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

Response of the Agency

'What we will do differently'

CPRD NIBSC MHRA

Contents

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, and of the actions it will take in response to the findings of the consultation.

2. Main findings

We have identified four main themes from what respondents have told us about engagement and involvement with the agency now and how they would like to see that developed in the future:

1. Awareness

   Levels of public awareness of the agency and its role and responsibilities, are still relatively low, although higher than when we previously surveyed stakeholders and patients some years ago.

2. Transparency

   There is a perceived lack of transparency about how the agency makes its decisions and the information that it currently provides.

3. Responsiveness

   There is a lack of responsiveness from the agency when concerns are raised, especially by patients, who say they often do not feel listened to and that the agency’s response is not always proportionate to the seriousness of patients’ issues.

4. Partnership (including patient and public involvement)

   The development of partnerships with stakeholders, including the involvement of patients in the agency’s decision-making process, as well as further development/use of digital communication channels, will be key to addressing the issues around awareness, transparency and responsiveness.

The four themes are linked to two other significant areas identified by respondents to the consultation:

- the Yellow Card scheme (the system for the reporting to the agency, by healthcare professionals and patients, of suspected side effects of medicines or possible problems with a medical device)

- the agency’s websites and use of digital communications.

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

The proposed actions will form part of our draft Patient and Public Engagement/Involvement Strategy which we are developing, and we aim to run a public consultation on the draft strategy in summer 2020.

The strategy will cover a 2020-25 timeframe and will co-ordinate measures to address the issues of a lack of public awareness and agency transparency and responsiveness. It will support the agency's transformation into a more public-facing organisation through greater involvement of patients in our work.

The agency's ambition is to become a 'patient-focused regulator' which recognises patients as partners, and which is seen by patients and the public as a valued source of reliable information and evidence that patient groups will use to support relevant outward-facing work with their own networks.

3. Agency response to themes identified from the consultation

3.1 Awareness

We recognise that the agency needs to put additional effort into raising its profile amongst patients and the public. In particular, our website and digital channels are where respondents to the consultation have said that people would prefer to see patient-friendly information about the agency, while also wishing for us to make greater use of the mainstream media to help raise public awareness about our role and responsibilities. The consultation has also highlighted that patients and their carers expect to see information about the agency in the healthcare settings they regularly attend including GP surgeries, hospital waiting areas and pharmacies.

Proposed approach (including indicative timings):

- Starting in summer 2020, we will begin to develop a communications campaign to explain the work of the agency – including highlighting the agency's successes – to patients, the public and healthcare professionals, and to explain our role now and in the future. A key component of the communications campaign will be use of the five channels identified by the consultation: general media outlets, healthcare settings, digital and social media channels, public forums and meetings, and patient and community group networks.

- On an ongoing basis, we will build on our work with health system agencies, patient groups and community organisations to extend the reach of our communications and signpost to our information.

- Starting in summer 2020, we will explore with the General Medical Council and the General Pharmaceutical Council the scope for building greater awareness of the agency amongst healthcare professionals through their Continuing Professional Development.

3.2 Transparency

We acknowledge that the agency’s current information and processes are neither readily accessible to nor easily understood by members of the public and that we need to tackle the perceived lack of transparency. Patients may not always agree with the decisions made by the agency, but we recognise that they must at least be included in the decision-making process and informed of the reasons for the outcome. The lack of patient-friendly information on the agency’s processes, how it makes its decisions and the regulatory frameworks in which it operates is another barrier to building public confidence and trust.

Proposed approach (including indicative timings):

- On an ongoing basis, we will build transparency into our regulatory systems, decision-making processes, committees and governance, and we will report on what impact the involvement of patients and public has had. We will report on progress on a six-monthly basis to the public Board.

- Starting in summer 2020, begin work to identify ways to ensure that patients can be better informed about the specific products used in their healthcare to enable them to make more informed decisions.

- Starting in summer 2020, we will begin to review how we can better take into account the needs of patients in anything we communicate, focusing initially on those areas that respondents told us are most important to them.

- On an ongoing basis, we will involve patient representatives, charities and community groups in helping us to develop our information for patients and the public.

3.3 Responsiveness

We acknowledge that the agency has not always responded in either a timely or proportionate manner when patients have raised concerns with us. There are examples of where we have engaged and responded effectively but we recognise that this is neither systematic nor consistent and that, in general, we may be better at responding to what are perceived as less contentious issues. We will incorporate the preferences and suggestions expressed by respondents to the consultation into our planning as we develop and shape our public-facing services moving forward.

Proposed approach (including indicative timings):

- Throughout 2020-21 we will seek to introduce a customer-focused culture, to support a more timely and proportionate response to concerns to encourage earlier engagement with those raising them.

- On an ongoing basis, we will seek to ensure that the examples of where we have engaged and responded effectively become the norm for the agency rather than the exception.

- In March 2020 we established a new customer service centre to provide a single point of contact and improve the experience of people who contact us, whether this is for advice, information or to make a report.

