

# Proposed Patient and Public Involvement Strategy 2020-25



## Submitted to

Medicines and Healthcare products  
Regulatory Agency (MHRA)

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The PHG Foundation warmly supports the Agency's plans to expand and strengthen meaningful public and patient involvement and engagement. We are a policy think-tank that is a charity of the University of Cambridge; our mission is making science work for health. Effective patient and public involvement is an essential element in the development of robust policy relating to scientific and technological innovations for healthcare, including for regulation.

We are committed to improving the way we engage and involve patients. Do you consider that our overall approach in the strategy will deliver this, and if not please tell us why?

Our 2019 report, [Our Healthy Future](#) was based on extensive research and analysis to identify key lessons for successful policy and regulation of emerging and future technologies and other innovations with potential health applications.

Our conclusions were that a healthy future necessitated a 'creative and inclusive approach to engagement and implementation' involving a wide range of organisations and stakeholders, and we called for incentives and structures to support 'wider participation in innovation from patients, citizens and others'.

The Agency's plans are clear steps towards fulfilling these recommendations, and we welcome them. In particular, the stated aims to clearly demonstrate both the processes for engagement and the outcomes it produces are very sound; transparency is an essential element in making policy decision-making processes more trustworthy, and more trusted by stakeholders including patients and the wider public.

Similarly, the commitments to responsiveness to patients and to producing and publishing meaningful measures of successful engagement are also welcome.

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Our research has clearly shown that potentially useful new science and technology can nevertheless pose real risks of exacerbating existing health inequalities, directly and indirectly (for example, through under-representation in data and other knowledge), so the Agency's commitment to broadening engagement with a specific focus on currently under-represented groups (including younger and older demographics, minorities, those with learning disabilities and those who do not have English as their first language) is very positive.

There may be a further need to make patient engagement more widely accessible, in that current Agency structures such as the Patient Group Consultative Forum are heavily weighted towards skilled 'expert patients' and may benefit from supplementation with more accessible, lighter-touch forms of consultation.

Moreover, the ability of patients to be able to 'draw on their experiences as a patient and as a consumer of medicines and medical devices and translate this into a population level perspective' (as stipulated) may be limited, since patients have a unique and not necessarily more widely representative perspective.

In order to recruit and retain representation from some under-represented groups, such as those with learning difficulties, certain minorities and those who do not have English as their first language, sustained efforts may be needed for recruitment, and additional resources will be required to facilitate meaningful involvement, such as interpreters, carers and patient advocates. There should be a commitment to provide such resources.

One further question from us would therefore be the extent to which citizen / public views in addition to patient voices are included. Patient representation is of course essential for success, and expansion of patient involvement including among less well represented groups is vital.

However, in order to build awareness of and trust in the regulatory process and in the products approved through this process among the wider public, much broader engagement is needed. We would therefore recommend distinct processes to expand this area of activity at different levels and ensure an equal representation of patient and non-patient voices.

Of note, new approaches and models for effective public engagement may be needed to achieve this.

One example is that the strategy makes reference to the use of patient speakers and advocates to help train staff 'about how we can engage patients and the public and involve them in our work'. These will no doubt be beneficial, but as patients are representative of specific sub-groups of the public only, it would be worth considering widening this plan to include others, such as community group representatives or other stakeholders.

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## What additional actions should we consider to improve our strategy?

The PHG Foundation recommends designing and implementing a range of different activities to ensure a suitable balance of public and patient engagement on different issues, and (for example) taking into account both 'late adopter' as well as 'early adopter' perspectives on new technologies and products. People for whom new health innovations may offer benefits but are less cognisant of these opportunities or more reluctant to embrace them can offer especially valuable perspectives in design, development and appraisal processes.

Initial engagement on the scope and nature of ideal engagement processes themselves may be a valuable initial step, and again we would encourage the Agency to engage with as wide a range of organisations and citizens as possible in this process, to optimise the benefits.

Constructive engagement with groups suspicious or sceptical about the benefits of innovations may be especially helpful to understand public concerns.

The Agency's commitment to work on public understanding of risk and effective risk communication is an especially valuable aim, and we recommend the work of the Winton Centre for Risk and Evidence Communication at the University of Cambridge in this regard. Actively tackling misinformation surrounding relevant products and devices, in partnership with others, may be an important part of these efforts.

There is also scope for the Agency to support wider societal awareness and debate about the potential impact of new technologies for health, particularly AI-driven technologies, especially when working collaboratively with other organisations as referred to in the Strategy, and via expanded public and patient engagement. This could further enhance awareness of the Agency and trust in both the regulatory process and, by extension, the products that receive regulatory approval.

Embedding patient and public voices could also involve strengthening the extent and nature of participant and public involvement at all stages in the development of new devices and technologies, including in the conception and research phases.

Partnership with the Health Research Authority to ensure that the questions about patient and participant involvement within the Integrated Research Application System probe meaningful engagement throughout the research process (question 14) would help to embed a culture of patient and participant engagement within the ecosystem for drug and device development.

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For example, PHG Foundation work on [Black Box Algorithms](#) highlighted that decisions about interpretability should form part of the design process, drawing on a range of stakeholder perspectives.

The Agency's draft policy looks to embedding patient and public involvement into the existing structures and processes. In the longer term, challenges around effective and proportionate of medicines and devices will require more sustained post-marketing surveillance infrastructures and processes that rely much more heavily on systematic and comprehensive feedback from patients. This transformation may require more substantial changes to MHRA processes and operating procedures. It would be good to see the draft strategy reflect these wider challenges over the medium to long term.

If we deliver our strategy, how do you think engaging with the MHRA would feel different from a patient perspective?

We feel it is better for individual patients, patient representatives and charities to comment on this.