date or all the other medications that that [the patient] is on that that could be interacting and put some other patient demographic details. That would take me 5 minutes? It doesn't sound a lot, does it? But that is going to be too much to do it in between patients.” *GP, N.W. England*

> “For any kind of reporting system just make it as short as possible. We just want to write this is the medicine, this is why it was prescribed, and this is the issue that I've noticed. But then patient details should get auto populated.” *GP, E. Midlands*

Awareness and education

GP partners with responsibilities for managing a variety of primary care practice roles were more likely to express a need for greater awareness of MHRA, but overall, many GPs felt there should be a clearer description of the MHRA roles, responsibilities, and links with other healthcare organisations. Case-based examples of how the different types of safety alerts and notices could be applied to work within the practice would help engage the wide variety of HCPs within primary care, especially the number of new roles with prescribing responsibilities.

While not a priority for pharmacists, some brief educational resources covering the MHRA roles and the different types of notices would be useful as understanding of the class system for recalls was low. As with other HCPs, awareness that individual pharmacists could subscribe to MHRA notices and recalls was low.

Several GPs noted that the Yellow Card scheme used to be integrated with the hard copy of the BNF and, as such, provided a regular reminder of the Yellow Card scheme existence. With the move to digital BNF this link has been lost. Yellow Card scheme awareness was good for pharmacists but not frequently used. Most organisations interviewed and about a quarter of individuals, noted that the MHRA had an opportunity to share Yellow Card success stories to both raise awareness of the scheme and to educate about patient safety issues, suggestions for these included cases, webinars, and newsletters.

Organisations felt the MHRA could do more to inform HCPs about its role and responsibilities, especially in relation to how it interacted or overlapped with other organisations. A few HCPs questioned whether the MHRA was the right organisation to be providing patient safety content, as they felt it lacked a clinical perspective or understanding of how information was used in practice or constraints of healthcare processes.

Some GPs and organisations thought the MHRA could provide more educational content. Cases were felt to be especially relevant and reflected how HCPs preferred to learn. Educational modules, bite-sized videos, FAQs, infographics, and short summaries were felt to offer the best opportunities for engagement. Some HCPs had seen MHRA webinars and found them useful, and this was an area that MHRA could expand, perhaps in partnership with professional bodies. This would also provide a way to target information by specialty.

Few HCPs were aware the MHRA produced patient-facing content. Some HCPs would find this valuable, especially if it were simple and visual. Other HCPs questioned whether the MHRA had the clinical experience necessary to be able to produce content of value.

Quotes on awareness and education

> “It's a bit unclear really, the remit of the MHRA. What's their role other than just cascading the information?” *Pharmacist, N.W. England*

> “Even something as simple as an organization chart showing how the MHRA links in with other bodies would be useful.” *Physician, N.E. England*

> “Insight into different organizations and roles would be really important…this is what this organization is for, this is what you should be doing…. [with]

current primary care structures even I get confused, and having a demystifying poster would be really helpful.” *GP, E. Midlands*

“I think there isn't that much real knowledge. So, I think a little bit of education about what the MHRA is and what it does, what it can't do, what it should do, how we should interact with it.” *GP, London*

“I live in a world of safety, and I find the MHRA too dry, and yet actually the MHRA could tell a story with this. This came through our yellow card system. This was what was shared with us. This allowed us to change something. And this made life safer.” *Physician, S.W. England*

“I was at a sponsored webinar and there was a link to the MHRA Yellow card system online …and I thought that was like really good and would make me more likely to use it.” *GP, London*

Engagement

Most secondary care physicians expressed a desire for the MHRA to engage more regularly with HCPs, and their professional colleges and organisations. A drop-off in MHRA presence at congresses and events was noted by some in senior roles, and some consultants felt the MHRA was less engaged with clinical safety research. The lack of ongoing consultation was noted by several, and more regular outreach would be welcomed. This could be done in partnership with clinical colleges or national organisations.

The lack of named contacts at the MHRA was a key frustration and was a priority request from organisations or HCPs with senior safety roles. Many felt the MHRA should play a greater role in terms of facilitating patient safety at the system level. There was a perceived lack of willingness of the MHRA to engage with safety issues outside of a narrow remit, for example, with safety issues relating to packaging or product design. Organisations and senior clinicians felt the MHRA could do more to communicate the rationale as to which patient safety issues they engaged with. A couple of organisations felt the MHRA and HCPs had different perspectives on what patient safety was, so the MHRA’s perspective could be more clearly communicated.