- From summer 2020 we are aiming to introduce a programme of training and support for our staff that will enable them to engage more effectively and earlier when patients first raise a concern.

- On an ongoing basis, we will seek to provide as many different communication channels as required so as not to exclude any specific patient populations and to cater as far as possible for the needs of those who contact us, as identified by the consultation.

- In designing new systems and processes we will seek to ensure that responses are personalised and proportionate to the nature of the issue being raised with us – including responding quickly where the seriousness of the issue demands it – and that there will not be a ‘one-size-fits-all’ approach.

- From summer 2020 we will begin to explore how we can introduce systems and standards of service delivery that focus on the importance of regularly updating those who have raised a concern and informing them about any other relevant issues and ongoing work, in order to build confidence and trust.

3.4 Partnership and involvement

We recognise that there is a lot of goodwill towards the agency achieving its aims in relation to greater involvement of patients in its work and that it should not try to ‘re-invent the wheel’ if it can work in collaboration with and through our different stakeholders. Respondents to the consultation have identified many and varied opportunities for working with others to help raise awareness and improve transparency. Patients have a strong desire to become involved in the agency’s processes at an early stage.

Proposed approach (including indicative timings):

- From summer 2020 we will begin to develop a process to more systematically involve patients in our regulatory decision-making processes, committees and governance. This shift to ‘patient-focused regulation’ will include developing the use of Patient-

Reported Outcomes in our licensing decisions. We will report on progress on a six-monthly basis to the public Board.

- On an ongoing basis, we will work in partnership with healthcare professionals, health system agencies, industry trade bodies, charities and patient and community groups to help us raise public awareness and improve transparency about our role and responsibilities and how we make our decisions.

- On an ongoing basis, we will approach the involvement of patients as a form of ‘partnership’ that will enhance our decision-making and contribute to better outcomes for patient safety.

- In February 2020 we introduced a monthly patient speaker programme, with patient advocates giving presentations to staff about the importance of engaging patients and involving them in our work. We will also include presentations from patient advocates in our ongoing corporate induction programme for new starters to the agency, to emphasise the importance of patient engagement.

- In autumn 2020 we will begin to develop a training, support and information programme to facilitate the greater involvement of patients – both for patient representatives, in order to equip them to become involved in our regulatory processes, and also for our staff to support them to engage with and involve patients earlier in our decision-making.

- From spring 2021 we will seek to introduce a schedule of regular public meetings where we will explain our work and ask patients proactively for their views on medicines, medical devices and other issues being considered by the agency (e.g. safety of vaccines) or which patients wish to raise with us, as well as seeking patient help in deciding our priorities.

- From autumn 2020 we will explore ways to provide greater opportunities for patient and public involvement in the development of patient safety information and more general materials to help explain to the public the benefit and risk approach to the regulation of medicines and medical devices.

- On an ongoing basis, we will continue to learn from existing processes and systems for patient involvement of our closest peers (including other regulators, the National Institute for Health and Care Excellence (NICE) and the National Institute for Health Research’s INVOLVE advisory group) for examples and models of good practice that we might seek to adopt for the agency.

- From summer 2020 we will introduce more formal processes for participation in our existing Patient Group Consultative Forum and publish more information about its activities in order to increase transparency, including how patient group representatives, research charities and patients/carers can join the Forum.

- From autumn 2020, the National Institute for Biological Standards and Control (NIBSC) will take forward a programme that seeks to engage and involve patients and the public with the work of NIBSC's Regulatory Science Research Unit, to help shape both the nature and prioritisation of its research activities.

- Starting in autumn 2020, we will develop conflict of interest policies in relation to all our patient and public engagement work.

- On an ongoing basis, we will set clear expectations for the extent to which the input of patient representatives will contribute to a final decision in the relevant process.

- From autumn 2020 we will explore how to develop systems for measuring and reporting on the impact of patient involvement where practical to do so.

- On an ongoing basis, we will promote opportunities for patient and public involvement across the UK, including in the Devolved Administrations and will work with stakeholders to reach as diverse a patient population as possible.

3.5 Yellow Card scheme

We acknowledge that we should first address any existing barriers to patients and the public reporting concerns and then consider making the Yellow Card scheme the focus of a public information campaign. An increased public profile for the Yellow Card scheme would of itself increase awareness of the agency and support the communications strategy to be developed in response to the consultation.

Proposed approach (including indicative timing):

- The agency has developed a strategy to further develop the Yellow Card scheme in 2020-21. This will address the need to make the system easier to use and more responsive to those who report concerns. The strategy will include a plan for encouraging reporting amongst both the public and healthcare professionals. It will be underpinned by a communications strategy to address low levels of awareness amongst both the public and healthcare professionals and to encourage reporting from these groups. This includes ongoing communications activity that started with an awareness campaign in February 2020 and will be followed by other campaigns – the next of which will focus on medical devices and women's health.

