



Medicines & Healthcare products  
Regulatory Agency

## **Medicines and Healthcare products Regulatory Agency consultation seeking views on how we engage and involve patients and the public in our work**

**Feedback received**

**‘What you told us’**

# Contents

1. Background .....	3
2. Subjects covered by the consultation and a summary of the responses received.....	4
3. Themes identified from the consultation .....	21
4. Cross-cutting areas of interest that support the themes .....	28

# 1. Background

The Medicines and Healthcare products Regulatory Agency ('the agency') is the UK regulator for medicines, medical devices and blood components for transfusion; responsible for ensuring that they meet applicable standards of safety, quality and efficacy. In addition to the regulatory centre, the Agency is also comprised of the Clinical Practice Research Datalink (CPRD) and the National Institute for Biological Standards and Control (NIBSC). CPRD is a data research service that aims to improve public health by using anonymised NHS clinical data. NIBSC is a global leader in the standardisation and control of biological medicines.

The agency intends to adopt a more systematic approach to listening to and involving patients. We wish to make sure that we hear and listen to the concerns and views of patients when safety issues, regarding medicines or medical devices, are identified and in the licensing of new medicines. We want to deliver a step-change in how the agency communicates with, engages and involves patients and the public in its work.

To help inform the agency's future engagement with patients and the public we ran a 12-week public consultation, from 15 July to 7 October 2019, on how to best engage and involve patients in the agency's work.

The consultation also looked at how patients and the public would like the agency to communicate with them. In addition, we sought views on how patients and the public would like to communicate with the agency to raise concerns and how it can best respond.

We promoted the consultation widely through the agency's existing stakeholder networks for patients/carers, healthcare professionals, fellow health system regulators, the NHS, academics/researchers and industry. We worked with other government departments, community groups and voluntary organisations to raise awareness of the consultation amongst communities and demographic groups with which we do not normally have direct channels of communication.

The consultation exercise was conducted primarily in the form of an online questionnaire, including a downloadable version for completion offline, which was also available as a Welsh language translation. In response to feedback received during the consultation period, we also developed a version of the questionnaire to facilitate responses from organisations on behalf of the members/supporters that they represent.

To further support the consultation process we ran a series of five engagement events at which we met with patient and healthcare representatives in England, Northern Ireland, Scotland and Wales. The comments and views expressed at each of those meetings have been taken into consideration during the compilation of this document.

This document is the agency's official report of the 808 consultation responses received.

## 2. Subjects covered by the consultation and a summary of the responses received

In total, we received responses from 808 individuals and organisations. We provide below a breakdown of the type of respondents (chart 1) and respondents' broad areas of interest (chart 2).

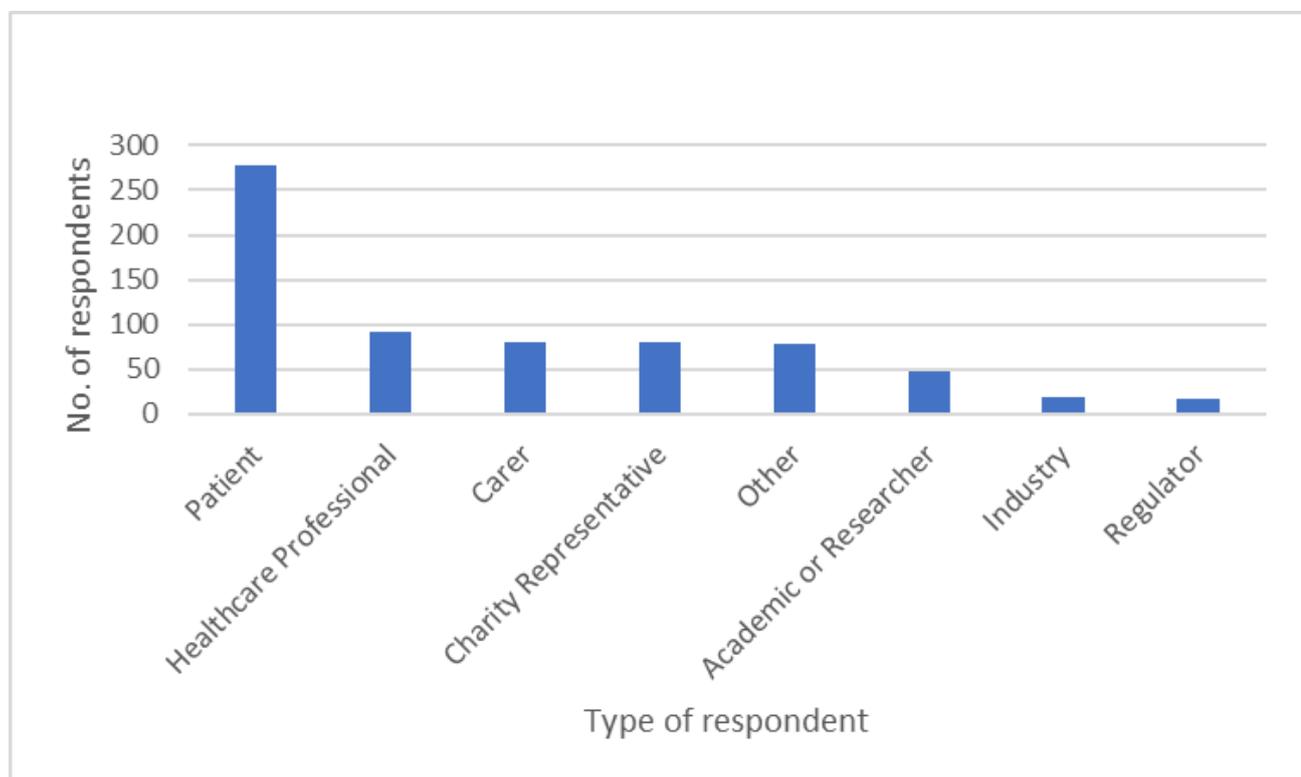
The consultation questionnaire was structured to enable us to receive both quantitative and qualitative responses. We wanted to encourage respondents to express their comments, suggestions and views with as few restrictions as possible. Out of 21 questions, nine could be answered in the form of free text, with no limit to the number of words used.

We have relied primarily upon these qualitative responses to help identify a number of key themes, or learning points, for the agency which are discussed later in this report: Awareness, Transparency, Responsiveness and Partnership (including patient and public involvement).

### 2.1 Profile of respondents and areas of interest

We asked respondents to describe themselves in relation to the regulation of medicines and healthcare products. Respondents self-identified as follows:

Chart 1: consultation respondent type  
[Respondents to the consultation analysed by the types with which they self-identified]



The number of responses we received for each respondent type was:

- Patient: 277 respondents
- Healthcare Professional: 91 respondents
- Carer: 80 respondents
- Charity Representative: 80 respondents
- Other: 79 respondents
- Academic or Researcher: 47 respondents
- Industry: 18 respondents
- Regulator: 17 respondents

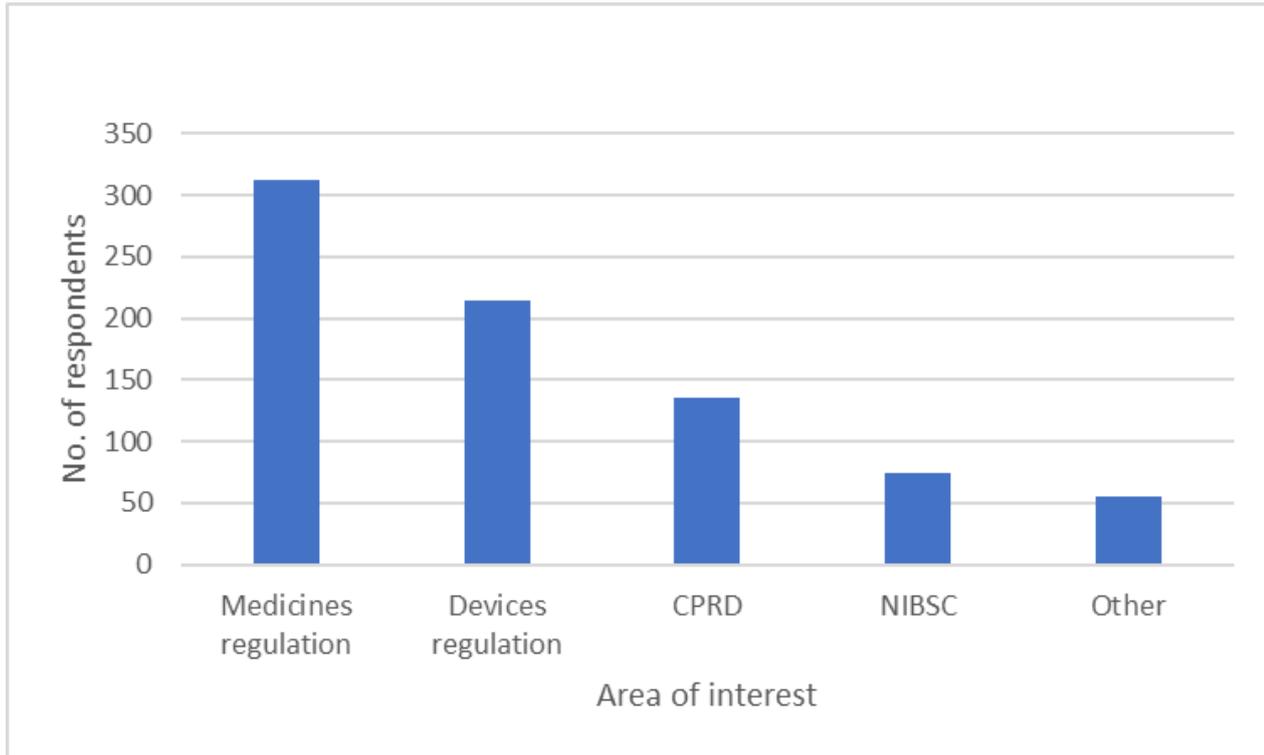
Respondents could select multiple descriptions – many identified with more than one type. Most responses, 67%, identified as patients, 22% as healthcare professionals, 19% as carers and a further 19% as health/research charity representatives. The ‘Other’ category captured a very wide variety of types, including for example: ‘lay member’, ‘NHS manager’, ‘prospective pharmacy student’, ‘public involvement professional’.