National organisations and secondary care clinicians noted that there would be benefits to patient safety if the MHRA could share Yellow Card data between input and output and provide more regular updates on reports status and trending data. Greater access to data

could help clinicians be aware of early trends, identify areas for additional monitoring, and aid in clinical safety research.

National organisations and ICS teams requested MHRA provide more information on organisation structure and key contacts. Organisations noted that, unlike most other national bodies, the MHRA did not provide named contacts, and this was felt to hinder engagement and make communication on important patient safety issues much more challenging. The absence of a named contact at the agency to respond to queries was also noted by some pharmacists and out of date information on inspectorate teams was noted by the pharmacy industry respondent.

Only one HCP, a GP, commented on the MHRA social media accounts, noting the content on these was operational and passive, without much prompting for interaction or discussion. This HCP suggested that a more clinical focus would be required to gain HCP engagement.

Quotes on engagement

> "We had two boxes where they were utterly identical except one had a dark blue and one had a black stripe…you couldn't tell them apart… and the MHRA say that's not our problem, that's the manufacturer's. How you use something, the human factors of it, the practical application of system safety and people working in system, …I've never seen [the MHRA] grasp that that mettle." *Physician, S.W. England*

> "I think just going out and listening is helpful. I think it's helpful for any organization to build in some check and challenge on how they are received." *Physician, S.W. England*

> *"If we're trying to improve patient safety and make healthcare safer, I think that MHRA do not use their influence as much as they could." Physician, S.W. England*

> "I can name someone at North West Surrey Integrated Care Services (NICS). I can name people at CQC, I can name people at NHS Resolution. I can name people and I could e-mail all of them in the next 5 minutes and I'd have a reply if they were there today. There is no one person at the MHRA who I can do that with, there is no sense of relationship." *Physician, S.W. England*

“We still have outstanding acknowledgements from just post Brexit…there is no closure. If we did that as industry, that would be frowned upon because it shows that we do not have correct processes and procedures in place to ensure end to end closure of an issue.” *Head of pharmacovigilance, pharmaceutical company, UK*

“It often feels like it's almost like a tick list exercise for someone. Someone just pressing a button and saying right, we've told the doctors now. We're covered if something goes wrong.” *GP, N.E. England*

“We no longer have a single point of contact. There is a strategic contact, and a working level contact. And that can make it difficult in terms of developing recommendations.” Patient safety professional, England

Summary of recommendations

Four key themes of the consultation:

1. Communication

1.1) Provide greater clarity on who should be receiving and actioning MHRA safety communications at an individual and organisational level.

1.2) Produce communications at frequencies to suit the needs of different HCPs.

1.3) Explore additional channels for the distribution of communications.

1.4) Optimise the design and content of safety communications.

2. MHRA websites

2.1) Optimise MHRA websites to help HCPs find information on the MHRA and safety issues.

2.2) Simplify Yellow Card reporting and explore better integration with clinical systems.

2.3) Increase usability and features of the MHRA products website.

3. Awareness and education

3.1) Raise awareness of MHRA roles, remit, and safety communications.

3.2) Create educational materials to increase understanding of safety communications, the Yellow Card scheme, and the MHRA.

3.3) Provide more patient-friendly safety information to support HCP’s communication with patients.

4. Engagement

4.1) Provide avenues for continual engagement with HCPs.

4.2) Strengthen relationships with professional bodies and patient safety organisations.

4.3) Increase engagement in improving safety at a system-level.

1. Communications

The MHRA produces or publishes a range of regular medicines and medical device communications for healthcare and industry professionals that individuals and organisations subscribe to. These include NatPSA, device safety information, recalls of medicines and devices, field safety notices, and drug safety updates. MHRA safety communications are predominantly text-based with simple, accessible designs and are currently offered at varying frequencies, from ‘as updated’ to daily or weekly summaries.

1.1 Recommendation

Provide greater clarity on who should be receiving and actioning safety communications at an individual and organisational level.

The consultation recommends that more guidance be provided within the body of communications, and on the appropriate MHRA webpages, on who MHRA communications are targeted at, and how each communication should be cascaded and actioned.

All MHRA safety communication notices and subscription sign-ups should be consolidated into one webpage. Content should be provided that explains the difference between the different types of communication and relevance for specific healthcare roles.

The consultation recommends that the MHRA optimise subscription options to give HCPs greater control over the type and frequency of communications they receive. Subscription preferences management should be optimised and allow subscription by speciality.