3.6 Websites and digital communications

We recognise that the agency's websites are its 'shop window' for the public and that the information it provides could be presented differently in order to make it more accessible for patients which would effectively remove a potential barrier to both transparency and raising awareness. The website and digital channels are key tools that we can use to support addressing the issues raised by the themes identified through the consultation.

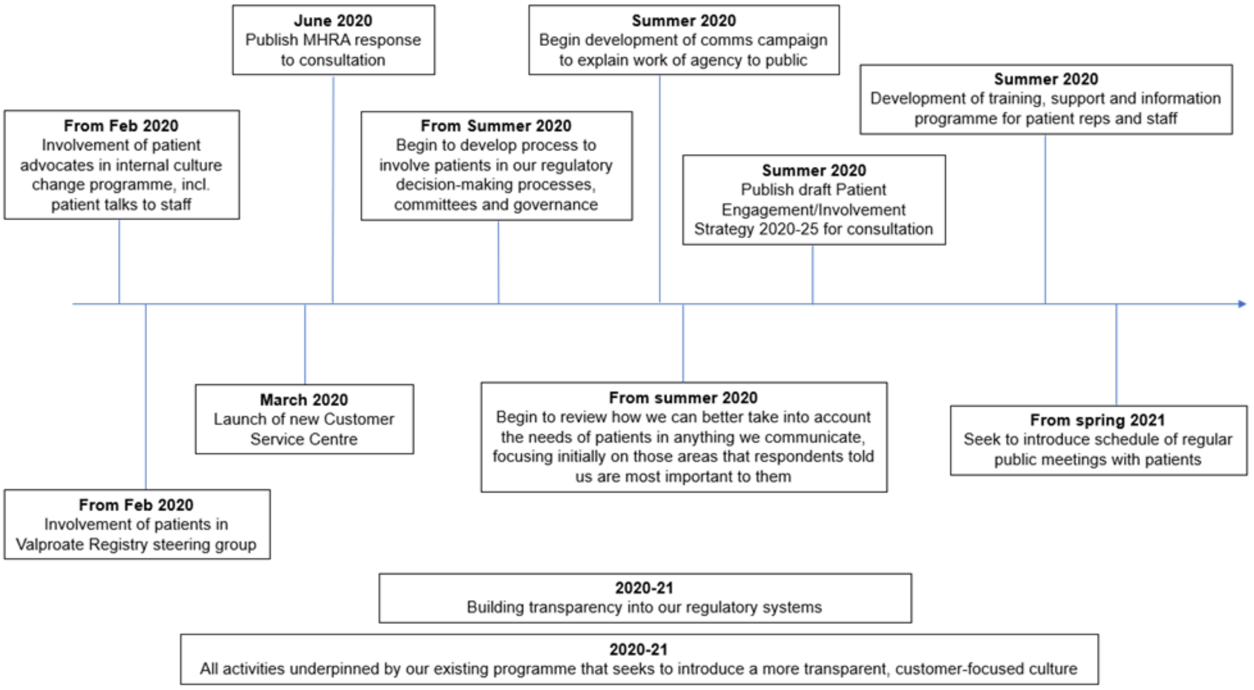
Proposed approach (including indicative timings):

- We have already started work to review the information provided across our different websites and will involve patients and healthcare professionals in that process as part of developing future content. Priorities include making our websites more accessible and to have clearer signposting for patients and healthcare professionals, while working within the structures of the current gov.uk website model where relevant.

- On an ongoing basis, we will seek to link more of our content from the websites of healthcare bodies and other stakeholders to support raising public awareness of the agency.

- On an ongoing basis, we will use a range of digital channels and tools such as our websites, videos, animations, social media posts, email bulletins and YouTube videos to convey explanatory information about the agency, its role and how it reaches the decisions it makes, including opportunities for patient involvement. This content will be engaging, accessible and easily shareable.

4. Phased timeline of key actions 2020-21



From Feb 2020
Involvement of patient advocates in internal culture change programme, incl. patient talks to staff

From Feb 2020
Involvement of patients in Valproate Registry steering group

March 2020
Launch of new Customer Service Centre

June 2020
Publish MHRA response to consultation

From Summer 2020
Begin to develop process to involve patients in our regulatory decision-making processes, committees and governance

Summer 2020
Begin development of comms campaign to explain work of agency to public

From summer 2020
Begin to review how we can better take into account the needs of patients in anything we communicate, focusing initially on those areas that respondents told us are most important to them

Summer 2020
Publish draft Patient Engagement/Involvement Strategy 2020-25 for consultation

Summer 2020
Development of training, support and information programme for patient reps and staff

From spring 2021
Seek to introduce schedule of regular public meetings with patients

2020-21
Building transparency into our regulatory systems

2020-21
All activities underpinned by our existing programme that seeks to introduce a more transparent, customer-focused culture

NB: Some timings subject to review pending outcome of consultation in summer 2020 on Patient and Public Engagement/Involvement Strategy 2020-25