We received responses on behalf of 44 organisations, of which 31 were patient groups (see List). The remainder were a mix of industry associations, individual pharmaceutical companies, healthcare professional representative organisations, academic/research bodies and other health system agencies.

Respondents told us that they were primarily interested in the following areas of the agency’s work:

Chart 2: broad areas of interest

[Respondents to the consultation analysed by the broad areas of the agency’s work in which they are interested]



The number of responses we received for each area of interest was:

- Medicines regulation: 313 respondents
- Devices regulation: 214 respondents
- Clinical Practice Research Datalink (CPRD): 135 respondents
- National Institute for Biological Standards and Control (NIBSC): 75 respondents
- Other: 55 respondents

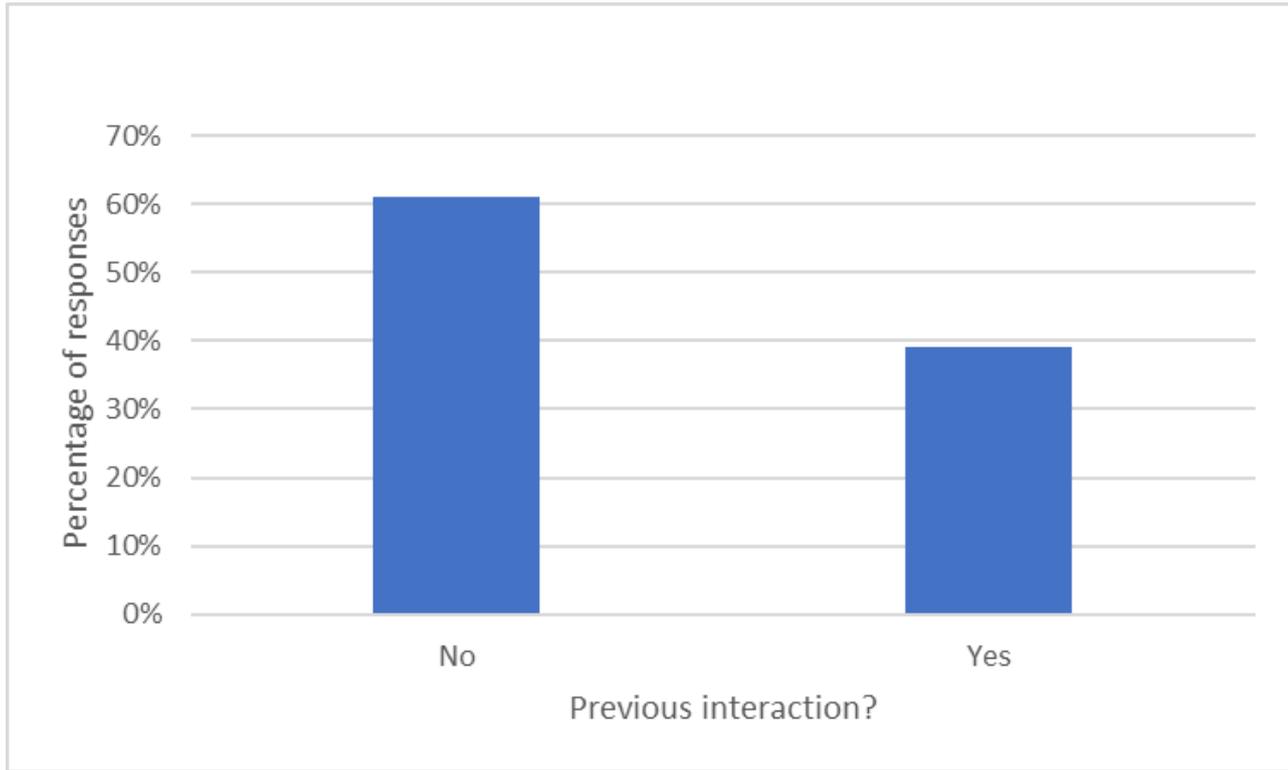
Responses in the 'Other' category included specific subjects such as patient safety, patient and public involvement, clinical trials.

## 2.2 Current levels of engagement

61% of all respondents to the consultation told us that they had not previously interacted with the agency. A lack of awareness of the agency and its role amongst patients and the public is one of the key consultation themes to which we will respond.

Chart 3: has the respondent previously interacted with the agency?

[Respondents to the consultation analysed by whether they have previously interacted with the agency]

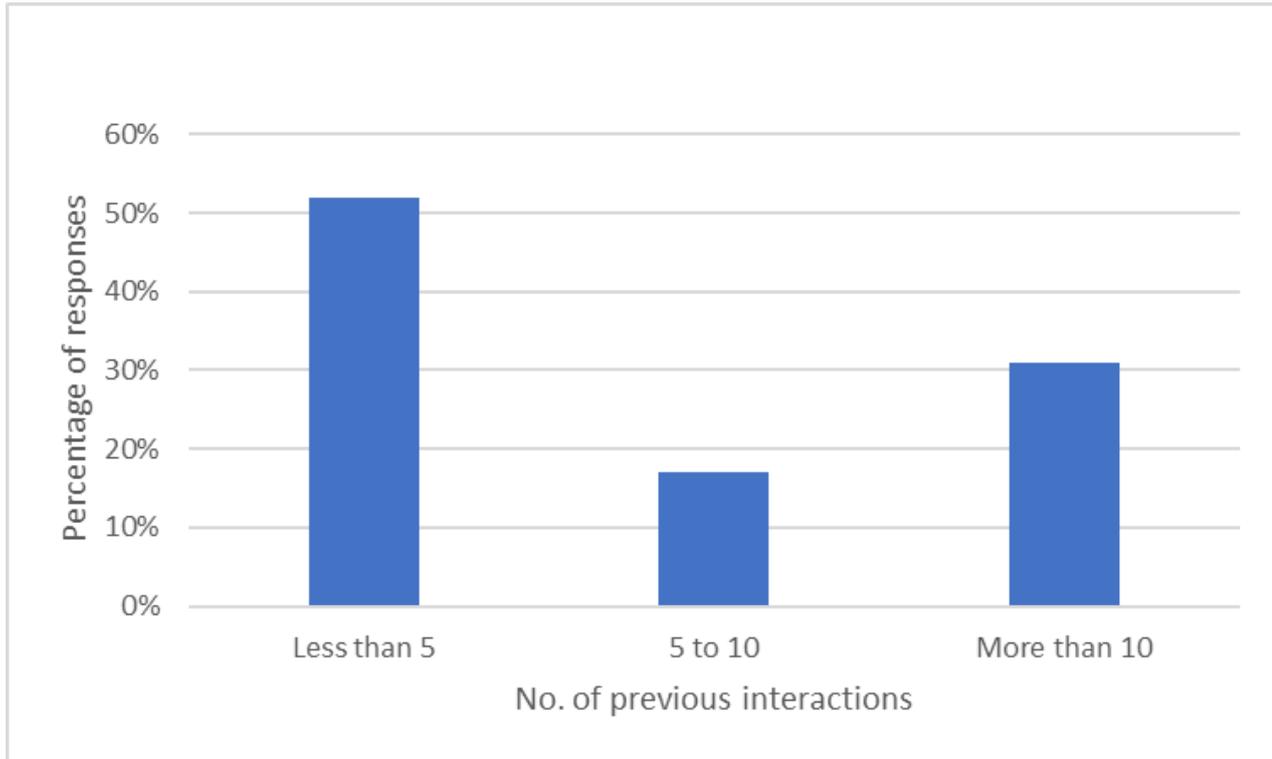


The respondents' answer to whether or not they had previously interacted with the agency was:

- No: 61% of all respondents
- Yes: 39% of all respondents

Of the 316 respondents who had already engaged with the agency, 52% had fewer than five interactions with us during the past three years. However, 31% reported ten or more interactions during that period. This equates to 90 respondents, about 11% of total respondents, having a high level of existing engagement with the agency.