The MHRA should review how it is evaluating the effectiveness of its safety communications and what processes are in place for ongoing collection of feedback so barriers to implementation are addressed, and local variation in response within the healthcare system is considered. The MHRA does not have direct oversight of organisations receiving MHRA safety communication, which means a partnership approach is essential. Devices typically have a wider remit that makes actioning communications more challenging.

The MHRA should work with partner organisations to provide guidance on receiving and disseminating MHRA communication within healthcare organisations and consider where duplication may occur. Organisations involved in the consultation noted they would need to develop their own local processes to reflect roles and structures and differentiate between organisational responsibilities and chains of dissemination, and end-user responsibilities (see Box 1).

BOX 1. Review of internal cascading of MHRA communications.

Organisations that wish to review their internal process may find the following prompts a useful starting point.

- Establish which roles should be receiving MHRA safety communications.
- Set up clear chains of dissemination.
- Consider how information will reach those who may not be on standard email distribution lists.
- Clarify organisational, individual and end-user expectations and responsibilities for actions at each stage.
- Provide one point of contact for those unclear about actions required.
- Consider if acknowledgement of receipt of communication is required and how this will be collected.
- Put in place a process for collecting feedback and process review.

1.2 Recommendation

Produce communications at frequencies to suit the needs of different HCPs.

The consultation recommends a greater range of subscription frequency options is provided to balance the needs of those requiring immediate updates with those wanting less frequent but more relevant communications. The options offered should be consistent across all communications.

Less urgent communications could be condensed into a once-weekly update, released on the same day each week, to reduce email overload.

Monthly or quarterly summaries, themed by speciality, with additional clinical context and perspectives, would increase relevance and utility for HCPs in clinical roles.

1.3 Recommendation

Explore additional channels for the distribution of communications.

MHRA safety communications are currently offered via email subscription, RSS feed, or via MHRA.gov.uk in HTML format or downloadable PDFs. Email remains the preferred channel for safety communication, but consultation provided a large number of additional channels

that the MHRA could explore, many of which are likely to be cost-prohibitive and appeal to only small numbers.

The additional clinical context desired by HCPs could be addressed through channels such as newsletters and webinars.

Many healthcare organisations and professional bodies summarise and distribute MHRA safety communications within their own communications. The consultation recommends the MHRA work more closely with external organisations to provide mutual support in the creating and distributing safety communications.

1.4 Recommendation

Optimise design and content of safety communications.

The consultation provided detailed feedback on the communication structure, design, and content of MHRA safety communications, and found current formats need revising to better support the ability of busy HCPs to extract and action information (see Box 2).

The consultation recommends the MHRA invest in user-testing of current and any re-designed communications to improve the ability of HCPs to review information and determine necessary actions quickly. The output should be templates and guidance that increases the consistency of regular communication and ensures clear distinctions between types and priority of communications. Priority classes could be reframed to refer to a timescale to action. Terminology should be reviewed for accuracy, and clarity of language should be improved to avoid ambiguous advice and jargon.

The MHRA could consider introducing a prioritisation scale for device notices, as though devices often affect small numbers of patients, malfunctions or other issues can still be critical. The MHRA should engage more with clinicians and professional bodies that are researching or working on device innovation or device safety in terms of device communication content and design.

The consultation recommended additional clinical context be provided, particularly in relation to risk-benefit data to support and guide clinical decision making. Providing patient-friendly content to explain risks and benefits would help support HCPs and patients in evaluating actions in response to safety information.

BOX 2. Making improvements in safety communication design

Design recommendations were focused on increasing the speed and ease of extracting the most relevant information to ensure effective action. HCPs want to know who should do what and when.

Structuring information

- Headlines should contain the key, relevant information (e.g., drug, issue, action).
- Include a very brief summary at the start.
- All key information should be on one page.
- Start with actions and finish with an explanation or background to the issue.
- Additional information in supplementary pages or on a pdf or webpage accessed via a link or QR code.

Aiding scanning

- Break up text, use subheads, bolding, and bullets.
- Use blocks and outlines to highlight key information.
- Add more visual elements for those who prefer to process information visually.

Facilitating action

- Be clear about who should receive and who should action communications.
- Using colour coding or other design devices to make priority clear.
- Add photos of devices to aid identification in the field.

2. MHRA websites

The MHRA maintains a number of websites, some with specialised functions. These include the MHRA.gov.uk site, the Yellow Card reporting sites, and the MHRA products website.

