UK Stakeholder Platform for Reclassification of Non-prescription Medicines

Meeting held on Tuesday 3rd February 2015 at 10:00am in Room R-M-337 3rd floor, Buckingham Palace Road

MINUTES

Present	**MHRA**
Simon Adams	Jan MacDonald (Chair)
Marguerite Beard-Gould	Colette McCreedy
Trevor Fernandes	Janine Jolly
Martin Duerden	Amanda Williams
Alpana Mair	**Observers**
Theo Raynor	
Ash Soni	Helen Darracott
Ruth Wakeman	Sunayana Shah

Apologies were received from, Roger Walker, Andrew Green, Johanne Barry, Bruce Warner, Bob McNab, Gul Root, Rob Darracott, and Paul Fleming.

1. Introduction

New members were welcomed to the meeting of the Platform and all members introduced themselves.

2. Minutes and matters arising

The minutes of the last meeting of the Stakeholder Platform held on 11 November 2014 which had been circulated prior to the meeting, were agreed.

3. Terms of Reference

The group considered and agreed the draft terms of reference which had been revised in light of discussion at the last meeting. These would be formalised and published.

4. EU and UK legislation and the UK reclassification process

4.1 Presentation on the legislative process and the current UK reclassification guidance

The group received a presentation on legal classification in the UK and the reclassification process, as outlined in the Reclassification Guideline published in December 2012. It was noted that the guideline was principally for use by those who wished to submit a reclassification application.

The group acknowledged the role of reclassification in empowering patients in self-care. Many stakeholders however felt they were not sufficiently aware of the role of reclassification to be able to comment authoritatively on reclassification consultations.

The group considered that it would be useful to establish how the roles of patients, pharmacists and doctors, could best be developed and clarified in the supply of reclassified and other non-prescription medicines. They considered it would be helpful to establish what risk minimisation measures are considered acceptable to patients, doctors and pharmacists and which risk minimisation measures have the most impact.

The group recognised that an improved understanding by stakeholders of the reclassification process and the use of non-prescription medicines would be valuable in obtaining more useful feedback on reclassification consultations.

Suggestions for improving engagement in the reclassification process included:

- A clearer explanation of the reclassification process and how risks are managed
- improved awareness and transparency about the Risk Management Plan (RMP) as this is a key document in the decision to reclassify a product.
- Improved transparency about how an assessment is undertaken and about the outcome, including when CHM advise against an application
- Better awareness by doctors, pharmacists and the public of new reclassifications other than from the industry
- A proportionate approach to risk management so that the patient benefit is not lost, doctors' workload is not increased unnecessarily and over medialisation of the condition is avoided

4.2 Discussion on Reclassification 'myths'

The group noted the comments below from MHRA on the points raised by members after their previous meeting.

a. **Is the cost of an OTC product considered as part of reclassification?**
The cost of an OTC product is not considered by MHRA; only safety quality and efficacy. The group noted that cost can be a barrier to some patients. They considered that the MHRA position should be more transparent.

b. **What is the evidence base considered before a medicine is reclassified?**
MHRA consider all the data submitted by an applicant company, which is under an obligation to submit all relevant information to the licensing authority. Where a specific issue arises which is not addressed by the applicant, assessors use MHRA resources to seek further data.

The group noted that evidence on the role of the pharmacist in the provision of a P medicine would be useful when considering a P to GSL classification but it was not always available or was anecdotal in nature. They suggested it may be helpful to advise pharmacists and other stakeholders how best to contribute comments to reclassification consultations.

c. **Is the active ingredient as well as the strength and dosage regimen for a P product considered against the evidence base for treating the particular condition?**

All these aspects are considered but for a reclassification the benefit: risk balance is the most important consideration. Thus the lowest authorised strength and dose of a product are often considered the most appropriate for a reclassification candidate. The group considered the example of simvastatin where there had been concern in relation to the efficacy of the product. They recognised that this was not the only factor which affected the success of this reclassification as the indication was for a symptomless long term condition. It was agreed that products which provide quick relief for easily recognisable symptoms are more likely to be successful.

d. **Do drug companies lead all reclassifications or does the MHRA encourage changes?**

Pharmaceutical companies nearly always lead reclassifications as they have access to the necessary data to support a reclassification application.

e. **POM to P changes are being promoted to save NHS money**

There is no evidence of money being saved.

The MHRA focus is on wider access and choice where it is considered safe.

The group noted the following points:

- there is a perception amongst GPs that POM to P represented a diversion from GPs to pharmacists to help reduce the pressure on GPs
- the government aim is for pharmacists to be the first port of call for advice and access to short term treatment of minor conditions
- to contribute to government aims, it is important that pharmacists are enabled by having access to a range of effective non-prescription medicines and suitable information.

f. **The cautions/ contra-indications for a product are modified by the MHRA after submission of a reclassification proposal**

These may be changed both by the applicant and MHRA as extra measures to safeguard patients.

g. **It is not worth responding to consultations on reclassifications as the decision has already been made**

The outcome of a reclassification may change if important new, hard evidence, not previously considered, is submitted in response to a consultation. Many respondents raise issues which either are not new or are not supported by suitable evidence.