Chart 4: number of interactions with the agency during the past three years  
 [Respondents to the consultation who told us they had previously interacted with the agency, analysed by the number of interactions during the past three years]



The respondents who told us that they have previously interacted with the agency, during the past three years, reported the number of those interactions as follows:

- Respondents who had less than 5 interactions: 52%
- Respondents who had from 5 to 10 interactions: 17%
- Respondents who had more than 10 interactions: 31%

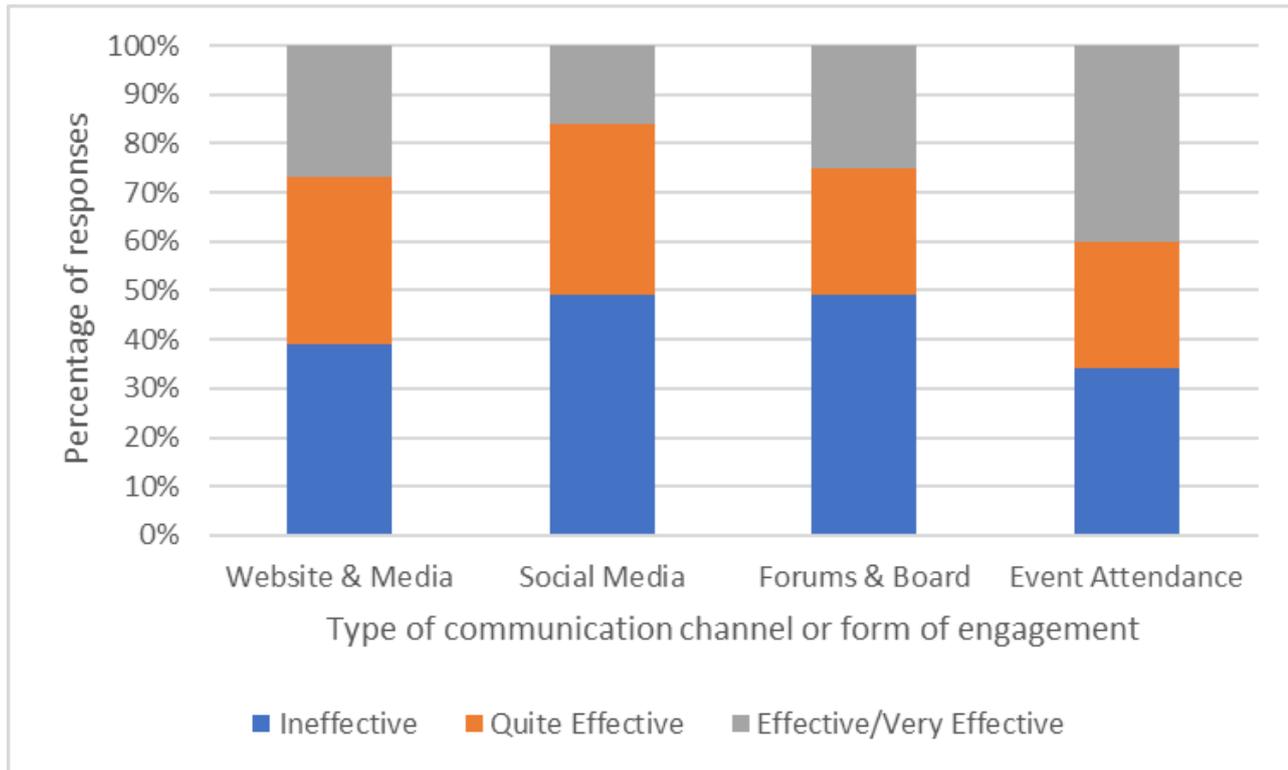
In relation to the existing interactions reported by respondents, the majority, 43%, concerned medicines while 26% were about medical devices and 17% in connection with clinical trials.

Other subjects of interaction that respondents told us about included the Yellow Card scheme, blood products and vaccines.

### 2.3 How the agency communicates and engages now

We asked respondents to review the agency’s existing channels for communication and engagement for their effectiveness.

Chart 5: the effectiveness of the agency’s current communications and engagement [Respondents rated the effectiveness of the agency’s current communications and engagement]



The respondents' rating of the effectiveness of the agency's current communications channels and forms of engagement was as follows:

- Website and mainstream media:
  - Ineffective: 39% of respondents to this question
  - Quite effective: 34% of respondents to this question
  - Effective/very effective: 27% of respondents to this question
- Social media:
  - Ineffective: 49% of respondents to this question
  - Quite effective: 35% of respondents to this question
  - Effective/very effective: 16% of respondents to this question
- MHRA forums and the agency Board:
  - Ineffective: 49% of respondents to this question
  - Quite effective: 26% of respondents to this question
  - Effective/very effective: 25% of respondents to this question
- MHRA attendance at conferences and other events:
  - Ineffective: 34% of respondents to this question
  - Quite effective: 26% of respondents to this question
  - Effective/very effective: 40% of respondents to this question

Of those respondents who expressed an opinion on the agency's main website (gov.uk) and our use of the mainstream media, 27% rated them as either 'Effective' or 'Very effective', 34% rated them as 'Quite Effective' and 39% as 'Ineffective'. In the case of the gov.uk

website this reflects comments from respondents that it is not currently found to be 'patient-friendly'.

The agency's current use of social media was rated as either 'Effective' or 'Very effective' by 16% of those who responded to this question, while 35% rated it as 'Quite Effective' and 49% as 'Ineffective'.

The agency's websites, use of digital channels and social media will be important tools in helping us to respond to the key themes of 'Awareness' and 'Transparency' in particular.

Of those who responded with regard to current face-to-face engagement activities (which includes public meetings of the agency Board, the Patient Group Consultative Forum and issue-specific stakeholder meetings) 25% rated them as either 'Effective' or 'Very effective', 26% rated them as 'Quite Effective' and 49% as 'Ineffective'.

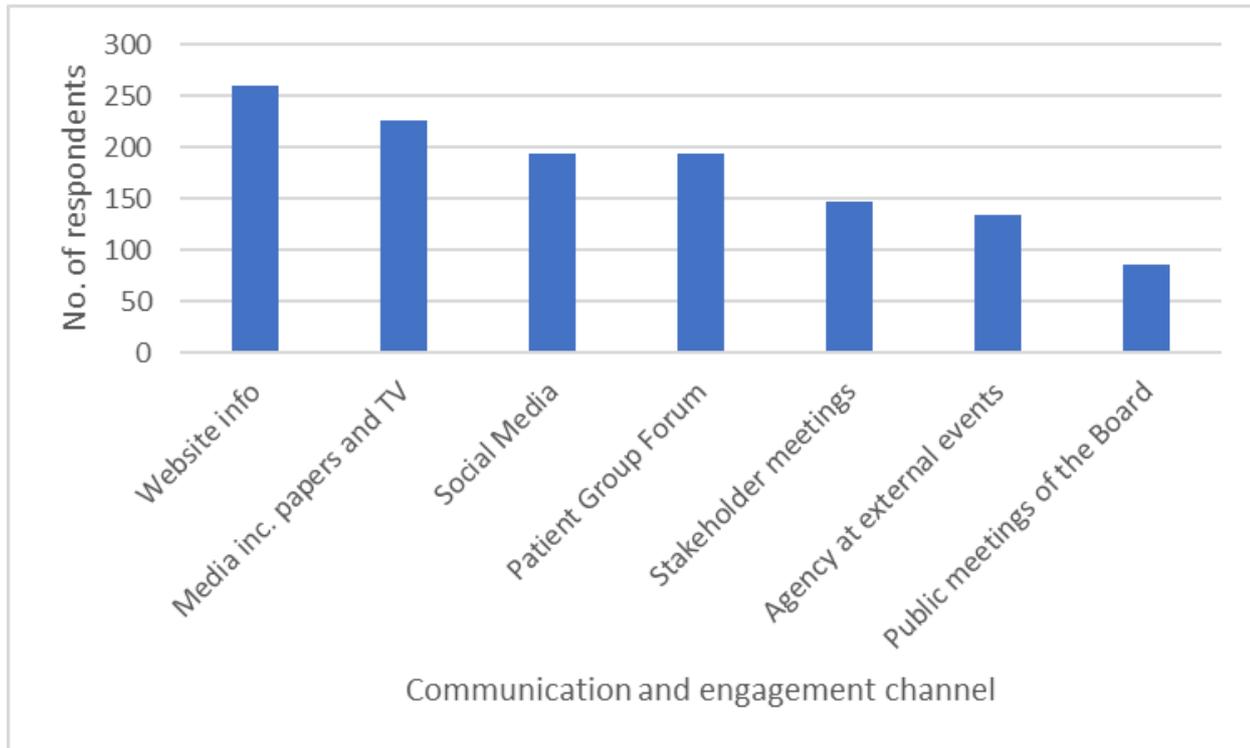
A lack of available public information on and promotion of such engagement events was frequently cited by respondents as a reason for rating these as 'Ineffective'.