2.1 Recommendation

Optimise the MHRA website to help HCPs find information on the MHRA and safety issues.

The consultation recommends improvements in the MHRA gov.uk menu structure, search, organisation of content and linking of information, and in the provision of contact information. The consultation acknowledged the limitations placed on the MHRA in regard to gov.uk optimisation but noted that there were valuable learnings that could still be applied by reviewing other websites.

The consultation found that HCPs expected the MHRA website to provide more information on the MHRA remit, roles, and organisation. The consultation also recommends providing more overarching information and guidance on medicines, devices, and patient safety issues. Consolidation of safety communication pages could help improve sign-up rates.

The consultation recommends the MHRA create a web or app repository of historical safety information to facilitate HCP access to safety data. Setting up an HCP testing panel as part of the development will help ensure the resource meets the needs of HCPs in terms of content and usability.

2.2 Recommendation

Simplify Yellow Card reporting and explore better integration with clinical systems.

The consultation recommended that the Yellow Card form be shortened and additional information requested only if necessary.

Integration of Yellow Card reporting with clinical systems like EMIS would simplify reporting by allowing automatic filling of patient information. The reporting of communicable diseases provides a good model for such integration.

The Yellow Card scheme report card is a physical part of the printed BNF, but the move to a digital BNF is believed to have contributed to reduced daily reinforcement of the Yellow Card scheme's existence. The consultation also recommends that the MHRA work with the BNF to determine if and where Yellow Card reporting might be more prominently integrated into the digital BNF.

The consultation recommends that HCPs receive ongoing updates about the progress of their Yellow Card reports and earlier and greater access to relevant related data.

2.3 Recommendation

Increase usability and features of the MHRA products website.

The consultation recommended a large number of requests for features and improvements to the MHRA products site (see Box 3).

The need to modernise and improve the usability of the product site was a key recommendation. Currently, due to poor usability of the MHRA site, many HCPs use the privately owned electronic medicines compendium (eMC) to access MHRA information.

Access to information should be assured to all relevant HCPs, and the improvements required to the geolocation restrictions near the Northern Ireland border are noted.

BOX 3. Suggested MHRA product website optimisations.

- Review site user experience, especially with regard to search, link labels, and number of clicks.
- Title documents to include the marketing authorisation holder's name in the file name.
- Clearly label out-of-date SmPCs.
- Improve search functionality to allow searching of SmPCs and product information leaflets (PIs) by manufacturer, by specific SmPC sections, or allowing exclusion of words (e.g., excipient ingredients).
- Include the medicine classification of each product, e.g. General Sales List (GSL), Pharmacy medicine (P), Traditional Herbal Remedy (THR).
- Provide a section on recently approved products.
- Ensure information is easy to find by grouping all information on each product, like SmPCs, PIs and Public Assessment Reports (PARs) and packaging labelling mock-ups.

3. Awareness and education

During the pandemic, the MHRA public profile was raised due to its role as the vaccine regulator. Still, overall awareness of the MHRA's broader roles, remit and organisational structure remains low, even among engaged HCPs.

3.1 Recommendation

Raise awareness of MHRA roles, remit, and safety communications.

The consultation identified the need to ensure HCPs are aware of the different types of safety communication that are available, and to continue to build awareness of the Yellow Card scheme. There is also a need for the MHRA to raise awareness of its broader roles and how it can support HCPs and patients.

3.2 Recommendation

Create educational materials to increase understanding of safety communications, the Yellow Card scheme, and the MHRA.

Case-based content has the most relevance for HCPs, but bite-sized educational modules on MHRA roles, safety communication types, and products like the Yellow Card scheme would also be valuable for HCPs and educators (see Box 4).

BOX 4. Suggested educational content for the MHRA to produce.

Educational content should be a mix of modules, video or print content. Content may need to be tailored for prescribers and non-prescribers. A variety of topics were proposed by the consultation including:

- Education modules on MHRA roles, Yellow Card reporting, medicines and device regulation and patient safety.
- Case-studies
- Content that explains the different types of safety communications.
- FAQs
- Visualisation of the patient safety landscape, including key organisations like the Health and Safety Investigation Board (HSIB), CQC, MHRA, etc, indicating any areas of cross-over.

3.3 Recommendation

Improve the way we support HCP communication with patients.

