



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Amanda Bryan
Vigilance & Risk Management of Medicines Division
MHRA
Room 14-212, Market Towers
1 Nine Elms Lane
London
SW8 5NQ

PRACTICE & QUALITY
IMPROVEMENT DIRECTORATE
Practice Division
Telephone: 020 7572 2537
Facsimile: 020 7572 2501
e-mail: sadia.khan@rpsgb.org

13 November 2007

Dear Ms Bryan,

Re: Consultation Letter MLX 343 – Proposals to amend the Prescription Only Medicines (Human Use) Order 1997 (The POM Order) to make the sale and supply of products containing more than 720mg Pseudoephedrine and 180mg Ephedrine subject to a prescription

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.

The Society requests that the following points are taken into consideration:

- i. The Commission on Human Medicines (CHM) has recommended that the legal status of medicinal products containing pseudoephedrine and ephedrine should be reclassified from P to POM in 24 months time (July 2009) unless the risk of misuse of these over-the-counter medicines in the illicit manufacture of methylamphetamine is

contained; or at any time before then should evidence emerge that misuse has not been contained. However, the MHRA is proposing an amendment to the POM Order with a transitional period for implementation of 1 April 2008.

The Society seeks feedback on why earlier legislative POM control is required.

- ii. It is unclear from the consultation document how long the transitional period is expected to last / when the legislation is intended to come into force. We suggest at least three months from the statute coming into force and the provisions taking effect otherwise numerous pharmacists will be committing offences. This scenario would impact on the Society's inspectorate as the Society has enforcement jurisdiction in pharmacies for breach of s58 of the Medicines Act 1968 (supply of POM without a prescription).
- iii. Section 7.8 (Annex B) highlights that 'the cost associated with the enforcement of the legislation will fall to the Royal Pharmaceutical Society as part of its inspection of community pharmacies'. Although the costs of inspection will not increase, possible investigation costs will increase if the transitional period is not sufficiently long to allow pharmacists to comply with the new legislation. The transition period needs to allow for existing packs held in stock within pharmacies to be exhausted. After the legislation comes into force pharmacists will no longer be able to supply the larger P packs - supplies of incorrectly labelled and leafleted products will be an offence.
- iv. Section 7.2 highlights that the CHM has recommended a limit of one pack per sales transaction. Section 13 states that 'pharmacists would be able to supply legally smaller packs up to a total of 720mg of pseudoephedrine or 180mg ephedrine, e.g. two packs containing 6 tablets x 60mg pseudoephedrine, but professional guidance would advise to restrict the sale to one pack (whatever size) in on transaction'.

The Society questions why the pharmacist (or an appropriately trained delegated member of staff) cannot sell two packs of 6 tablets x 60mg pseudoephedrine – we do not envisage a risk to the customer in this scenario. The Society's Code of Ethics for Pharmacists and Pharmacy Technicians also allows for pharmacists to use their professional judgment if faced with a request for more than one pack (e.g. adult and infant formulations).

The Society wishes to highlight that if a professional restriction was put in place, this would not be enforceable unless it was a mandatory professional requirement or where a breach of the Code of Ethics occurred as a result of the sale.

The Society believes that the focus of the professional guidance should be on areas of possible high risk (requests for excessive quantities, multiple repeat requests etc) not restricting sales to one pack per transaction.

To summarise, the Society opposes the proposal to make it an offence for pharmacists to sell more than the amounts specified (see Section 13) in one transaction. We believe that if faced with a scenario where for example a customer requests both an adult formulation and a liquid infant formulation at the same time, pharmacists should be able to exercise their professional judgment and consider supplying both products without having committed a criminal offence. An alternative approach might be for the CHM to amend the POM Order to specify a higher limit - c1400mg pseudoephedrine – this would enable pharmacists to still supply one pack of solid / one pack of liquid dose formulation in a single transaction if deemed to be appropriate.

In terms of pack size restrictions, the Society supports the proposal to restrict pack size provided that the points previously made concerning the transition period / legislation coming into force are taken into account.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely

Sadia Khan
Lead Pharmacist for Self-care