The agency's presence at external conferences and events was rated as either 'Effective' or 'Very effective' by 40% of those who responded to this question, while 26% rated it as 'Quite Effective' and 34% as 'Ineffective'.

We also asked respondents to tell us which of the existing communication and engagement channels they preferred:

Chart 6: communication and engagement channels preferences

[Respondents told us their preferences regarding the agency's current communications and engagement channels]



The order of preference identified by the responses to this question was:

- Website information: 259 respondents
- Media, including newspapers and TV: 225 respondents
- Social media: 193 respondents
- Patient Group Consultative Forum: 193 respondents
- Stakeholder meetings: 147 respondents
- MHRA attendance at external events: 134 respondents
- Public meetings of the agency Board: 86 respondents

Respondents expressed a clear preference for the use of the agency's main website (gov.uk) and mainstream media (TV, national newspapers) as the channels through which they would like to be informed about our work. Social media and the Patient Group Consultative Forum are also seen as important channels for communication and engagement.

We asked those respondents who had previously interacted with the agency to provide examples of engagement that they considered to have been either particularly effective or not so effective.

The agency's work to engage a wide range of stakeholders about the regulatory action taken in relation to sodium valproate was commonly cited as an example of very effective engagement. By contrast, issues related to surgical mesh and other medical devices, such as breast implants, were mentioned by respondents as examples of the agency's engagement with patients as being ineffective.

Many respondents told us that the agency has been ineffective at engaging with them because they felt that their issues had been ignored or that they had never received an adequate response. Others told us that, once the agency did respond, the engagement was generally very good. A key message from the consultation in this respect is that the levels of our engagement are neither systematic nor consistently effective across all areas of the agency's work.

'[The] Valproate stakeholders network is the gold standard of patient and public involvement. I regularly use the example when trying to engage with local health services' PPI groups. It's been great to be involved in promoting the Yellow Card and reviewing the promotional materials. I feel valued by the MHRA.'

'When I reported the devastating problems I suffered/am suffering, with a Rectopexy mesh implant, you did nothing apart from acknowledging receipt of my report.'

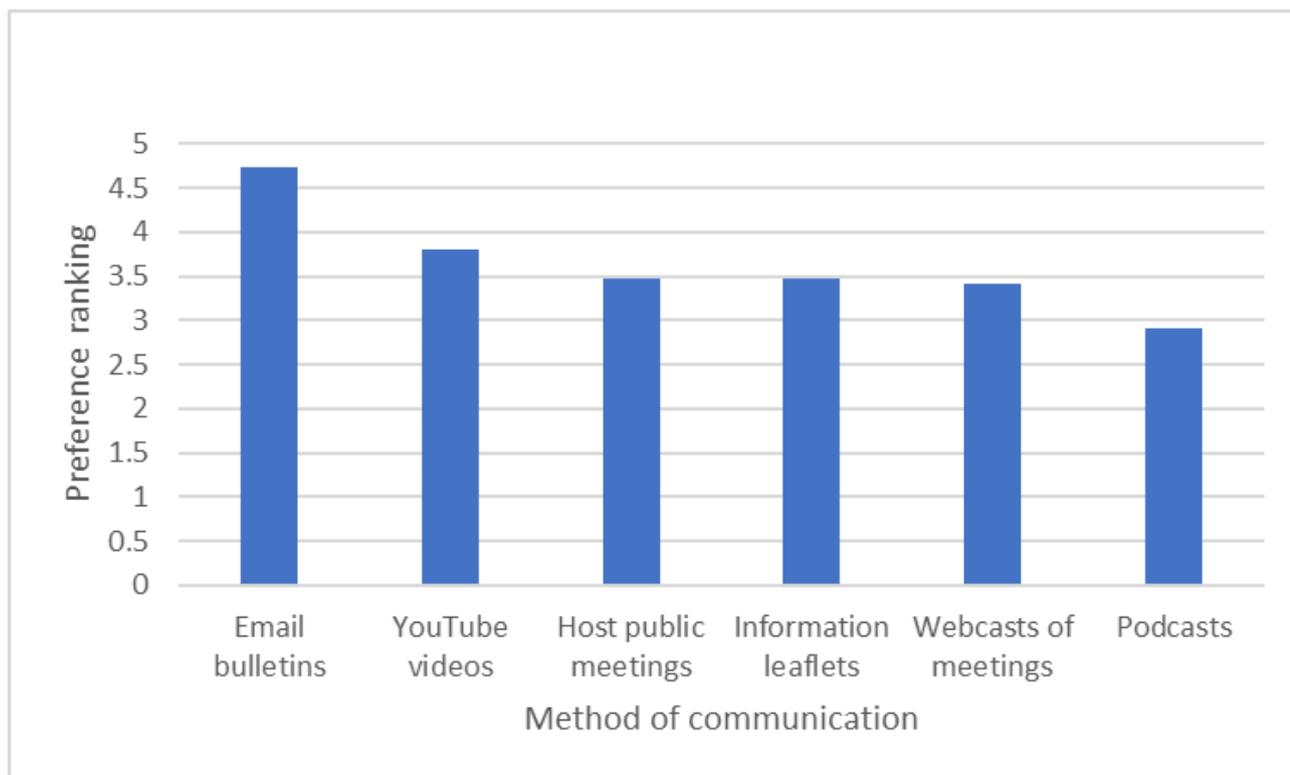
## **2.4 How the agency should communicate with patients and the public in the future**

We consulted on what respondents think are the most effective additional ways that we should communicate information to patients and the public about the agency's role, responsibilities and decisions.

Respondents ranked the suggestions we provided in order of preference as follows:

Chart 7: preferences for how the agency should communicate in future

[Respondents ranked their preferences for how the agency should communicate and engage in the future]



The responses to this question identified an order of preference ranking for future communication methods:

- Email bulletins: 4.74 aggregated score based on preference
- YouTube videos: 3.8 aggregated score based on preference
- Hosted open/public meetings: 3.47 aggregated score based on preference
- Information leaflets: 3.47 aggregated score based on preference
- Webcasts of meetings: 3.42 ranked score based on preference
- Podcasts: 2.9 ranked score based on preference

There was a clear preference for digital channels such as email and online videos, although face-to-face public meetings and the availability of hard copy information leaflets were also favoured.

We also asked for suggestions of any other ways by which we should try to increase public awareness and understanding of the agency's work.

Aside from an increased general media presence and greater use of digital/social media content aimed at patients, with effective images and clear language, respondents told us that the agency should seek to raise its profile by working in partnership with patient groups and research charities. We should also seek to take advantage of the settings within which healthcare is delivered (GP surgeries, hospitals and pharmacies for example) to provide more information about the agency and, crucially, to partner with healthcare professionals and other health system agencies to enlist their help in increasing understanding of the agency's work.

Examples of the suggestions received from the consultation:

'Posters in GP surgeries, hospitals and pharmacies. QR codes on posters or medicine packages so when they are scanned on mobile device it brings up information on who you are and what your role is.'