This consultation identified the need for increased engagement with patients on safety issues and risk-benefit evaluation. This could be by providing simple and visual materials for HCPs to use with patients or by ensuring relevant MHRA safety communications have a box with a patient-friendly explanation of the issues.

4. Engagement

MHRA engagement with HCPs, professional bodies and patient safety groups has recently reduced in some areas. These groups want to understand the MHRA capacity to engage and to continue to build on the outreach initiated in this consultation. The MHRA is in an important position in having safety responsibilities across the whole of the UK, unlike most other organisations; it should therefore play a more visible role in coordination and sharing of safety information and contributing to system level responses to patient safety issues beyond those covered by statutory requirements.

4.1 Recommendation

Provide avenues for continual engagement with HCPs

The consultation recommends using a variety of channels and panels to increase direct engagement with HCPs. This could include more regular consultations, surveys, forums, webinars, and question-and-answer sessions, as well as MHRA attendance or participation at clinical conferences.

The consultation also recommends the MHRA invest in engaging HCPs and the public with the results of the MHRA work. This could be with case-studies, webinars, blogs, newsletters, social media activity, or increased participation in events and conferences.

The MHRA should map existing HCP relationships, identify gaps, and establish a process to build and maintain engagement.

4.2 Recommendation

Increase engagement with HCPs on device safety.

The consultation recommended the MHRA engage more with clinicians and professional bodies that are researching or working on device innovation or device safety. HCPs suggested the MHRA should be participating in more clinical working groups.

The MHRA should produce more content providing insight into MHRA work in device regulation. A dedicated communication list for those interested in MHRA work in device safety and regulation should be established.

4.3 Recommendation

Strengthen relationships with professional bodies and patient safety organisations.

The consultation recommends a range of measures to deepen engagement with key external stakeholders. These include the need to explore if professional bodies could collaborate with the MHRA to add clinical context to selected safety communications or co-host webinars, and to explore how the MHRA could support professional bodies with their medicines, devices, and patient safety initiatives.

The consultation recommends strengthening strategic relationships with patient safety organisations and professional bodies to enable collaborative development of recommendations. As part of this, the MHRA needs to: provide clarity on MHRA roles and responsibilities, supply organograms and organisational charts, provide named contacts of an appropriate seniority, and ensure succession planning is in place. The consultation recommends that one person at the MHRA take overall responsibility for external relationships protocols.

4.4 Recommendation

Increase engagement in improving safety at a system-level.

The consultation recommends improved provision of national information, especially in relation to Northern Ireland protocols. The MHRA should create annual reviews or reports of patient safety data at a national level.

The consultation recommends that the MHRA consider how its safety alerts and recalls can be integrated into national systems.

The consultation noted that many HCPs believe the MHRA has a unique and powerful ability to influence patient safety, nationally and globally, which is under-utilized (see Box 5).

BOX 5. Improving system level engagement

- Be more open with MHRA data to ensure awareness of and therefore earlier action on data signals.
- Support system-wide efforts to improve access to patient safety data, held by MHRA and national health care organisations, by those researching patient safety issues.
- Increase transparency and explain why the MHRA does not engage in some frequently raised topics, including medicine naming or packaging design issues that lead to patient harm.
- Help centralise previously published patient safety reports from any organisation.
- Be an active part of discussions about how patient safety organisations work together and address gaps and crossovers in remit.
- Provide ongoing avenues for feedback and consultation.

Implementation of the recommendations

MHRA will communicate details of the key recommendations to internal and external stakeholders. These will be evaluated in the MHRA risk communications strategy and selected findings will be acted upon in a timely and coordinated manner.

Some actions are already underway. Other actions will take longer to implement — in particular, integration of MHRA safety communication or Yellow Card reporting with clinical systems which will require a feasibility study and extensive engagement with stakeholders in the NHS and other healthcare organisations.

Many respondents have expressed willingness to continue providing ongoing advice concerning safety communications, which will continue to be of great value to the MHRA, HCPs and the public.

We have reviewed all the comments received and thank everyone who took the time to contribute to this consultation.

Next steps include establishing criteria to evaluate the recommendations and developing an action plan. Evaluation criteria will include the degree to which a recommendation positively impacts patient safety and adds value to HCPs. The degree to which a recommendation is

achievable by the MHRA and how it relates to the priorities set by the Secretary of State will also be considered. Further engagement should take place to share learning with HCPs, patient safety, and professional organisations, including the Department of Health and Social Care (DHSC), NHS, HSIB and others, and to provide regular updates on progress.