

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Libby,

Re: All Party Parliamentary Groups – written evidence on proposals to restrict the availability of medicines containing ephedrine and pseudoephedrine

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

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.

Please find attached the Society's written submission.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care

RPSGB submission to the All Party Parliamentary Groups – Proposals to restrict the availability of medicines containing ephedrine and pseudoephedrine

(1) From your perspective, how much of a problem is methylamphetamine abuse?

Following a meeting at the PAGB headquarters on the 22nd March the RPSGB was made aware of the Serious Organised Crime Agency (SOCA) assessment concerning the threat to the UK from methylamphetamine. The report states that 'harm that is currently caused to the UK from methylamphetamine is comparatively low, the threat of future harm is great'.

In light of concerns linking methamphetamine to cold remedies, SOCA previously liaised with the RPSGB and advice was issued to pharmacists highlighting that requests for inappropriately large quantities of products containing ephedrine and pseudoephedrine should be treated with caution. See Law and Ethics Bulletin. The Pharmaceutical Journal 2007: vol 278: p114 (27 January 2007).

A discussion amongst stakeholders has indicated that although the intelligence picture in the UK is still limited, over-the-counter (OTC) pseudoephedrine has only been implicated in one case (Isle of Wight). The Society 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. Federal restrictions in the US have limited availability to behind the counter bringing the US more in line with / akin to a Pharmacy category (which the US currently lacks). This has reduced domestic illicit laboratories (not yet much of a UK problem) without reducing imports from Mexico.

(2) Do you feel that there is a need for reclassification of ephedrine and pseudoephedrine-containing medicines?

No. As there is a low intelligence picture implicating ephedrine and pseudoephedrine-containing medicines, reclassification appears to be a disproportionate response to the problem. The Society advocates a more measured stepwise approach to the possibility that purchases could be used to manufacture methamphetamine.

The Society's Council agreed at its March Committee meeting to strongly oppose the proposal to reclassify all ephedrine and pseudoephedrine containing medicines from P to POM status.

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 / ephedrine containing products gives a clear signal of faith in the profession. Pharmacists can select the right product for each patient, based on symptoms, or recommend no treatment or a referral as necessary.

(3) Do you feel pharmacists are well placed to manage the sale of ephedrine and pseudoephedrine containing medicines?

Yes. 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 / public 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 OTC medicines such as cold remedies from pharmacies can help improve patient choice, convenience and access to treatment.

(4) What impact do you think reclassification will have on consumers' accessibility of medicines containing ephedrine and pseudoephedrine?

People want choice and convenience. Pharmacists can offer fast, convenient and safe access to effective self care options for those who may need it. Reclassification to POM status will decrease consumers' accessibility to a well-used and trusted OTC product. Pseudoephedrine / ephedrine containing medicines are widely used as decongestants and there are currently many OTC products that could be affected by this reclassification. 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 at a time when a pandemic 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 OTC 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.

(5) What impact do you think reclassification will have on doctors' workload and NHS costs?

The Society believes that it 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 a national minor ailments scheme to relieve GP workload. A national scheme may impact on existing schemes in Scotland, Northern Ireland, Wales and some parts of England.

(6) Consumers will be forced to pay a higher price for their medicines if the reclassification goes ahead, do you think this is justified?

The Society 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).

(7) What measures would you recommend?

At the Society's March Council meeting, it was agreed that the potential for widespread misuse could be controlled via retaining P status and tightening control through pharmacy (limit maximum pack size to 720mg pseudoephedrine / ephedrine and restrict to one pack per purchase). In addition, it was agreed that the products should be added to a 'watch list' of substances liable to misuse.

The Society would also consider providing support for development of practice guidance to help prevent the diversion of pseudoephedrine / ephedrine containing products. Support could also possibly be provided for development of training material aimed at pharmacy staff'.

(8) Do you believe that OTC products are readily available to replace those that contain ephedrine and pseudoephedrine?

Alternative OTC products are cited in Consultation Letter MLX 337. The Society has not collated statistics on the number of commercially available products containing the alternative ingredients.

A search of standard information sources has indicated that further research is required to establish the efficacy of alternative decongestants.

The Society notes that there will be a reduction in choice available to manufacturers in formulating OTC products if pseudoephedrine / ephedrine are removed.