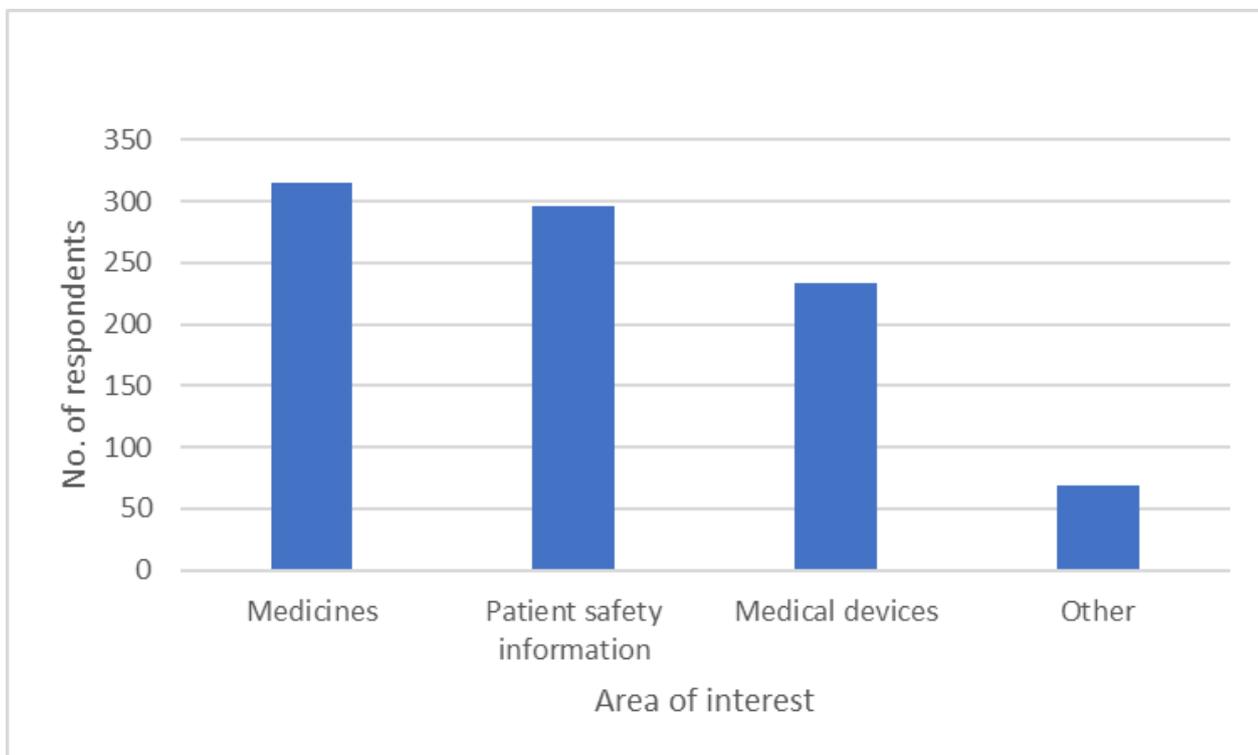
'Working with patient organisations is key for the MHRA, especially around developing materials that are suitable for people living with Parkinson's and other conditions.'

We will consider these, and similar suggestions, in this report as these relate directly to the themes of 'Awareness' and 'Partnerships' (see sections 3.1 and 3.4 below).

### 2.5 How we involve patients in our work

We want to do more to involve patients and the public in the work of the agency, including early in the regulatory decision-making process. We therefore consulted on what opportunities and areas are of most interest to respondents. Medicines and patient safety information were the two most preferred by respondents:

Chart 8: opportunities to become involved  
[Respondents told us which areas of the agency's work were of interest to them for future involvement]



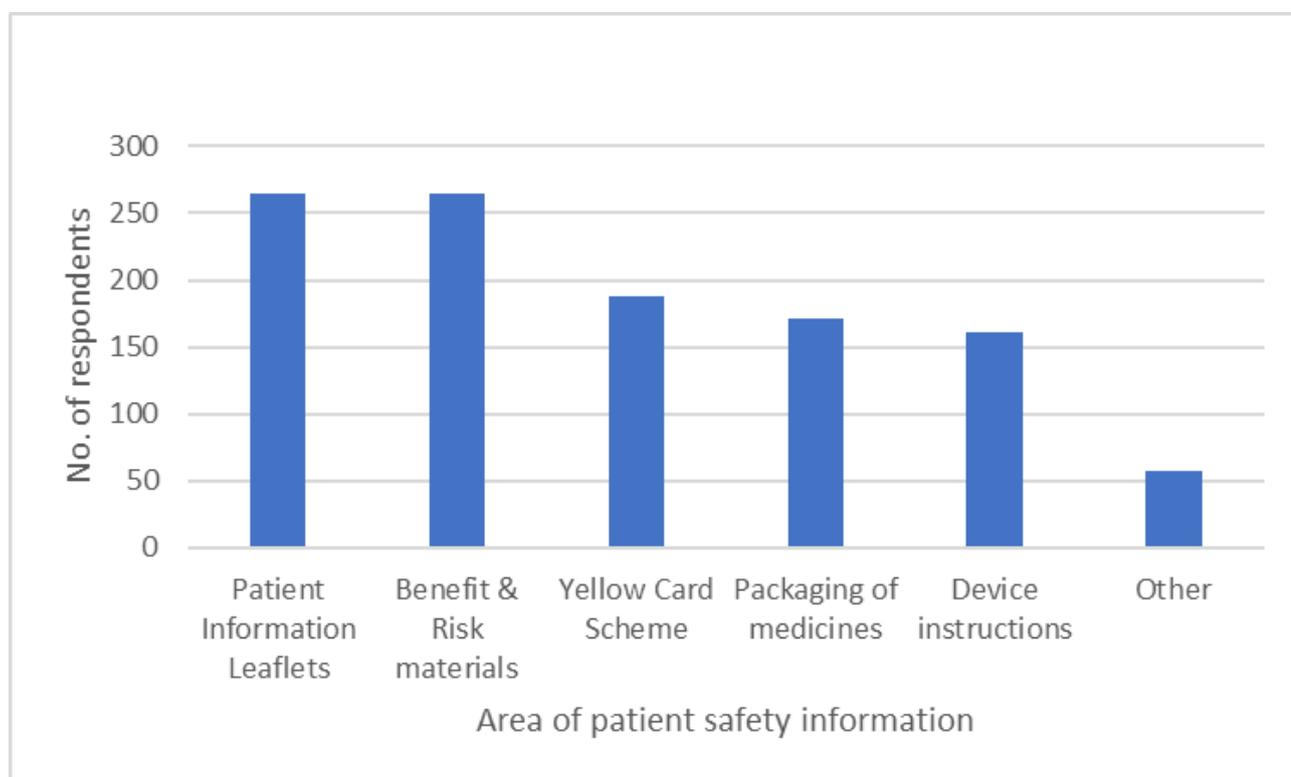
The number of responses we received for each area of interest was:

- Medicines: 315 respondents
- Patient safety information: 296 respondents
- Medical devices: 233 respondents
- Other: 69 respondents

We asked those respondents who expressed an interest in patient safety information for more details of which aspects they would most like to be involved in:

Chart 9: areas of patient safety information

[Respondents told us which areas of patient safety information they would like to be involved in]



The number of responses we received for each area of patient safety information was:

- Patient Information Leaflets: 265 respondents
- Materials to explain the benefits/risks of medicines and devices: 265 respondents
- Yellow Card Scheme: 188 respondents
- Packaging of medicines: 171 respondents
- Medical device labelling and user instructions: 161 respondents
- Other: 57 respondents

Patient Information Leaflets and the development of materials to explain the benefits and risks of medicines and medical devices were the two equal areas of most interest to respondents. The Yellow Card scheme for the reporting of adverse drug reactions and

medical device incidents is another aspect of the agency's work in which respondents told us they are keen to become involved.

Through this consultation exercise we received a large amount of useful feedback and suggestions regarding the Yellow Card scheme, which is detailed below as an area of the agency's work that cuts across each of the four themes.

We also asked respondents to tell us about any other ways in which we should seek to involve patients and the public in the work of the agency.

Respondents told us that patients should be involved ideally throughout the decision-making process and that the agency should look to its peers (NICE, NHS England and NHS Improvement for example) for models of patient involvement.

Transparency through having formal processes for the selection of patients and patient groups was considered important. Potential conflicts of interest (the level of pharmaceutical industry funding of a particular patient group, for example) and having clear policies in place for managing this is another important aspect of building confidence and trust in the agency's involvement of patient representatives. Setting expectations around any limitations to their involvement and providing feedback afterwards are crucial elements.

Respondents pointed to the provision of information and training to support patients to become involved as a factor in enabling greater involvement in our processes. Patient involvement does not have to always require participation in meetings but could also be through online surveys and questionnaires, for example.

Some examples of what respondents told us:

'Create a formal mechanism through which patients and the public can input into the decision-making process, including hearing patient testimony as appropriate.'

'I think you should have patient representatives in all your workstreams to give a different perspective and be diverse and also be mindful of being 'equal'.'

