UK Stakeholder Platform for Reclassification of Non-prescription Medicines

Meeting held on Monday 7 December 2015, 10.30AM, in Room RT410, MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ

MINUTES

Present	**MHRA**
Simon Adams	Nick Harlow (item 5)
Marguerite Beard-Gould	Janine Jolly
Johanne Barry	Jan MacDonald (Chair)
Trevor Fernandes	Colette McCreedy
Alpana Mair	Nesta Thomas
Theo Raynor	Amanda Williams
Gul Root	
Ash Soni	**Observers**
Ruth Wakeman	Paul Fleming
Bruce Warner	Helen Darracott

Apologies were received from Rob Darracott, Martin Duerden, Andrew Green, Bob McNabb, Roger Walker, and Sunayana Shah.

1. Introduction

Platform members were welcomed to the meeting of the Platform and all members introduced themselves. Bob McNabb, who was unable to attend, was thanked for sending comments on all of the agenda items, which would be taken with each item.

2. Minutes and matters arising

The minutes of the last meeting of the Stakeholder Platform held on 8 September 2015 which had been circulated prior to the meeting, were agreed.

Platform members were asked to note the revised job descriptions and application forms for pharmacist, GP and patient members of the ad hoc stakeholder groups, which would be set up by CHM to consider specific reclassification applications. The job descriptions had been revised to reflect discussion at the September meeting.

Platform members suggested the following further amendments:

- In the patient/parent/carer description bullet points 4 and 5 should be amended to ‘An interest in patient empowerment and the role medicines play in improving health’.
- In the community pharmacist description ‘(employee or owner)’ should be deleted.
- The healthcare professional descriptions should stipulate that the professional should be currently working in a patient facing role.

Platform members noted that MHRA would be contacting patient organisations to recruit patients with relevant experiences.

3. Risk minimisation measures used in reclassification

Platform members' views were sought on the risk minimisation measures (RMMs) contained within a Risk Management Plan (RMP) currently used in the reclassification process, their fitness for purpose and whether they could be improved or replaced by other measures.

The Platform discussed the importance of RMMs, and the pros and cons of questionnaires and protocols.

The Platform agreed that many pharmacists did use protocols and questionnaires when a product was first reclassified to become familiar with supply in the OTC setting. However, once familiar with a product and the materials, pharmacists were able to use their professional judgment to decide on the most appropriate questions to ask a patient, and communicated in a more natural manner. It was noted that protocols and questionnaires could be cumbersome and not very user friendly. When followed literally by pharmacists and their staff they could be regarded by patients as a barrier to the conversation, and this disempowered pharmacists. Platform members agreed that educational materials, protocols and questionnaires should be non-mandatory, but noted that they should still be considered as a RMM as part of a reclassification application where appropriate.

The Platform noted that access by pharmacists to summary care records would be of value in the supply of non-prescription medicines.

The Platform agreed that a lot of consideration was given to the RMMs required the first time a product was requested or suggested by the pharmacist in response to treatment advise sought by the patient. Attention also needed to be given to repeat supplies.

The platform agreed that it was also important to consider RMMs to manage the risk of online sales and sales from vending machines; there were different needs for different methods of supply of non-prescription medicines. It was also suggested that any RMMs should be tested with patients.

The platform discussed the value of Post Authorisation Safety Studies (PASS) as a RMM and agreed that this was a valuable tool in some cases provided the study is designed well and will provide meaningful statistics. PASS could also be a way of testing that protocols are in place and or whether they are acceptable to pharmacist and patients in practice and that they provided the desired outcome (people who should and who should not be using the product have been correctly identified by the pharmacist and/or the patient).

The Platform was enthusiastic about using 'active packs' as a RMM – where all the relevant information is available on the packaging. When well designed and clear this acted as a good aide memoire for the pharmacist when discussing whether a product was suitable for an individual and explaining how to use it correctly. They enabled pharmacists and their staff to use their

consultation skills to discuss suitability of the product with the patient. It was also a useful summary for the patient after purchase including when the product remained in the home for future use.

The platform agreed that the patient leaflet was also important and noted that healthcare professionals and patients might not be aware that improvements had been made to the design and presentation of information in these statutory elements of a product's marketing authorisation. It was noted, however, that a patient would not be able to read the leaflet until after purchase.

It was agreed that the content of the summary of product characteristics was the most important document to review during a reclassification procedure – and good patient information and supplementary materials would flow from this. The platform agreed that it was important that views of doctors, pharmacists and patients were sought on RMMs that were proposed in a reclassification application.

4. Communicating decisions on reclassification

Platform members were provided with an overview on how information about new reclassifications was communicated by the MHRA, marketing authorisation holder and professional bodies. The MHRA stated that they were planning to include in future reclassification guidance methods of communicating the outcome of a reclassification process.

Platform members' views were sought on the preferred and most effective methods of communication to include in a best practice model for communicating new reclassifications.

The Platform agreed that patients usually find out about new medicines through advertising, which is regulated under the Human Medicines Regulations. The PAGB pre-vet advertising, as do the MHRA for significant reclassifications. It was, however, agreed that advertising shouldn't be the only way patients know about new products and that the MHRA should communicate new reclassifications directly. Possible ways to do this included the development of a digital platform, combined with social media.

It was suggested that as well as the announcement of individual reclassified products, the MHRA should include the self-care message more generally in the communications, in particular highlighting which indications (rather than substances) pharmacists could provide advice on.

It was agreed that more use could be made of the NHS choices website to inform patients about new reclassifications and their correct use. This should also be an important source of information about medicines that have been reclassified from non-prescription to prescription only for safety reasons.

Whilst this would not be a matter for MHRA to address the Platform considered that the self-care/'use your pharmacist' message could be more widely promoted in GP surgeries. Additionally, GPs should be made more aware of reclassified products and indications that pharmacists can advise on. More use could also be made of the BNF to inform pharmacists and GPs of

new reclassifications. The MHRA agreed to develop a digital platform with a communications strategy and to initiate contact with CCGs to discuss methods of engaging with GPs. **Action: MHRA**

5. Communicating the work of the stakeholder platform for reclassification of non-prescription medicines

MHRA outlined plans for communicating MHRA work on the Platform and the process the MHRA undertakes to reclassify a medicine. MHRA stated that they were planning to have digital content ready to be published in Q1 2016. It was envisaged that the content would include information on the regulatory framework including myths and misconceptions, information about the Platform itself, as well as information on the ad hoc groups, including a call to invite people. **Action: MHRA**

6. Review of membership of the stakeholder platform for reclassification of non-prescription medicines

Platform members noted plans that the membership of the Platform would be reviewed after one year. Platform members were invited to discuss the mix of stakeholder representation and methods to maximise attendance at meetings.

Some members of the Platform suggested that half day meetings may improve attendance, although those travelling from further away stated that it would make little difference to them. It was agreed to distribute a poll to the Platform to get availability for half day meetings. **Action: MHRA**.

It was accepted that there were barriers to attendance. For professionals, this was usually a financial barrier as locum fees would need to be paid. Patients may find it difficult to find the time for attendance and travel for free.

The Platform considered it important that all the devolved countries were represented on the platform. It was also noted that a GP attendance had been low. Options to maximise participation were discussed, including nominating deputies, increasing the numbers of representatives per sector and using technology to support ‘virtual’ meetings. It was agreed that a survey should be distributed to gain the views of all Platform members, including those who had not been able to attend the meeting. **Action: MHRA.**

7. Next steps

The next meeting would be on **23 March 2015, 10.30am – 2.30pm.**