The group considered that this aspect should be clarified for those responding to consultations. The involvement of a Stakeholder Group at an earlier stage of the reclassification assessment process would provide an opportunity for key stakeholders to be involved before the consultation was issued.

h. **The more responses received then the more impact these responses will have on the final decision**

A number of factors affect the weight of responses, such as the nature or safety implications of the issue raised and whether from an individual or organisation. A good quality response is preferable to numerous poor quality ones.

The group considered this needed to be clarified in the explanation on the outcome of a reclassification.

i. **If a product is reclassified to P, it is only a matter of time before it becomes GSL**

This is not necessarily the case. Certain products, currently P, are very unlikely to ever be available as GSL, such as those where there is good evidence that the role of the pharmacist was necessary to ensure safe supply, by intervention or other means.

The GSL classification reflects a lifecycle element in the use of medicines, based on safety in use. Patients become familiar with a product from pharmacies and when they feel competent to self-medicate without help, they seek greater choice in where to obtain their medicines.

j. **Manufacturers are no longer interested in switches to P**

Based on experience of POM to P reclassifications so far, companies have become more realistic about the likelihood of commercial success for future candidate products. The Reclassification Guideline of December 2012 was aimed at streamlining the reclassification process to encourage well-considered reclassifications. The industry observer noted that reclassifications are the principal source of innovation in the OTC pharmaceutical industry.

The group considered it would be helpful to have information about why reclassifications were not taken forward to completion, where the reason was not clear.

<u>Overall Discussion on 'myths'</u>

The group suggested that more information and clarification on all the above issues would be useful for doctors and pharmacists. This may be a suitable topic for an article in the professional press, which might also provide an opportunity to introduce the Stakeholder Platform and its role.

5. Successful and unsuccessful reclassifications

The group discussed the factors which influenced the success of two reclassified products:

a. **Levonelle**

Following reclassification, this has been one of the most successful products. The group considered this was influenced by the following factors:

- a pharmacy protocol was provided, together with a questionnaire
- training was widely available to support pharmacy practice
- the POM product had been available in some areas under a Patient Group Direction (PGD) and experience from this was used to inform the supply method for the P product
- the product met a very specific healthcare need for women and there was a clear public health benefit
- there were few changes to the Summary of Product Characteristics, the key one being the age restriction to 16 years
- the reclassification was supported by a wide range of healthcare professionals.

Pharmacy Platform members suggested that the protocol, questionnaire and training were needed at the time because of the sensitivity of the therapeutic area. However, pharmacy practice had moved on considerably since this reclassification and product specific protocols and questionnaires might not be needed in the future.

b. **Simvastatin**

The reclassification of simvastatin was not considered to have been a success. The Group considered that the factors which had contributed to this were:

- the indication was different from the POM product
- the efficacy of the lower dose 10mg product was considered sub-therapeutic, where the majority of data supported the higher strengths
- pharmacists had little faith in the product, in spite of the questionnaire (considered too complicated) and pharmacy training provided
- the condition treated by the product was symptomless and patients could not relate to it.

The group considered that the lessons to be learnt were:

- the indication should be easier for patients to understand i.e. associated with reducing cholesterol levels
- efficacy should be suitable
- a suitable pharmacy diagnostic tool should be made available
- complicated questionnaires should be avoided.

In addition to concerns about the indication and the dose, overall, the Group considered that the reclassification of simvastatin was perhaps ahead of its time with regard to the therapeutic area. The Group also agreed that further consideration was needed of what doctors, pharmacists and the public would like to see reclassified.

6. Public Consultation

The group noted that the new reclassification guideline included a new style of consultation, on the basis of the public assessment report rather than a summary prepared by the applicant.

The group reviewed the recently published consultation document for Soleve. They considered it was an improvement over the earlier style but also put forward suggestions for further improvements. In particular it would help if the document was written with specific reader groups in mind. It needed to include focussed questions and be divided into sections aimed for example at members of the public (label and leaflet) and professional (SPC and RMP). The style may need to differ for POM to P compared to P to GSL applications.

The group continued with a discussion on the value of public consultation, especially in relation to the extent to which respondents such as patients and members of the public could influence the outcome of a reclassification proposal. In reality only informed patients might be in a position to respond to a consultation in its present form. The group questioned whether public consultation was the best way to obtain feedback and suggested another form of effective 'engagement' may be worth considering. The group suggested it might be unrealistic to involve large numbers of members of the public nationally and that a patient consultative group may be a more effective way to obtain suitable input to a proposed reclassification.

In terms of healthcare professional engagement, involvement in the stakeholder group for a specific reclassification may be preferable to the present public consultation arrangements. The stakeholder group would give professional organisations the opportunity for greater involvement and influence at an earlier stage in the process.

It was agreed that further consideration was required to establish whether these different ways of consulting would be feasible; and how a new process would operate. For the stakeholder group it would be important to establish a suitable dialogue between MHRA and professional organisations such as the Royal Pharmaceutical Society and the Royal College of General Practitioners. Issues to consider included avoiding any conflicts of interest and ensuring that views expressed by professional organisations reflected a representative opinion and not that of an individual.

7. Next steps

The group noted that the provisional work plan would be circulated prior to the next meeting.

8. Date of next meeting

To be notified.