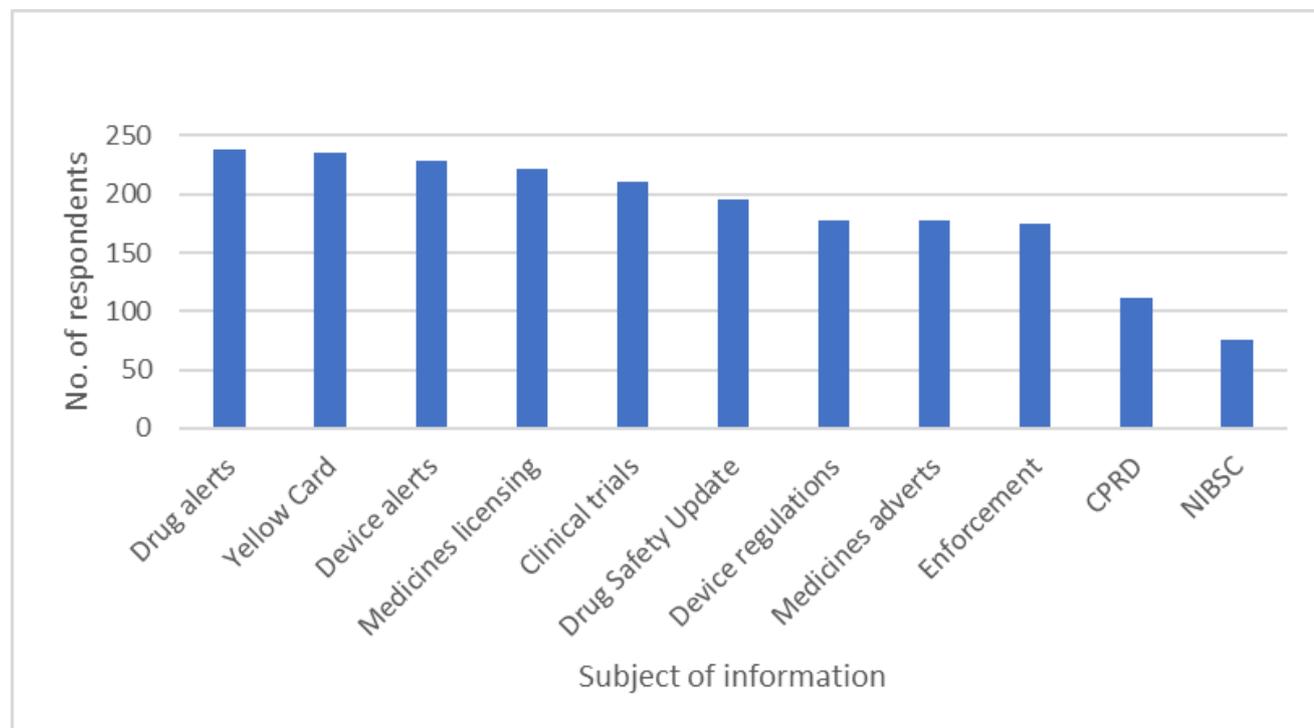
We will consider these, and similar suggestions, later in this report as these relate directly to the 'Partnership' theme (see section 3.4 below).

## **2.6 Priority topics on which we publish information for the public**

We asked respondents to tell us their preferences for what information we should publish that is more specifically aimed at patients and the public. The areas of most interest are drug and medical device safety alerts, the Yellow Card scheme reporting systems, licensing decisions for medicines and clinical trials authorisation.

Chart 10: preferences for subjects about which the agency should publish more information aimed at patients and the public

[Respondents told us their preferences for the subjects about which the agency should publish more information aimed at patients and the public]



The number of responses we received for each subject was:

- Drug alerts: 238 respondents
- Yellow Card Scheme: 236 respondents
- Medical device alerts: 229 respondents
- Licensing decisions for medicines: 222 respondents
- Clinical Trials: 210 respondents
- Drug Safety Update: 196 respondents
- New medical device regulations: 178 respondents
- Advertising of medicines investigations: 178 respondents
- Inspection and enforcement actions taken: 175 respondents
- Clinical Practice Research Datalink (CPRD): 112 respondents
- National Institute for Biological Standards and Control (NIBSC): 76 respondents

We also asked for respondents to tell us any other topics, areas or issues about which we should publish information for patients and the public. Some examples are: 'more public-friendly available information on the whole drug approval and testing process', 'safety of vaccines', 'early access to medicines schemes' and 'a medical devices registry'.

## 2.7 How concerns are raised with us and how we respond

We asked how patients and the public should be able to communicate with the agency in order to raise concerns about the safety of medicines, medical devices or other matters within our regulatory remit. The responses to this question were given entirely in free text.

The importance of personal contact was emphasised and all methods of engaging/communicating should be available and tailored to the needs of the individual raising the concern. Respondents' experience is of an over-reliance, by similar organisations, on using online methods only and we have been cautioned to avoid this.

Some examples of the suggestions made by respondents:

'Patients would often like to have a conversation as their issues are often complex and they would like someone to listen to the issue they are experiencing.'

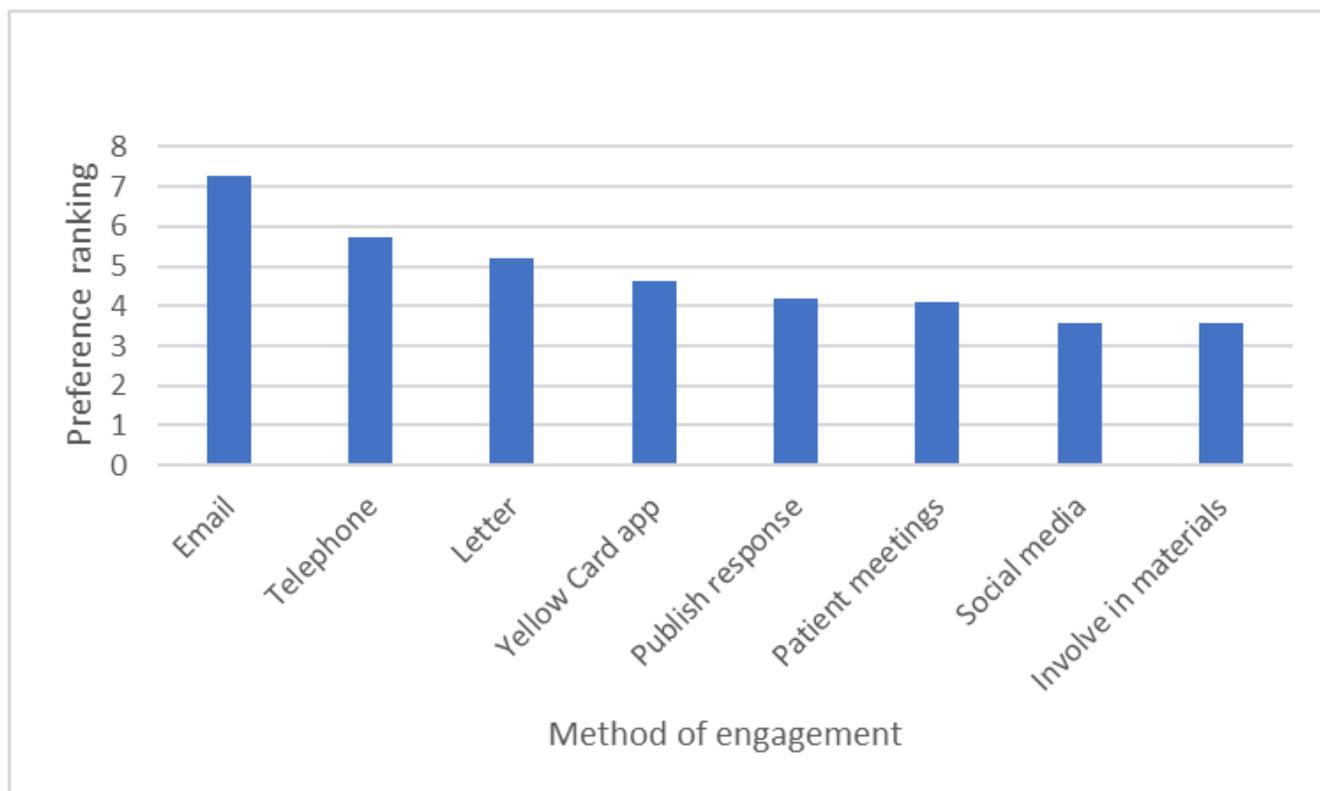
'People have different communication preferences, so a suite of choices should be offered – including telephone and email. A variety of options will ensure that people with communication difficulties can get in touch too.'

We also sought views on how we could most effectively engage with patients and the public once they have raised a concern.

From the options we suggested, there is a clear preference for direct personal contact by email primarily but also telephone and letter. Some respondents felt that the use of the Yellow Card app to keep someone informed, after they have reported through the Yellow Card scheme, is important. Publishing the agency's response online and inviting individuals to participate in relevant meetings or forums were other options that we should consider. There was less preference for either the use of social media in this regard or to involve those who have raised concerns in the development of materials to explain the benefits and risks of medicines or devices.

