UK Stakeholder Platform for Reclassification of Non-prescription Medicines

Meeting held on Tuesday 11th November 2014 at 2:00pm in Room R-Y-335 3rd floor, Buckingham Palace Road

MINUTES

Present

Simon Adams
Johanne Barry
Martin Duerden
Margaret Peycke
Theo Raynor
Gul Root
Ruth Wakeman

MHRA

Jan MacDonald (Chair)
Colette McCreedy
Janine Jolly
Amanda Williams

Observers

Helen Darracott (observer)
Sunayana Shah

Apologies were received from Paul Fleming, Roger Walker, Andrew Green, Bill Scott, and Ash Soni.

1. Introduction

Members were welcomed to the inaugural meeting of the UK Platform for Reclassification of non-prescription medicines. They noted that Minutes of the meeting would be published on the MHRA website.

Members were invited to outline their background and highlight their views on reclassification including the challenges and opportunities.

Some issues raised by members included:

- GP knowledge about OTC medicines needs to be improved
- Information on reclassification decisions and the Risk Management Plan should be transparent and understandable
- The reclassification guidance should be made more user friendly
- A suitable range of OTC products should be available which can be supplied by a pharmacist in response to patients' symptoms
- Improved integration of pharmacy in NHS services including urgent care could contribute to more successful reclassifications
- It was important to have a predictable reclassification process involving good collaboration of all stakeholders.

2. Background to the establishment of the Stakeholder Platform

As background, members considered how the Stakeholder Platform had been established. The initiative was based on the findings of an EU Platform Working Group on Promoting a Good Governance of Non-prescription

Medicines in Europe which had recommended that National Stakeholder Platforms should be established to share views and develop strategies to reach a common approach to supporting patient access to non-prescription medicines. In addition a national pilot workshop on reclassification and good governance of non-prescription medicines, held in June 2014, had recommended the establishment of a national overarching strategic platform for reclassification and the use of ad hoc reclassification stakeholder groups to consider specific reclassification applications.

Platform members noted that this Strategic Platform was being established by the MHRA; the ad hoc reclassification stakeholder groups would be set up as advisory groups to the CHM and Chaired by a CHM member, with secretarial support from the MHRA.

Members agreed that it was important to have a suitable balance of patient representatives, academic/ experts and healthcare professionals as members of the Stakeholder Platform. It was also suggested that an NHS England representative would be an important additional member of the platform.

3. Discussion and agreement of Terms of Reference

Platform members discussed the draft Terms of Reference and the following points were made on some of the issues that could be considered within the Terms of Reference:

- It would be useful to consider whether it is possible to achieve some consistency and simplification in the type of risk minimisation measures which are applied to newly reclassified products – currently there is a variety of different types of protocol for delivery of products which represents a barrier

- Consideration should be given to how much pharmacists can be enabled and empowered to be in a position to use their professional judgement in supplying a product

- The promotional style for new products was considered an important success factor

- Improved dissemination of information to healthcare professionals about a reclassification (e.g. the justification for the revised conditions for the marketing authorisation (including the Summary of Product Characteristics and risk minimisation measures) may help towards better engagement in the reclassification process

- Patients' perceptions of the roles of pharmacist and GP and the inter-relationships between them are not always clear and need better understanding

- In considering critical success factors, where a product represents a clear benefit to patients, there are consequential benefits to all other stakeholders

- The options for taking a pro-active approach to reclassification need careful consideration and a ‘wish list’ of products is best avoided; it would be preferable for an ‘expert group’ to consider the type of medicine which would benefit patients if it could safely be made more widely available.

- Consideration should be given to a whole systems approach encompassing NHS care and self-care using OTC medicines to ensure people move seamlessly between the two systems.

It was agreed that a revised version of the Terms of Reference would be circulated to include the following points;

- It is important that the Terms of Reference express objectives which were achievable by the Platform
- An overall vision statement should be included
- Although safety must remain the priority for reclassification there should also be an improved focus on benefit to the public
- The statements should be more general and cover the scope of work by the Platform rather than the details.

Platform members considered arrangements for future meetings and agreed to meet 3 - 4 times a year initially, with the first few meetings held on a formal basis. Subsequently consideration may be given to ‘virtual’ meetings.

4. Development of Workplan and Prioritisation of issues

Platform members discussed what should be the elements of the workplan and focused on a work stream on analysis of key elements of the reclassification process that require stakeholder engagement,

They noted that certain ‘myths’ had developed amongst stakeholders, such as the view that it is not worthwhile responding to public consultations on reclassification applications (ARM Consultations). These perceptions needed to be identified and corrected where necessary.

The following points were discussed.

- It was important that all Platform members understood the reclassification process to facilitate discussion of the specific aspects where stakeholder involvement was required i.e. through the ad hoc reclassification stakeholder groups and through engagement with stakeholders during the public consultation phase

- It would be helpful to review past reclassified products, to learn what critical elements contributed towards success or lack of success and what would be improved with the new procedure that was outlined in the revised reclassification guideline, published in December 2012. e.g. have the revisions to the SPC undertaken as part of the reclassification been an

advantage or disadvantage? Also the possibility of reviewing applications which were unsuccessful could be investigated

- To improve patient engagement, it is important to looked at improved channels of communication

- It would be useful to establish exactly what support pharmacists neededto supply a newly reclassified product, including how to manage GP referrals when appropriate.

- It is also important that healthcare professionals were equipped to understand where they could make an impact on public health in relation to providing advice on the use of and/or supplying non-prescription medicines

The Group agreed to prioritise topics for the workstream by focusing on one topic at a time.

The Agenda for the next meeting would include:

Revised Terms of Reference for Platform
Overview of the reclassification process introduced in 2012
Review of case studies of reclassified products
Consideration of the composition and ways of working of ad hoc reclassification stakeholder groups
Review of the work plan.

5. Plans for the next meeting

To prepare for the next meeting, members were asked to:

a. Submit before the meeting, details of 'myths' concerning reclassification
b. Consider topics for inclusion in the Work plan.
c. Provide feedback on the revised Terms of Reference, which would be circulated for comment

6. Dates for future meetings

The proposed dates for the next meetings would be in February, June and October 2015. Further details would be circulated.