

UK Stakeholder Platform for Reclassification of Non-prescription Medicines

Meeting held on Tuesday 8 September 2015, 10AM, in Room RT416,
MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ

MINUTES

Present

Johanne Barry
Rob Darracott
Gul Root
Ash Soni
Ruth Wakeman
Bruce Warner

MHRA

Jan MacDonald (Chair)
Colette McCreedy
Janine Jolly
Nesta Thomas
Amanda Williams

Observers

Paul Fleming
Helen Darracott

Apologies were received from Simon Adams, Marguerite Beard-Gould, Martin Duerden, Trevor Fernandes, Andrew Green, Alpana Mair, Bob McNab, Theo Raynor, Roger Walker, and Sunayana Shah.

1. Introduction

Platform members were welcomed to the meeting of the Platform and all members introduced themselves. For members who were attending their first meeting a background to the Stakeholder Platform on Reclassification was provided.

2. Case studies – chloramphenicol and tamsulosin

The Platform discussed the factors that influenced the success of two reclassified products:

a. Chloramphenicol

This was considered to have been a successful reclassification. The following factors had contributed to the success:

- It was a product that pharmacists wanted to be available as a P medicine
- It was indicated for condition for which people already sought advice in the pharmacy
- The RPS guidance was useful in ensuring supply was appropriate
- Pharmacists would be supplying the product under the same circumstances as a GP
- The indication was easily identified, with clear red flag symptoms that required referral to a doctor
- there were few changes to the Summary of Product Characteristics, the key one being the age restriction to 2 years

The Platform considered that there were some difficulties with the reclassification:

- Many pharmacists had wanted the lower age range to be 18 months; this would have saved more unnecessary visits to the doctor, with no greater risk to public health. The reason for the two year age cut-off had not been explained clearly enough
- There had been negative press about the availability of the product from pharmacies including from the medical profession
- Whilst the scientific evidence of microbial resistance is absent, if this product was reclassified now there might be difficulties due to national and European concerns about antimicrobial resistance
- The supply model should have included referral to the most appropriate healthcare professional which may not necessarily have been a doctor (in this case an optometrist or contact lens practitioner might have been most appropriate).

b. Tamsulosin

The reclassification of tamsulosin was not considered to have been a success. Factors contributing to this were:

- The complicated two week, then four week, supply; patients would rather go straight to their GP if they had to eventually attend their GP at the two or six week point
- Part of the supply model involved sending patients to their GP; however, GPs were not prepared for or aware of this model.
- The questionnaire was too long, for both pharmacists, and patients

The Platform considered that the lessons to be learnt were:

- GPs should be fully engaged with their role in the OTC pharmacy supply model.
- The frequency and duration of supply should be simpler.
- Positioning this product as part of a “men’s health MOT” might have worked better, although funding would have had to be addressed
- Complicated questionnaires should be avoided.
- What had been gained by access had been lost by making the supply model too complicated.

The Platform considered that the reclassification of tamsulosin had perhaps been ahead of its time with regard to the therapeutic area and with respect to the pharmacist/GP shared care model. It may have been better to develop a supply through a PGD first to inform the reclassification. The Platform also considered that a challenging reclassification such as this might be more successful if pharmacists had access to the summary care record. However, the Platform considered that the availability of the P product had worked well generally in raising awareness of prostate problems, bringing men into healthcare, albeit not necessarily into pharmacies.

3. Ad hoc groups

The Platform members’ views were sought on the membership, recruitment, governance and procedures for setting up and running ad hoc stakeholder

groups which would be set up to consider specific innovative POM to P reclassification applications. It had been proposed that membership of the ad hoc groups would comprise:

- Chair (A member of CHM and appointed by CHM)
- Representative of the Royal Pharmaceutical Society
- Representative of the Royal College of General Practitioners
- Consultant in the relevant therapeutic area
- GP with a special interest in the relevant therapeutic area
- Pharmacist with a special interest in the relevant therapeutic area
- Practising GP
- Practising employee community pharmacist
- At least four patients/patient representatives

The Platform considered that it was critically important that the membership included practising healthcare professionals who had regular patient contact. It was also agreed that all members of an ad hoc group should be confident in expressing their opinion within a diverse group of people with different levels of knowledge, skills and experience and that this needed to be reflected in the recruitment process.

The Platform discussed the option of having the meeting as a webinar to enable more people to attend. However, it was agreed that this was not a preferable option as a face to face meeting would enable better discussion and exchange of views between the different stakeholders.

The Platform agreed that, depending on the reclassification application, consideration should be given to widening the membership of the group to include, for example, pharmacy support staff and other healthcare professionals. Independent pharmacy owners should not be excluded from membership of a group provided they were pharmacists practising in a patient facing role and met the other recruitment criteria.

Consideration was given to proposals for recruitment and desired skills and experience of members of an ad hoc group. The Platform also discussed what should be the main focus when considering a reclassification, and what information and support members of an ad hoc group would need to ensure they could effectively advise CHM. A number of suggestions were made and it was agreed that specifications for ad hoc group members should be amended to reflect the views of the group and circulated for further comment.

4. Public reclassification report

The Platform was provided with an example of a draft public reclassification report, revised based on comments received from the previous meeting.

The Platform agreed that the revised report was an improvement on previous versions. It was agreed that a clear, very high level summary of the conclusions of the reclassification assessment should be included in a one page summary at the beginning of the report and that the report should include information about any consultation with an ad hoc group and/or CHM, as applicable.

The Platform noted that the comments made would be reflected in the style and content of future public reclassification reports.

5. Next steps

The next meeting would be on **7 December 2015**.

At the next meeting it was proposed to consider further the running of an ad hoc stakeholder group; analyse the risk minimisation measures used as part of the reclassification process and analyse the communication of decisions on reclassification.