Chart 11: preferences for how the agency should engage with an individual once they have raised a concern

[Respondents ranked their preferences for how the agency should engage with an individual once they have raised a concern]



The responses to this question identified an order of preference ranking for how the agency should engage with an individual once they have raised a concern:

- Email: 7.26 aggregated score based on preference
- Telephone: 5.73 aggregated score based on preference
- Letter: 5.21 aggregated score based on preference
- Yellow Card app: 4.61 aggregated score based on preference
- Published response online: 4.17 aggregated score based on preference
- Patient meetings/forums: 4.09 aggregated score based on preference
- Social media: 3.59 aggregated score based on preference
- Involvement in developing materials to explain benefit/risk of medicines and medical devices: 3.55 aggregated score based on preference

We also asked respondents to tell us, in their own words, any other ways in which the agency could most effectively engage with patients and the public once they have raised a concern.

The importance of personal contact was again emphasised, along with the need to respond in a timely fashion and manner that is proportionate to the level of concern being raised. Offering the individual the choice of options for follow-up that are appropriate to their individual needs was a point made by several respondents. The importance of maintaining an open and ongoing dialogue was also stressed in order to ensure confidence and trust in the agency's response – communicating regularly with those who have raised a concern to keep them updated with subsequent discussions/events/decisions and also to make them aware of any previously raised issues with regard to their concern and any ongoing work with regard to this.

Some examples of the points made by respondents:

‘...it is important to ask each individual to confirm their preferred communication and information format, in order to meet their particular needs...’

‘Direct contact makes you feel heard and that your concerns are being acted upon. It is also important to be transparent and publicly acknowledge these concerns...’

The responses received to the questions about raising concerns have informed primarily the key themes of ‘Responsiveness’ and ‘Transparency’ outlined below.

### 3. Themes identified from the consultation

We have identified four main themes from the consultation responses, and which were also highlighted by the detailed feedback we received at each of the engagement events. The themes relate to what respondents told us about engagement and involvement with the agency now and how they would like to see that developed in the future: Awareness, Transparency, Responsiveness and Partnership (including patient and public involvement). The four themes are inter-related and are further cross-cut by two other significant areas identified by respondents to the consultation: the Yellow Card scheme and the agency's websites and use of digital communications.

We detail each of the themes below, including potential actions for the agency identified at this initial stage.

#### 3.1 Awareness

There are still relatively low levels of public awareness of the agency.

The following comments are typical of those made by many of the respondents to the consultation, over 60% of whom had never previously interacted with the agency:

'I am a member of patient support groups and for most members the response to questions about MHRA is usually something like "MH who?"'

'I don't think the average member of the public knows very much about the work of the MHRA. I suspect most people wouldn't know that the MHRA is anything to do with medicines.'

The low levels of awareness are reinforcing a general lack of clarity and understanding about the agency's role and responsibilities, illustrated by the following comments:

'From a public perception it may be unclear what the roles of NICE/MHRA are and how they are different... Generally, the public have a very limited understanding of medicines regulation and how it applies to them and the medicines that they are prescribed.'

'I think the MHRA needs to be clearer about exactly where its responsibilities lie so it is not held accountable for wider systemic issues in healthcare. I also feel that there is still a lot of public ignorance regarding the yellow card system so perhaps there is some scope for a wider communication drive.'

There is a clear call throughout the responses to the consultation for the agency to significantly raise its profile amongst patients and the public in order that they are aware

there is an organisation looking after their safety in relation to medicines and medical devices.

The consultation respondents have identified many constructive ways in which the agency could raise awareness of its work. We have grouped these into five broad areas:

- Advertise and have articles in the general media
- Provide information in the settings in which healthcare is delivered
- Use digital and social media
- Host public forums and meetings
- Collaborate with patient and community groups

We provide a flavour of each below.

Greater proactive use of the general media, including possible advertisements on TV, newspaper and magazine articles and radio programmes:

‘The MHRA must advertise its existence on TV and advertise the yellow card scheme.’

‘... adverts in national and local newspapers, health care magazines etc.’

Provide leaflets, posters and other advertisements for use in healthcare settings and other public spaces across the UK where patients, their carers and families are likely to see them:

‘Promote information throughout GP surgeries, A&E, in and around all aspects of hospital dept where applicable. I live in N. Ireland and there is no information [about] the work. The word needs to be spread throughout the UK not just the mainland.’

‘Make better use of posters etc in GP surgeries, hospital waiting areas etc. people read them when bored and are a captive audience in waiting areas!’

Increase use of digital and social media in order to reach specific demographics and provide content that can be easily shared:

‘Social media, for example Twitter, where most organisations have a presence and can re-tweet relevant information relating to specific risks.’

‘I know about this through a medical charity but my daughters would never find out except by social media (Instagram etc).’

Host public forums and meetings across the UK in order to provide opportunities for meeting patients, carers and their families to listen to their concerns and demonstrate how the agency’s role and responsibilities are relevant for them:

'Let us have our say. Arrange seminars in different cities in the UK this including Wales, Scotland and N. Ireland not just in the mainland. For patients and the public, have information to take away with us.'

'Four meetings per year for patients and public to raise awareness of how MHRA works.'

Increase collaboration with patient and community groups who can raise awareness amongst their members and public networks:

'Offer summaries about your work that patient organisations could post on their websites. Let your staff be interviewed about their roles by patient organisation magazines.'

'Running popups at local CCG, Healthwatch and council public health events and awareness raising and demo sessions in larger community pharmacies.'

### 3.2 Transparency

Low levels of awareness and the lack of clarity about the agency's role and responsibilities are further compounded by a perceived lack of transparency around how the agency makes its decisions and the information that it currently provides. This can result in a lack of confidence, particularly amongst those patients who feel they have not been listened to or engaged with effectively.

The following comments from respondents serve to illustrate the concerns expressed, through the consultation, about the transparency of the agency:

'Need [more] clarity about the role of MHRA and how it fits in with the chain of regulation and licensing regarding European standards, NIBSC, NICE, etc. I am still a bit hazy what comes first in the line of regulation...'

'The MHRA website and communications do not appear to be intended for, nor are suitable for, informing or engaging patients and carers. It does not fully explain its role, especially on regulatory matters, in a way that is understandable to patients/lays. There is no area on the website which is suitable for patients.'

'If patients and public are to be involved in the Agency's work and decisions there needs to be some evidence that the input from the patients... will be taken seriously and acted upon.'

Respondents did however also make suggestions for how the agency might seek to remedy the perceived lack of transparency:

'It would be useful to publish details on the process of how decisions are made (particularly with regards to authorising new medicines/devices) and why! Also just making some user-friendly animations/videos etc where you explain what you do and how decisions are made!'

'MHRA could be more transparent in its decision-making processes and that there is scope to improve the way in which information is provided. We believe that MHRA could learn from other organisations that promote and share their workings with public, patients and patient associations.'

'It is...important that the Agency communicates its work to as broad a section of society as possible, particularly 'seldom heard' groups who may lack health literacy.'

### 3.3 Responsiveness

A number of those respondents to the consultation who have previously interacted with the agency by reporting a concern have told us that the agency's response was neither timely nor proportionate given the seriousness of the issues raised.

This perceived lack of responsiveness further feeds the overall sense of a lack of transparency and trust on the part of those patients, especially those whose consultation responses included references to specific issues concerning surgical mesh, breast implants, vaccines and fluoroquinolones.

The following examples of a lack of responsiveness, combined with a failure to listen, were provided by respondents to the consultation:

'The last time I used the general enquiry email address I received an auto response saying I would receive a reply within 3 weeks. I believe that if a patient is concerned enough to write to the agency they should be treated with a little more respect – an automated reply and a long delay is very off-putting.'

'Be more understanding to real patients. There are too many women all over the world saying their breast implants made them ill and no one is listening! This is not a coincidence and NOT psychological! Listen!'

Respondents have also provided examples of where the agency's engagement with them has been more positive:

'Patient Consultative Events – very useful and well managed with appropriate information. Board meetings with 'Qs and As' – extremely helpful; transparent and informative.'

'Personal interaction with people at the agency is exceptional. I am from a patient organisation and have also heard this comment from a European biotech. All of us seriously impressed by the people we have engaged with – their ability to communicate, to teach, to answer questions, to demonstrate flexibility.'

The consultation respondents identified ways in which the agency could improve how it responds to those who raise concerns:

'Communicate regularly with those who have raised a concern to keep them updated with subsequent discussions/events/decisions. Ensure those who have raised a concern are made aware of any previously raised issues with regard to their concern, and any ongoing work with regard to this.'

