



Patient and Public Engagement Strategy

April 2009 – March 2011

Patient and public engagement strategy

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is embarking on a new programme of activity which seeks to engage patients and the public in its work and the decisions it makes. As the regulator of medicines and medical devices, the Agency collectively makes thousands of decisions each day based on extensive evidence of quality, safety and efficacy required for each product. The Agency's first patient and public action plan, however, reflects the need and expectation for public bodies to listen to the views and experiences of patients and the public and this plan seeks to ensure their input makes best use of their expertise and time.

MHRA is the Government Agency responsible for ensuring that medicines and medical devices work and are acceptably safe. The Agency's aims are:

- Protecting public health through regulation, with acceptable benefit-risk profiles for medicines and devices
- Promoting public health by helping people who use these products to understand their risks and benefits
- Improving public health by encouraging and facilitating developments in products that will benefit people.

If the Agency is to be successful in its mission of safeguarding public health, it is essential it listens to the views and experiences of those who are most affected by the decisions the Agency makes, namely patients and the public.

Whilst MHRA has involved patients and the public in its work for some years now, in many cases it has done so in a rather ad-hoc way. Engagement activities have included seeking views through written consultations, the introduction of lay members in the Agency's various advisory committees, and working with patient organisations on the Yellow Card campaign, Always Read the Leaflet and where contentious decisions have been under consideration, for example the introduction of thalidomide for the treatment of multiple myeloma.

Last year, the Agency consulted stakeholders about its five-year strategy. Probably the single clearest message from the whole consultation exercise was the broad support for greater engagement of the public in its work, mainly from public and patient groups but also from other stakeholders. The Agency responded to this by setting as one of its key targets for 2008/9:

“To agree a two-year action plan to develop the involvement of patients and the public with a view to improving the quality of decision making within the Agency and the level of understanding of its work, and with reference to both product-specific decisions and wider policies.”

Patient and public engagement (PPE) is now considered as a key component of public bodies and other bodies with public duties. By not engaging with patients and the public, the Agency risks criticism for being out of line with public expectations.

Vision for patient and public engagement

The Agency's vision of PPE is to:

- Identify areas of work where the Agency can build and strengthen co-operative and mutually beneficial relationships with patients and the public
- Encourage and promote patient and public engagement in Agency activities, where appropriate, ensuring that the partnership is meaningful and effective
- Ensure that plans and decisions made within the Agency have been considered and influenced by patients and the public where relevant in their development
- Engage a diverse range of individuals within the Agency's work so that views reflected come from a wide constituency of people
- Ensure that the engagement of patients and public is championed and promoted at a senior level within the Agency
- Engage and consult with Agency staff and other stakeholders in the development of patient and public engagement within the Agency.

To ensure that all in the Agency have a shared understanding of PPE, we offer the following definition:

to listen to patients and the public, understand their perspectives and interact with them, so that the Agency's policies, communications and regulatory decisions are informed and, where appropriate, influenced by their views.

Making patient and public engagement a reality in the Agency

As engagement with patients and the public develops, the need to consider PPE should become the normal way of working and incorporated into each relevant project at the planning stage. It will be necessary however to develop contact points and mechanisms across the Agency to identify issues where views of patients and the public are critical. It is also important that processes developed work towards real dialogue and that there is flexibility to discuss ad hoc issues that either patients and/ or the public want to raise with the Agency or that the Agency needs their views on. The appointment of a PPE Manager goes some way to address this, but it should be stressed that engaging with patients and the public is not the exclusive responsibility of the PPE Manager. Rather, the remit of this role should be thought of as:

- Providing a strategic overview of the Agency's relationship with its patient and public stakeholders
- Sharing knowledge of patient and public engagement activities across the Agency
- Assisting Agency staff to engage with patients and public in relevant and appropriate ways
- Ensuring that contact with patients and the public is conducted in an open and accessible way
- Bringing stakeholders together through regular events to share information and exchange views.

In order to successfully embed PPE throughout the Agency, a number of influences must work together including:

- Leadership – patient and public engagement needs strong corporate momentum, with direction and leadership at high levels that is consistent over time, providing the same messages to all parts of the Agency.
- Status – patient and public engagement needs sufficient status to compete fairly with other calls on commitments and resources. It has acquired status through the consultation on our five-year strategy but that needs to become fully embedded in corporate policy.
- Knowledge – staff need to be able to understand the purpose and value of engaging patients and the public, and how to do it. Their understanding and commitment will from time to time need to be strengthened by development events or key messages.
- Systems - these must be designed to enable the work to be done in the right places, at the right times and in ways that are likely to be most effective.
- Resources – time, money and skills will be needed.

These factors will reinforce each other in embedding engagement within and across the Agency.

How the Agency will engage with patients and the public

There are numerous quantitative and qualitative methods of engaging with patients and the public. These include citizen's panels, focus groups, workshops, opinion surveys and deliberative events, to name but a few. However, the key to successful engagement is to ensure that the methods chosen are the most appropriate given the purpose of the engagement and the target audience.

Strategic priorities for patient and public engagement in the Agency

1. To improve decision making and policy development

Patients and the public are the group of stakeholders who benefit most from what the Agency does or who suffer most if the products it licenses or regulates do not work well or are not safe enough to be used. Consequently, they have perspectives that deserve to be heard and which are capable of helping the Agency in its mission of safeguarding public health.

Strides have already been made to bring public perspectives into the Agency's work through the appointment of lay members on all Committees and Expert Advisory Groups. As the first lay member recruits come towards the end of their first term of office, discussions have started as to how their contribution can be enhanced through improving the recruitment and appointment processes, providing better inductions and more support to them, and evaluating their contribution.

