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Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Bryan,

Re: Consultation Letter MLX 337 – Proposals to restrict the availability of medicines containing pesudoephedrine and ephedrine by a change to legal status from Pharmacy (P) to Prescription Only (POM) together with a restriction in pack size

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

Pharmacists are experts in the use of medicines and can provide information and advice relating to the management of various conditions including minor ailments. We believe that supply of over-the-counter medicines such as cold remedies and nasal decongestants from

pharmacies can help improve patient choice, convenience and access to treatment. In addition, trained pharmacy staff, including medicines counter assistants can safely and competently supply such products or refer to the pharmacist where necessary.

The Society has considered the options for action set out in the consultation letter.

Option 1 – no action until the threat is proven
We agree that this is not an effective response.

Option 2 – a package of non-statutory measures on the sale of pseudoephedrine and ephedrine containing medicines
The Society believes that Option 2 is the most viable of the four options proposed.

Options 3 and 4 – POM control
The RPSGB strongly opposes the proposal to reclassify these products as prescription only and requests that the points cited in the attached briefing sent to Parliamentarians are taken into consideration.

In addition, the following matters have been highlighted by colleagues in Scotland.

Recent efforts by the Scottish Executive and the pharmacy profession have sought to enhance the delivery of pharmaceutical care to patients. In Scotland, a number of methods are being used to do this. Amongst these are the extension of prescribing rights to pharmacists, the promotion of self-care, POM to P switches and the launch of the Pharmaceutical Care Services Contract for community pharmacy.

In Scotland, there now exists as one of the four core elements of the contract, a national Minor Ailment Service (MAS). This service not only offers patients faster access to pharmaceutical care, advice, and where needed, treatment for minor ailments, including colds and influenza, it contributes to reduced demands on GP time by allowing GPs to spend more time with those patients who need to be seen by a doctor. The proposal to reclassify pseudoephedrine to POM status could significantly impact on the MAS whilst also impacting on the delivery of patient care by GPs.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely

Sadia Khan
Lead Pharmacist for Self-care

INTRODUCTION

This briefing sets out the RPSGB's position on an important matter that has been raised in Parliament and is the subject of a consultation by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Concerns have been raised by the Association of Chief Police Officers (ACPO) and the Serious Organised Crime Agency (SOCA) that pseudoephedrine and ephedrine can be extracted from common cold remedies relatively easily and used in the manufacture of methylamphetamine, currently classified as a Class A controlled drug.

In light of concerns linking the manufacture of methylamphetamine to cold remedies, SOCA has previously liaised with the RPSGB and advice has been issued to pharmacists highlighting that requests for inappropriately large quantities of products containing pseudoephedrine and ephedrine should be treated with caution.

Following recommendations from the Commission on Human Medicines (CHM), the MHRA announced a consultation in March 2007 on proposals to restrict the availability of medicines containing pseudoephedrine and ephedrine.

The proposals include a change to legal status from Pharmacy availability (P) to Prescription Only Medicine (POM), together with a restriction in pack size[1].

The RPSGB, as well as patients and consumers, strongly oppose the proposal to reclassify all pseudoephedrine and ephedrine containing medicines from Pharmacy (P) to Prescription Only Medicine (POM) status. The intelligence picture in the UK implicating pseudoephedrine and ephedrine containing medicines is still limited, and reclassification appears to be a disproportionate response to the problem and out of step with other countries. In particular, it would have an impact on drug accessibility and NHS costs, and drive up GPs' workload.

The pharmacy profession, the industry and wholesalers recognise that this is a critical issue and are putting forward a practical solution. In terms of monitoring supplies to pharmacies,

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[1] The United Kingdom has a three-tiered classification system. The legal status of medicinal products is part of the marketing authorisation (MA) and products may be available either on a prescription (Prescription Only Medicines [POMs]), or available in a pharmacy without prescription, under the supervision of a pharmacist (P) or on general sale from any retail outlet (GSL).

wholesalers track who they have supplied pseudoephedrine and ephedrine to and the RPSGB can provide targeted inspection in areas where there may be peaks in supply.

THE CURRENT SITUATION

The Government's current position

In April 2007, Health Minister Caroline Flint MP responded to a House of Commons written question, asking the Secretary of State for Health whether she would publish advice received on making medicines containing pseudoephedrine available on prescription only.

The Minister referred to the concerns raised by ACPO and SOCA that pseudoephedrine and ephedrine can be extracted from cold remedies relatively easily and used in the manufacture of methylamphetamine. The Minister said that although the prevalence of misuse of methylamphetamine is believed to be currently low in the United Kingdom, ACPO are receiving increasing levels of intelligence about the prevalence of methylamphetamine.

The Minister went on to refer to the work of the Commission on Human Medicines (CHM) which has considered the evidence of a risk to public health from the availability of pseudoephedrine and ephedrine. The CHM has recommended that changing the legal status of pseudoephedrine and ephedrine, together with restricting the pack size is necessary to protect public health in the UK and that a consultation exercise should be conducted on these proposals. Ministers have accepted this advice and a full public consultation exercise by the MHRA commenced on 7th March 2007.