'I would like to see the Agency acknowledge the concern, act on it and keep those who raised the concern informed of any progress. When the concern has been fully addressed a public notice (in a Q&A format) on your website could be helpful. Those who raise concerns need to see that you are taking their concerns seriously.'

### **3.4 Partnership and involvement**

The consultation has highlighted that there is a great deal of goodwill amongst patient groups, healthcare professional organisations and industry, across the UK, to work in partnership with the agency to raise its public profile and in developing the systematic involvement of patients in its work.

The consultation respondents have identified many opportunities for how the agency could work in partnership with other groups, organisations and individuals to help achieve its aims to improve awareness of the agency's role and responsibilities and for greater involvement of patients in its decision-making and other areas of work. We have grouped these into five areas of potential partnership (including patient involvement in its own right):

- Healthcare professionals
- Health agencies and the settings within which they provide healthcare
- Industry trade bodies
- Charities and community groups
- Patients involved as partners

We provide a flavour of each below.

Respondents suggested that we should work much more closely with healthcare professionals, especially GPs and pharmacists who have regular opportunities for face-to-face conversations with patients:

'The public rely on their doctor to know what is happening and to supply them with the correct medicine that is safe and, more especially, safe for each individual patient. The MHRA needs to liaise more closely with every doctor and ensure that every doctor knows – and keeps up to date with – the Agency's work.'

'Perhaps pharmacists, because of their frequent and valuable opportunities to interact face-to-face with patients, should collaborate more with MHRA to communicate issues and concerns.'

To support greater collaboration with healthcare professionals, the agency should also seek to make use of the broader system of health agencies and healthcare settings to provide information to patients about its role and responsibilities. Many respondents told us that it is the GP surgery, hospital waiting room or pharmacy where they would expect to see such information:

'Why don't you seem to have any footprint in hospitals, GP surgeries or pharmacies in terms of advertising and informing the public? This is where patients and family members are most likely to take interest in who licenses and regulates the industry?'

'Most people using medication have to visit their GP surgery, hospital and pharmacy from time to time. It would make sense to make these the places where it is really easy to send info and get info from the MHRA... Incidentally, it is crucial that information is available and is sought from groups of patients in their first language i.e. not solely English.'

Respondents from the pharmaceutical and medical devices industry trade bodies offered to partner with the agency:

'There are already some good cross functional working groups through the Association of the British Pharmaceutical Industry (ABPI) networks. MHRA involvement could be strengthened in this area.'

'The Medical Technology Group (MTG) is keen to engage with the MHRA regarding both its work on medical devices and communication with patients. The MHRA has a hugely important and often complex role in ensuring that medical devices are safe and effective. Where issues arise the MHRA needs to be able to communicate the potential risks to patients in a clear, effective and appropriate manner. As such, the MTG would like to work with the MHRA to understand its communication objectives.'

Respondents stressed the importance of the agency working with charities and community groups to assist in trying to reach demographics and communities across the UK that could otherwise be overlooked in any awareness raising campaign:

‘Charities can act as conduits to the public and support public bodies like the MHRA to engage with different groups, including engaged members of the public, and hard to reach groups.’

‘...always bear in mind what may be best for those 'hardest to reach'. Use local groups, charities or community/faith leaders to find a conduit for relevant information. Not everyone reads English, not all have a smartphone.’

The potential benefits of the involvement of patients as partners in the agency’s work was referenced in many of the consultation responses. Amongst patients and their representative groups, there is an expectation and desire to be involved throughout the medicines’ approval process and in many other aspects of the agency’s work:

‘Supporting the Agency to access real-life experiences of diseases and their management and to obtain information on the current use of medicines. This will contribute to understanding the value, as perceived by patients, of the scientific evidence provided during the evaluation process for the purposes of benefit/risk decision-making; contributing to more efficient and targeted communication to patients and consumers, to support their role in the safe and rational use of medicines.’

‘Monitoring of devices and medicines and their impact in the real world. Involve patients more in deciding what the priorities of the work of MHRA are. Deciding safety priorities. Coproducing resources and processes. Don't involve them at the end of a product but use them as partners. Create more proactive patient engagement and consultation opportunities.’

Respondents also recognised many of the potential challenges presented by greater patient involvement and made suggestions for how the agency might address these:

‘There are several ways in which MHRA could further involve patients: Follow the examples set by NICE (with the group “Patients in NICE”) and NHS England (that has an established Patient and Public Participation groups and policies). The way in which patients are selected for these groups is transparent. Create a formal mechanism through which patients and the public can input into the decision-making process, including hearing patient testimony as appropriate in the decision-making process.’

‘In order to effectively engage with the MHRA patient organisations need to know how to do this. We think it is important for the MHRA to note that staff turnover in the patient organisation sector, in particular in the areas of research, policy and communications can be high. For this reason we suggest that patient organisations and the MHRA would benefit from regular training events – this would allow continued engagement and ensure that patient organisations are up-to-date on any new ways of working within the MHRA. This is something that is done by other national bodies in the health sector and we have found these training events useful.’

## 4. Cross-cutting areas of interest that support the themes

### 4.1 Yellow Card scheme

Patient reporting through the Yellow Card scheme is at its highest ever level. However, the consultation has pointed to a significant lack of awareness of the scheme amongst patients that is symptomatic of the agency's overall profile and presents a major obstacle to even better rates of patient reporting.

The following comments from respondents serve to illustrate relatively low awareness levels of the Yellow Card scheme amongst both the public and healthcare professionals. Patients, if they are aware of its existence, may still think that only a healthcare professional can make a report:

'Patients are not aware of the yellow card system, I wasn't until I started this survey and yet I have spent three years taking care of my husband in and out of hospital, it was never mentioned. This needs to be in the public domain as a matter of course.'

'The public do need to be made aware that they can easily report to the Yellow Card scheme themselves. Too often we hear of ADR sufferers not reporting as they believe only their doctor can do this.'

Respondents provided suggestions for how the agency might increase awareness of the Yellow Card scheme, while at the same time making it more accessible for the public to report. While many of the respondents' suggestions for raising awareness of the Yellow Card scheme mirror those for how to increase the agency's public profile (more prominent information in healthcare settings, for example) there was a strong sense that this subject warrants a high-profile publicity campaign delivered through the mainstream media.

'I think the public have almost no knowledge of the MHRA and what you do. The yellow card scheme should be TV/social media ads to grow awareness.'

'Public health adverts on TV to ensure the public know about the MHRA and how to report side effects of medicines on the Yellow Card Scheme. No one other than health professionals have heard of this scheme. Also, all medicine boxes should have a label on requesting patients report side effects to MHRA.'

Feedback from those respondents who had experience of using the Yellow Card scheme to report an issue also reflected the concerns about a lack of responsiveness and transparency on the part of the agency that were outlined under those themes above:

'Yellow card update should be available to be amended online. At the moment you have to send an email to amend details. I've never been contacted by the yellow card scheme since I filed years ago.'

'A yellow card was submitted by my GP after an exceptional response to a pneumonia jab. Never heard anything more but I realise that may be down to the GP.'

## 4.2 Websites and digital communications

Respondents to the consultation recognise the important role that the agency's websites and use of digital channels, such as social media, play in providing information to the public about its work, decisions and responsibilities. Many respondents felt that the websites in particular do not currently provide information that is either patient-friendly or easy to navigate and that the use of social media could be more effective:

'The website was felt not to be very "public friendly" (due to using the .gov platform) and would benefit from being more public focused and transparent.'

'Clearer information on social media would be very welcome. Currently the MHRA's use of Facebook and Twitter feels ineffective. The content is aimed at professionals, rather than the general public, and would not be understood by many people.'

There were suggestions for how we might use the agency's websites and digital channels to improve the information available for patients and to support overcoming the issues relating to awareness and transparency outlined above under those themes. Websites and social media were also viewed as vital tools for use in building the collaborative partnerships that will help the agency to move forward:

'Working with patients to improve the accessibility of the website and provision of information is important to increase public awareness and understanding of the Agency's work. This should go alongside developing infographics and YouTube/podcasts explaining the work of the Agency in an interesting and clear manner. These could be accessed via the MHRA website as well as via search engines and through links on related organisation websites (e.g. NHS England, Medical Research Council, Association of the British Pharmaceutical Industry, Health Research Authority).'

'Increased social media content aimed at patients, with effective images and clear language. The Agency will need to ensure that the social media platform used is the most effective one for the patient group it is trying to reach.'

The actions we have identified to begin to address these issues are set out in the 'Response' section of this report, grouped by theme. The actions are informed by the interests, preferences and other suggestions expressed by respondents to this consultation.