



Pseudoephedrine – Background Fact Sheet

- ✓ Pseudoephedrine (PSE) is a decongestant, used in cough and decongestant remedies to treat nasal and sinus congestion caused by the common cold, sinusitis, hay fever, or other respiratory allergies. It has been available over-the-counter (OTC) for over 50 years, either in single-ingredient preparations, or more commonly in combination with antihistamines, paracetamol and/or ibuprofen.
- ✓ Medicines containing pseudoephedrine will remain available over-the-counter and measures will be put in place to control the supply through pharmacies.
- ✓ The pharmacy controls that will now be put in place are:
 - Pack size restriction to 720mg total content of pseudoephedrine (the law will be changed to make this a legal requirement)
 - Limit of one pack per sales transaction
 - A recommendation to the pharmacy profession for personal sale of these OTC medicines by a pharmacist
 - An awareness campaign for the pharmacy profession and other healthcare professionals (A full training programme, called MethGuard UK, is already in place to do this)
- ✓ In October, a CHM expert working group will be set up to develop further plans for pharmacy controls. These are:
 - Arrangements for sales tracking and monitoring, by industry, wholesale dealers and retailers. This was proposed by PAGB in our response to the consultation.
 - Pharmacy recording of sales and requirement for customer identity to be checked. This is done in other countries and will also be implemented here if the records help with enforcement.
 - A proposal to the Home Office to make pseudoephedrine (and ephedrine) a controlled drug under the Misuse of Drugs Regulations to enforce record-keeping and a specified limited quantity to be supplied to an individual per day/week. This in line with measures already taken in the US, Australia, and New Zealand to stop people making purchases at multiple pharmacies (known as 'smurfing').
- ✓ In addition, a risk:benefit review of nasal decongestants will be undertaken and advice will be given on the place of pseudoephedrine relative to the other decongestant products.
- ✓ If, after two years or earlier if necessary, there is evidence that PSE products are being frequently, and to a wide extent, abused then the ingredient will be reclassified as prescription-only.
- ✓ One pack should be enough for 3 days treatment. People generally find they only need to take a decongestant product for 1 or 2 days when they have a cough / cold.
- ✓ Cold remedies that are currently available at the supermarket or other retail outlets, or on open-shelves at the pharmacy **do not** contain pseudoephedrine. People have always needed to ask their pharmacist to purchase pseudoephedrine products.

- ✓ Pseudoephedrine products account for 10 per cent of the cold and flu market and so there are many other alternative products, such as those containing phenylephrine, that are not affected by the restrictions and are still available in larger pack sizes. If people are unsure, they should ask their pharmacist for advice.
- ✓ In 2006, just over 10 million packs of medicines containing pseudoephedrine were sold, at a retail value of £40million.
- ✓ Restrictions on the supply of pseudoephedrine products have been imposed by the Medicines and Healthcare products Regulatory Agency (MHRA) as a precautionary measure, aimed at preventing criminals extracting the ingredient from the medicine and using it, along with other precursors, in the illicit manufacture of the class A drug Methylamphetamine (commonly known as 'crystal meth').
- ✓ Methylamphetamine is not currently a major problem in the UK, and its synthesis from over-the-counter medicines is extremely rare. To date, there has only been one case of OTC medicines being misused by criminals in this wayⁱ.
- ✓ The decision to introduce these restrictions followed a public consultation (MLX 337), that was held by MHRA and ran from 7 March to 29 June 2007.
- ✓ There was strong support for this outcome from industry, pharmacy and the majority of medical and consumer bodies.
- ✓ Increased pharmacy control, whilst still keeping pseudoephedrine available over-the-counter, is in line with the action taken in other countries. The United States, Canada and Australia have all taken similar measures, which have shown to be effective.
- ✓ If this ingredient had been reclassified as a prescription-only medicine (POM), the likely result would have been an increase in GP visits, at huge cost to the already over-burdened NHS.
- ✓ Recently, Detective Sergeant Andy Waite, who co-ordinates national intelligence on methylamphetamine, said that methylamphetamine has yet to take off in Britain: "We are not seeing a great deal in terms of manufacture. There are certainly no signs of an epidemic. It is a slowly fermenting problem."ⁱⁱⁱ
- ✓ The Serious Organised Crime Agency (SOCA) has established that the limited UK demand for methylamphetamine is being met mainly by importation from overseas and not from home laboratories. Having made pseudoephedrine prescription-only would not have prevented criminals importing it from other countries, sourcing it from the internet or using other starting materials. The experience from other countries is that those making methylamphetamine on a larger scale will source bulk material or break into warehouses or factories.

ⁱ ACPO National Problem Profile edited April 2007 version for and at the request of MHRA for consultation purposes and SOCA Methylamphetamine Profile June 2007

ⁱⁱ The Guardian, Crystal meth yet to take off in Britain, say police, 10 July 2007

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