Medicines & Healthcare products Regulatory Agency

Consultation:

Seeking views on how we engage and involve patients and the public in our work

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If you would like to read more about the work of the Medicines and Healthcare products Regulatory Agency before you complete this questionnaire, please see www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about.

For information about the Clinical Practice Research Datalink (CPRD) please see www.cprd.com

For information about the National Institute for Biological Standards and Control (NIBSC) please see www.nibsc.org

You can participate in this consultation anonymously but if you choose to provide your email address we will add you to our mailing list to offer you future opportunities to hear about or get involved in our work.

This questionnaire will take approximately 10-15 minutes to complete, or longer if you wish to offer additional comments.

Please note that you do not have to answer every question.

CPRD NIBSC MHRA

1. Awareness of our work

Have you previously interacted with the Agency (examples of interactions could include email correspondence, telephone calls, responding to tweets or attendance at meetings)?

Yes [X] No [ ]

If 'Yes' please answer the following:

Please tell us approximately how many interactions you have had with us during the past three years?

- Less than 5 interactions [ ]
- From 5 to 10 interactions [X]
- More than 10 interactions [ ]

Please tell us which broad areas of our work you have interacted on (select all that apply):

- Medicines [ ]
- Medical Devices [ ]
- Blood Products [ ]
- Clinical Trials [ ]

Other - use the text box below

We have communicated with CPRD about the data which they have access to, along with issues related to transparency

2. How we communicate and engage now

Currently we communicate our decisions to patients and the public primarily through the Agency's website, articles in the media and via social media. We also work with TV programmes to include storylines on important topics, such as fake medicines.

Information on specific medicines is made available via the Patient Information Leaflet, which should be included in every medicine pack and provides information on using the medicine safely.

We engage directly with patients and the public by public meetings of the Agency Board, attendance at relevant conferences/events and through our Patient Group Consultative Forum. The forum has 100+ members, including individuals and patient group/research charity representatives and provides patient views on matters of regulation and policy.

a) Referring to the examples of communication and engagement listed below please tell us how effective you think the Agency currently engages with you about its work – where applicable, please rate each example.

   N.B. Even if you answered 'No' to Q.1 you may still wish to give your views on these examples of how the Agency currently communicates and engages.

	Very Effective	Effective	Quite Effective	Ineffective	N/A
Information on our website - www.mhra.gov.uk					X
Public meetings of the Board					X
Issue-specific stakeholder meetings, for example to receive patient views on the packaging of medicines					X
Patient Group Consultative Forum					X
Media – including TV, national newspapers and other press					X
Social media					X
Agency attendance at relevant conferences/events					X

Other – use the text box below to give details and a rating on the effectiveness

Given that use MY data is a movement of patients relatives and carer which is supportive of the safe, transparent and effective us of patient data to drive research, it is difficult to get a complete understanding of the way which CPRD operates with the data it receives.

b) Using the box below, please give any examples of where the Agency has engaged with you about its work that you think were particularly effective or others that were not so effective:

We asked for a list of the practices that submitted data to CPRD but were told that this could not be provided, but that individual practices should make this clear (leaflets, posters, etc). So in effect it is impossible for us to find this out.

3. How we communicate with you in the future

We aim to increase public awareness and understanding of the work that we do.

Please tell us what you think are the most effective additional ways that we should communicate information to patients and the public about our role, responsibilities and decisions.

a) To help us prioritise, please select as many options as you like from the examples below and rank them in order of preference (with 1 being highest):

	Rank 1-6
• Regular email bulletins/infographics	[X]
• More information leaflets	[ ]
• Webcasts of relevant public meetings	[X]
• YouTube videos explaining the Agency's work	[ ]
• Podcasts to explain specific aspects of our work	[X]
• Host open/public meetings to explain specific areas of regulation	[X]

b) Are there any other ways by which you think we should try to increase public awareness and understanding of the Agency's work? Please use the space below to give your suggestions.

Better engagement with the wide network of patient groups, and in particular with groups such as use MY data, which have a specific interest in secondary uses of patient data for research.

4. How we involve you in our work

We want to do more to involve patients and the public in our work, including early in the regulatory decision-making process.

a) Please tell us whether you would be interested in the following opportunities to be involved in the work of the Agency:

- Medicines [ ]
- Medical Devices [ ]
- Patient safety information [ ]
- Other - please specify using the text box below

We would be interested in the general work undertaken by CPRD, its ways of working and the overall transparency within which it operates.

b) If you would like to be involved in the development of patient safety information, please tell us which specific information areas are of interest to you:

- Patient Information Leaflets [ ]
- Packaging of medicines [ ]
- Medical Device labelling and user instructions [ ]
- Yellow Card Scheme (see https://yellowcard.mhra.gov.uk/) and other mechanisms for reporting issues of patient safety [ ]
- Materials to explain the benefits and risks of medicines and devices [ ]
- Other - please specify using the text box below

Information on the beneficial uses of patient data.

c) Please use the text box below to tell us about any other ways in which you think we should seek to involve patients and the public in the work of the Agency and the regulatory decision-making process.