Engaging with patients and the public will also give the Agency and the public greater confidence and reassurance in the decisions it takes and policies it develops. Again, the Agency already does this through its consultations, although

there is scope for improvement by updating stakeholder consultation lists and identifying the appropriate patient and consumer groups for each consultation. Work in this area has already started with the development of a contact database with over 200 patient groups, most of whom have indicated an interest in being consulted with.

However, the Agency recognises that on some issues, a more active and probably discursive engagement is required. As a pilot, it is looking at engaging patients and the public on the issue of the early access to medicines which have not yet undergone the full current regulatory process.

2. To develop a better understanding of the issues affecting patients and the public

Patients and the public also have issues that are not currently on the Agency's agenda but which could be critical to safeguarding public health. There is a need for us to listen to the unsolicited views of patients and the public and to enter into a constructive dialogue with them.

This has already started happening. Some Agency staff recently met with key critics of the Agency who had had a bad experience with a medicine. These meetings helped persuade the Agency that doctors had insufficient information about how to manage withdrawal problems associated with this product. Not only did the Agency learn something, but we hope that its reputation with those critics is enhanced. These encounters also allowed some misconceptions about the Agency to be set straight.

With hundreds of patient groups, one early task is to identify the key ones where there will be most mutual advantage in engagement and to develop relationships with them. One of the challenges will be how to bring their views back to the Agency and give them proper consideration. The processes and mechanisms to achieve this will need to be considered.

3. To improve our communications directed at patients and public

Communicating effectively is an important part of the Agency's work. The Cabinet Office has recently developed a programme which puts consumer insight at the heart of the policy making and campaign development process. This is being rolled out across Government and works on the premise that for any communication to be successful, it is essential to understand the target audience. Through understanding, it is possible to develop insight, and from insight messages can be created that, delivered via the right channels, will resonate profoundly with those they were intended for.

The PPE Manager will work closely with the corporate communications and marketing and the press office functions to ensure that communications are strategically planned and delivered. For example, work has already commenced on identifying people more likely to buy counterfeit products and engaging with them so as to understand their behaviour. Insight gained will feed into the anti-

counterfeit campaign the corporate communications and marketing team are developing, which feeds into the Agency's counterfeit strategy.

Developing relationships with patient and consumer organisations will help the Agency tailor and improve its communications around what it does and how it does it, and open up new channels through which patients and the public can be reached. These will also help get urgent safety messages out to the right people within a time scale that is proportionate to the level of risk involved. The new contact database of patient groups will help in doing that.

Risks

There are a number of risks associated with this work that will require managing:

- Engagement can raise expectations amongst our stakeholders that the Agency may not always be able to fulfil
- It will be necessary to guard against an approach that is merely tokenistic
- Care is needed about the extent to which views expressed are representative of patients or the public

Action plan

This action plan identifies a range of activities that will help build the Agency's capacity and capability to successfully engage with patients and the public and help the Agency deliver its strategic priorities.

It is a living document, and therefore needs to have the scope to review and update actions on an ongoing basis in the light of learning that will emerge from its implementation. This will provide the flexibility to amend, build upon, rethink and extend actions to ensure engagement remains both meaningful and appropriate.

Implementing engagement activities

- Undertake an information gathering and opinion seeking exercise to underpin the forthcoming early access to medicines review (year 1)
- Develop insight through engagement to combat counterfeiting medicines and devices (year 1)

Supporting lay members on expert committees

- Clarify the role of lay members and evaluate their experience of and their contribution to the Agency's committees with a view to making their future contributions as effective and appropriate as possible (year 1)
- Establish the induction and training needs for lay members (year 1), and provide opportunities to meet those needs subject to the availability of resources (year 2)

Raising the Agency's profile/ building relationships with external organisations

- Raise awareness of the Agency's interest in PPE and establish contacts in the voluntary sector through participating in appropriate conferences and events run by other organisations (year 1 and 2)

- Meet with at least 20 of the larger patient organisations (at least 10 in the first year) to further raise their awareness of the Agency and its work and to provide an opportunity for them to raise issues of concern that are within the remit of the Agency

Building internal understanding of patient and public engagement

- Promote patient and public engagement throughout the Agency through a co-ordinated programme of internal activities (year 1)
- Prepare and disseminate a PPE guide for MHRA staff which indicates why, when and how it should be done (year 2)

Developing supporting systems within the Agency

- Ensure that horizon scanning mechanisms are in place within the Agency to identify at an early stage the issues coming onto the Agency's agenda which deserve specific input from patients and/or the public (year 2)
- Provide all those in the Agency who undertake written consultations with facilities for identifying and consulting with key patient/consumer organisations which have a potential interest in the issue under consideration (year 1)
- Set up suitable mechanisms through which unsolicited views of patients and the public can be identified, sifted, brought into the Agency and considered by appropriate people (year 1)

Evaluation

Evaluate the extent and effectiveness of the Agency's patient and public engagement programme towards the end of the second year

Cost/resource implications

The Agency recognises the need to make a financial commitment in order to successfully embed and undertake PPE activities. A budget of £44,000 has been agreed to implement the first year of the action plan (April 2009 onwards). This includes the cost of out-sourcing some engagement exercises and of supporting lay members on committees. The budget will be reviewed towards the end of year one, and additional resource sought where required in order to successfully undertake activities planned for year two.

Conclusion

This strategy is an Agency wide strategy, and as such implementation will involve the effort and cooperation of all staff. It seeks to support the Agency in its mission by putting the public at the heart of safeguarding public health.