

29 August 2007

Dear Sir/Madam

## **OUTCOME OF CONSULTATION MLX 337 ON PROPOSALS TO RESTRICT THE AVAILABILITY OF MEDICINES CONTAINING PSEUDOEPHEDRINE AND EPHEDRINE**

Thank you for responding to consultation exercise MLX 337, on 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 in the light of reports of misuse of these medicines in the manufacture of the Class A controlled drug methylamphetamine. The responses to the consultation exercise were considered by the Commission on Human Medicines (CHM) in July 2007 and I am writing to inform you of the outcome.

In summary the CHM advised that

1. 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 (OTC) medicines in the illicit manufacture of methylamphetamine is contained; or at any time before then should evidence emerge that misuse has not been contained.

2. The following pharmacy measures should be put in place as soon as possible to control the supply of OTC medicines containing pseudoephedrine and ephedrine:

- (i) Pack size restriction to 720 mg total content of pseudoephedrine or ephedrine
- (ii) Limit of one pack per sales transaction
- (iii) A recommendation to the pharmacy profession for personal sale of these OTC medicines by a pharmacist
- (iv) An awareness campaign for the pharmacy profession and other healthcare professionals should be implemented concurrently.

3. A CHM Expert Working Group will be established to advise on the practical aspects of the measures proposed including detailed plans for the implementation of sales tracking of products and pharmacy recording of sales to customers. The impact of the strengthened pharmacy controls will be monitored closely by the Working Group and if the pharmacy controls put in place do not contain the risk, reclassification to POM will proceed in 2 years' time (July 2009) or earlier if necessary.

4. A full review of risks and benefits of all decongestants in the class should be carried out.

The responses to consultation have today been published on the MHRA's website ([www.mhra.gov.uk](http://www.mhra.gov.uk)) together with the minutes of the CHM meeting, which include the CHM recommendations in full.

May I take this opportunity to thank you again for responding to this consultation, which has helped to ensure that all perspectives on this issue have been taken into account. We consider the CHM's recommendations to be a tough yet proportionate package of measures to address the risk in the UK and will continue to work with stakeholders in moving forward. The effectiveness of the pharmacy controls will be closely monitored and we are ready to act should these measures fail to contain the risk.

Yours faithfully

Dr June Raine  
Director, Vigilance & Risk Management of Medicines Division