The All-Party Parliamentary Group for Primary Care and Public Health and the All-Party Parliamentary Group for Drug Misuse have also begun a joint inquiry into the MHRA's proposals.

The problem of methylamphetamine abuse

A discussion amongst stakeholders has indicated that although the intelligence picture in the UK is still limited, 'over the counter' pseudoephedrine has only been implicated in one case in the Isle of Wight.

The RPSGB is aware of the steps to restrict availability that have already been taken in countries where methylamphetamine abuse is an established problem, including the US, Canada, Australia and New Zealand.

Since 2006, federal restrictions in the US have limited availability to 'behind the counter' bringing the US more in line with the UK Pharmacy category, which the US currently lacks.[2] Note that this need not be a pharmacy dispensary counter, it could be behind a general merchandise counter at the front-end of a pharmacy or non-pharmacy store. Individual states must follow the federal law, plus they can add further restrictions. Only one state, Oregon, has limited the two ingredients to prescription-only. The federal restrictions have reduced domestic illicit laboratories (not yet much of a problem in the UK) without reducing imports from Mexico.

SOCA has indicated that 200 tablets of 60mg pseudoephedrine would produce a maximum 11g; with 1g being one hit.

The management of sales by pharmacists

- Pharmacists are well placed to manage the sale of pseudoephedrine and ephedrine containing medicines. Pharmacists educated and trained in Great Britain must now complete five years training, including a degree course, pre-registration year and a registration examination. Patient safety is paramount, and safe use of medicines starts by visiting your pharmacy.

- Pharmacists are experts in the use of medicines and can provide information and advice relating to the management of various conditions, including minor ailments. Supply of medicines such as cold remedies from pharmacies can help improve patient choice, convenience and access to treatment.

- The Government is committed to making medicines more widely available to the public and expanding the role of pharmacists. Allowing pharmacists and their support staff to continue to manage the supply of pseudoephedrine and ephedrine containing products gives a clear signal of faith in the profession.

THE IMPACT OF RECLASSIFICATION

The accessibility of medicines

Consumers expect choice and convenience. Pharmacists can offer fast, convenient and safe access to effective self care options for those who may need it. Reclassification to prescription

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[2] In the US there is a two-tiered classification system: over the counter (OTC) and prescription-only (Rx-only). OTC medicines are available from any retail outlet.

only (POM) status will decrease consumers' accessibility to a well-used and trusted product. Pseudoephedrine and ephedrine containing medicines are widely used as decongestants and there are currently many products that could be affected by this reclassification.

There will be a reduction in choice available to manufacturers in formulating these products if pseudoephedrine and ephedrine are removed. Reformulation could mean lengthy delays to the introduction of replacement products and significant disruption to access of cold treatments should manufacturers be forced to reformulate. This carries particular risks at a time when there are concerns that a pandemic influenza outbreak might strike. Clearly such a move would increase risk to public health and be entirely disproportionate to the threat. Manufacturers may also decide not to reformulate products leading to their withdrawal from the market.

Reclassification also sends a negative signal to the public and media about these products. It draws attention to an abuse potential that might be interpreted in the media as something intrinsically wrong with the active ingredients as opposed to their use as possible precursors for the illicit manufacture of methylamphetamine.

Doctors' workload and NHS costs

The RPSGB believes that reclassification will increase workload, particularly if there is a bad flu season. NHS costs could also increase as a result of the reclassification. In the long-term, consideration may need to be given to setting up national minor ailment schemes to relieve GP workload in England, Wales and Northern Ireland – however any national scheme will impact on existing local schemes[3]. In Scotland, reclassification could result in potential withdrawal of pseudoephedrine and ephedrine products from the existing minor ailment scheme, causing patients to have to visit a GP for a prescription.

Medicine prices

The RPSGB does not believe that the majority of the population should be inconvenienced in order to reduce what is currently seen as a small future risk when other, more proportionate, approaches could be used. Reclassification might also transfer costs from the public (via Pharmacy sales) to the NHS (as free prescriptions).

CONCLUSION: THE SOCIETY'S RECOMMENDATIONS

- The RPSGB believes that the potential for widespread misuse could be controlled by retaining 'P' status and tightening control through the pharmacy by limitation of pack sizes to 720mg (equivalent of 12 x 60mg tablets) and restriction to one pack per purchase. The Society suggests that the products should be added to an MHRA 'watch list' of substances liable to misuse.

- The RPSGB would also consider providing support for development of practice guidance to help prevent the diversion of pseudoephedrine and ephedrine containing products. Support could also possibly be provided for development of training material aimed at pharmacy staff as well as input into public education campaigns. The Society does not favour any one particular course provider over another.

- In terms of monitoring supplies to pharmacies, wholesalers track who they have supplied pseudoephedrine and ephedrine to. The RPSGB can provide targeted inspection in areas where there may be peaks in supply.

- The RPSGB recommends that pseudoephedrine and ephedrine containing products should not be available for self-selection.

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[3] A community pharmacy minor ailment scheme enables patients to consult a participating community pharmacy, rather than their medical practice, for advice and treatment for minor ailments. In the UK, different models are used for delivery.