ROYAL PHARMACEUTICAL SOCIETY

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Abiodun Aderogba
Medicines and Healthcare Regulatory Agency
Area 3-M
151 Buckingham Palace Road
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31st August 2012

Dear Abiodun Aderogba,

**Re: HOW TO CHANGE THE LEGAL CLASSIFICATION OF A MEDICINE IN THE UK**

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

The RPS welcomes the proposals for clear guidance on the procedures for changing the legal classification of medicines, however would like the MHRA to consider the following points:

**1. Introduction**
The introduction makes reference to the different classification of medicines and explains that "if further experience demonstrates that access to professional advice is not required for safe use of the medicine, it may then be reclassified as a General Sale List (GSL) medicine", however we believe that to ensure medicines are supplied appropriately and safely, professional advice should always be available where medicines are sold or supplied. General retail stores will not be able to offer the expert advice available in pharmacies and untrained staff will not be able to intervene where there is an issue, e.g. with overuse, repeat purchases, nor could they provide further information about treatments.

**4.1 Evaluation of the switch candidate by applicant**
The RPS has developed strong partnerships with specialist groups who can offer expert advice at this stage. Additional the RPS can help applicants work through practical issues and provide a general view on the suitability of a POM to P switch.

**4.2 Scientific Advice Meetings**
We agree that it is critical to involve key stakeholders, such as relevant professional bodies at scientific advice meetings. Representatives from our specialist groups can additionally provide expertise at these meetings. We also believe that it is imperative to include pharmacists in these meetings as they can provide a view of how the switch may affect day to day practice.

We support the view that the aim of these meeting would be to verify the non-prescription supply model, to ensure that the process for sale and supply of the P medicine is clear and will work in practice.

It may not be appropriate to discuss future P to GSL reclassifications at these meetings as it will change the focus, and points to be considered would be different to a POM to P

reclassification, however it would be useful to be made aware of any proposed plans at this stage.

This section states that “advice meetings are not compulsory, but are at the discretion of the applicant”, however we feel that these meetings are strongly advised for all novel POM to P reclassifications, as from experience, these meetings are particularly beneficial for all parties involved.

**5.4 Application routes**
This section makes references to MAs and names, however does not provide details of naming POM and non-prescription products that differ in strength. We think that this point should be clarified to include this information, i.e. where medicines are of different strengths they should be distinguishable by name to avoid confusion.

**5.5 Content of Reclassification Applications**
***Reclassification clinical overview***
Again we believe that all medicines should be sold or supplied in a pharmacy where advice from a pharmacist and trained pharmacy support staff can be sought.

***Risk management plan***
It is important that for any new POM to P switch a comprehensive training pack is provided for pharmacists and their teams and as the professional body we are able to support manufacturers when developing their resources. The RPS additionally produces professional guidance for pharmacists on newly classified P medicines and it would be useful to ensure that any training is aligned with the RPS guidance.

**6.1 Major Applications**
***Stakeholder advice***
We would like further clarification on which organisations or individuals should be involved at this stage. Pharmacists can provide a valuable contribution and offer their expert advice on clinical and pharmacy delivery.

***Public comment***
This provides an opportunity for organisations such as the RPS to gather views from our members and present a collective response. It also allows pharmacists who will be impacted by the reclassification to present their views.

It would be useful for the MHRA to alert stakeholders directly when reports are published on the website for consultation. This will also be a reminder to those who have already provided comments to make further observations as necessary.

**6.2 Standard Applications**
Although standard applications do not require expert advice, we would recommend to still involve certain stakeholders, including the RPS, at an early stage, as these reclassifications may not be as straight forward as originally anticipated. The RPS has commented on such applications previously and has highlighted issues. Perhaps it may be more suitable to contact stakeholders directly where necessary.

**7.1 Completion of application procedures**
Once a medicine has been successfully reclassified, it would be helpful to directly inform stakeholders involved. The RPS would be particularly interested in this information as it will impact production and publication schedules for our member support resources.

**8.1 RMP implementation**
This section makes reference to specific risk management activities after approval, including training, education, pharmacy sales protocol, public advice, which the RPS can assist with. The RPS has provided professional support directly to manufacturers to assist them in producing guidance.

**Appendix 2**
This section makes reference to the provisions of Part III of the Medicines Act 1968 and GSL medicines. It may be useful to provide illustrative examples of "with reasonable safety" as well as providing a definition.

**Appendix 3**
Risks and benefits of all reclassifications should be made clear as this will provide those commenting to understand why a medicine should be reclassified.

***1. POM to P reclassifications application***
Inclusion of an SPC and mock up patient information is important as stakeholders are able to make suggestions for improvement, for example where information can be confusing.

***2. Content of P – GSL reclassification application***
- The RPS is interested in the justification on how GSL products may be safely and appropriately supplied without the supervision of a pharmacist.
- Information for GSL medicines should contain clear details for patient about situation where they should seek advice from pharmacists.

**Appendix 4**
Again the RPS agrees that pharmacy educational material is provided where necessary, and can support with relevant training and support material for pharmacists.

Thank you for providing the RPS with the opportunity to comment on this consultation. We hope these points are useful.

Kind regards,

Helen Chang
Senior Professional Support Pharmacist