MHRA areas that are of interest to patients:

- do private companies access CPRD and if so, what is their primary research interest (pricing marketing?)?
- is the data collected good enough for research? If not, why not - is it systems or human failure?
- is my GP helping research by submitting data to CPRD, if not, why not?
- is submitting my side effects to YellowCard tantamount to providing data that supports PROMs?

5. Priority topics or issues on which we publish information

The following is a list of areas of our work for which we currently publish information on our websites. For more information, please visit:
www.mhra.gov.uk
www.cprd.com
www.nibsc.org
https://yellowcard.mhra.gov.uk

a) If you would like us to publish information about these areas, that is more specifically aimed at patients and the public, please rank them in your order of preference (1 being highest). Select as many as you wish:

	Rank 1-11
Authorisation of Clinical Trials *[a clinical trial is a type of research that studies a test or treatment given to people]*	[ ]
Licensing decisions for medicines *[the approval of medicines for marketing in the UK]*	[ ]
Advertising of medicines investigations *[decisions made by MHRA on adverts reported to have breached the legislation on advertising medicines]*	[ ]
Medical Device Alerts *[the communication, to UK healthcare professionals and the public, of safety concerns about specific medical devices]*	[ ]

New Medical Device regulations [ ]
[new regulations that strengthen patient safety and ensure the availability of new devices are due to apply from May 2020]

Yellow Card Scheme reporting [ ]
[the reporting to MHRA, by healthcare professionals and patients, of suspected side effects of medicines or possible problems with a medical device – see https://yellowcard.mhra.gov.uk]

Drug Alerts [ ]
[the communication, to UK healthcare professionals and the public, of safety concerns about specific medicines]

Drug Safety Update [ ]
[a monthly newsletter to inform UK healthcare professionals, and other subscribers, about the latest updates in medicines safety advice]

Inspection and enforcement actions taken [ ]
[inspections and enforcement actions undertaken taken by MHRA to protect public health, e.g. to remove falsified and unlicensed medicines or counterfeit and non-compliant devices from the market]

National Institute for Biological Standards and Control (NIBSC) [ ]
[NIBSC plays a major national and international role in assuring the quality of biological medicines through developing standards and reference materials, product control testing and carrying out applied research – see www.nibsc.org]

Clinical Practice Research Datalink (CPRD) [X]
[CPRD receives de-identified data from a network of GP practices across the UK and provides anonymised data for public health research. Research using CPRD data and services informs the development of clinical guidance and best practice – see www.cprd.com]

b) Are there any other topics, areas or issues about which you think we should publish information for patients and the public? Please use the text box below to give details.

6. How you raise concerns with us and how we respond

We would like you to tell us how you think 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.

Currently patients and members of the public can report concerns about adverse drug reactions and medical device incidents online through the Yellow Card scheme (see https://yellowcard.mhra.gov.uk/). Issues can also be raised by telephoning the Agency or by email or letter.

a) Please use the text box below to tell us your preferences for how you think patients and the public should be able to communicate concerns to the Agency (speaking to someone in person for example) and any other suggestions for making it easier to raise issues that are within the Agency's regulatory remit – for example, patient representation meetings/forums.

We would also like you to tell us how you think we could most effectively engage with patients and the public once they have raised a concern.

b) Please tell us your preferences for the ways in which the Agency should engage with you once a concern has been raised. Please select as many options as you like from the examples below and rank them in order of preference (with 1 being highest):

	Rank 1-8
• Direct contact – email	[X]
• Direct contact – telephone	[ ]
• Direct contact – letter	[ ]
• Yellow Card app *[https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/ Scroll down on that website for information on the Yellow Card app]*	[ ]
• Published response online	[X]
• Social media channels	[X]
• Invitation to patient representation meetings/forums	[X]
• Involvement in the development of materials to explain the benefits and risks of medicines and medical devices	[ ]

c) Please use the text box below to tell us about any other ways in which you think the Agency could most effectively engage with patients and the public once they have raised a concern.

We have highlighted our main points in the accompanying letter.

7. Any other comments or suggestions

Is there anything else you would like to tell us regarding how we engage and involve patients and the public in our work? Please use the text box below.

8. About you

a) Are you primarily interested in (tick all that apply):

- Regulation of medicines [ ]
- Regulation of medical devices [ ]
- Clinical Practice Research Datalink (CPRD) [X]
- National Institute for Biological Standards and Control (NIBSC) [ ]
- Other – please specify using the text box below

b) Which of the following would best describe you in relation to the regulation of medicines and healthcare products? Please select all that apply:

- Patient [ ]
- Carer [ ]
- Healthcare professional [ ]
- Academic/researcher [ ]
- Regulator [ ]
- Health/research charity representative [ ]
- Other – please specify using the text box below

use MY data is a movement of patients, relatives and carers.

c) If you would like to be added to our contact list for future opportunities to hear about or get involved in our work, please give your email address below.

chris@usemydata.org.uk alison@usemydata.org.uk

Thank you for your time in completing this questionnaire.

Please send a copy by email to engagement@mhra.gov.uk

or by post to:

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