

Amanda Bryan  
MHRA  
Room 14-212, Market Towers  
1 Nine Elms Lane  
LONDON SW8 5NQ

Dear Ms Bryan

### **CONSULTATION LETTER MLX 337**

#### **PROPOSALS TO RESTRICT THE AVAILABILITY OF MEDICINES CONTAINING PSEUDOEPHEDRINE AND EPHEDRINE BY A CHANGE TO LEGAL STATUS FROM PHARMACY (P) TO PRESCRIPTION ONLY (POM) TOGETHER WITH A RESTRICTION IN PACK SIZE**

I am responding on behalf of Community Pharmacy Scotland (formerly the Scottish Pharmaceutical General Council) which is the body recognised to represent Scottish pharmacist contractors in negotiations with the Scottish Executive on matters pertaining to the provision of pharmaceutical care services.

Our comments on the proposals set out in the above consultation letters are as follows.

Community Pharmacy Scotland has considered carefully both the evidence put forward in relation to the reports of the misuse of pseudoephedrine and ephedrine in the manufacture of methylamphetamine and the supplementary information subsequently published on the MHRA website. We share the concerns of others about the possible consequences if the misuse of methylamphetamine were to increase dramatically, but we do not find the evidence presented sufficiently compelling to support such a draconian proposal. There are also other reasons to argue against the proposal.

Pseudoephedrine and ephedrine are popular products, widely used either alone or in combination with other analgesics or other ingredients, for the symptomatic relief of colds, flu and other similar conditions. They are the product of choice for many patients who wish to self medicate. In Scotland, where it is also possible for community pharmacists to prescribe for patients registered with them for provision of the Minor Ailment Service (a core service under the new pharmaceutical care services contract), pseudoephedrine has consistently featured as one of the top 10 items prescribed. The evidence therefore suggests that these products are both effective and valued. By contrast, the feedback from our members on the alternative products currently available is less positive.

If the decision is taken to reclassify these products from P to POM, Community Pharmacy Scotland has concerns about the potential pressure on the NHS if patients decide not to continue with self medication but instead seek an appointment with their doctor. The change would also have consequences for prescribing under the Minor Ailment Service because (most) pharmacists would be unable to continue to prescribe the products unless and until a PGD was put in place. The procedures for the introduction of a PGD

are cumbersome and we therefore fear that part of the rationale behind the introduction of this service – to improve ease of access for patients to NHS services – will be lost.

Evidence has been presented from other countries on the ease with which people have been able to obtain supplies of pseudoephedrine and ephedrine for use in illicit manufacture of methylamphetamine. However the controls in place on these products were not as strict as they are in the UK plus there is evidence that the products used for manufacturing were not purchased but stolen from other points in the supply chain. In Scotland we also have additional safeguards because many patients receive the product as a result of a MAS consultation rather than an OTC sale.

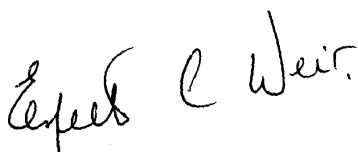
The supplementary evidence from one pilot study suggested that teenagers were able to obtain large supplies of the products relatively easily. However the survey took place before RPSGB issued further guidance on a pharmacist's obligations in relation to the sale/supply of these products and before this consultation raised awareness of the problem.

Community pharmacies already have informal procedures in place to allow them to monitor the purchase of certain products, e.g. codeine linctus, paramol tablets, kaolin and morphine mixture. The suggestion that control will only be effective when products are prescription-only fails to recognise the input which pharmacists can bring to this issue. Other options are available and it may be that we should explore the provision of educational material. In any event, it is our view that by taking a pro-active stance on the supply of this product, through ensuring that appropriate standard operating procedures are in place, pharmacists will be able to contribute to any necessary restrictions around supply, **without the need for legal measures.**

In order to recognise the concerns that exist around the availability of these products, Community Pharmacy Scotland does support the proposal to limit the maximum pack size to 720mg of pseudoephedrine (12 x 60mg tablets or 24 x 30mg tablets in a combination pack or equivalent in other formulations) for all relevant authorised products.

Our comments may be made freely available.

Yours sincerely

A handwritten signature in black ink, appearing to read 'E C Weir', written in a cursive style.

Dr E C Weir  
Head of Policy & Development