

MHRA PUBLIC ASSESSMENT REPORT

Controlling the risk of misuse of medicines containing pseudoephedrine and ephedrine

July 2009

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EXECUTIVE SUMMARY

(Please note that this summary is intended to be accessible to all members of the public, including health professionals)

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating the effectiveness and safety of medicines and medical devices in the UK. We continually review the safety of all medicines in the UK and inform healthcare professionals and the public of the latest updates on the balance of risks and benefits associated with medicines. The following MHRA Public Assessment Report presents an update on the impact of measures introduced to control the potential misuse of medicines that contain pseudoephedrine (PSE) and ephedrine (EPH), in the manufacture of the Class A controlled drug methylamphetamine.

PSE and EPH are nasal decongestants (drugs which help to clear a blocked nose) contained in many cough and cold medicines sold over-the-counter (OTC) in UK pharmacies. There is concern that PSE and EPH can be extracted from these medicines and used in the illegal manufacture of the Class A controlled drug methylamphetamine (commonly known as 'methamphetamine', 'crystal meth' or 'ice'). Because of this concern, the MHRA held a <u>public consultation</u> in 2007 on whether to reclassify OTC medicines containing PSE or EPH to prescription-only medicines (POM).

Following the consultation, The <u>Commission on Human Medicines</u> (CHM; an independent body who give advice to government Ministers about the safety, quality, and efficacy of medicines) advised that a number of measures should be introduced to control the supply of OTC medicines containing PSE and EPH. These measures included reducing the pack size for OTC products containing PSE and EPH and a restriction on sale to one pack per transaction.

CHM also advised that a working group be set up to monitor the effectiveness of the pharmacy controls and to advise the CHM on implementation of other measures that should be put in place to minimise the misuse of OTC medicines containing PSE or EPH in the illicit manufacture of methylamphetamine. The CHM also advised that products containing PSE or EPH should be reclassified to POM in July 2009 unless the risk of their misuse in the manufacture of methylamphetamine was contained. Based on recommendations from CHM, the following legal sales restrictions were put in place on April 1st 2008:

- It became illegal to sell or supply any product that contains more than 720 mg PSE or 180 mg EPH without a prescription
- It became illegal to sell or supply a combination of products that between them add up to more than 720 mg PSE or 180 mg EPH without a prescription in one transaction
- It became illegal to sell or supply a product that contains PSE and a product that contains EPH in one transaction

In addition the <u>Royal Pharmaceutical Society of Great Britain</u> issued guidance that the sale and supply of products containing PSE or EPH must only be made by pharmacists or suitably trained pharmacy staff under the supervision of a pharmacist.

Impact of restrictions and CHM recommendations

In July 2009, the Working Group presented to the CHM an update on the impact of the tighter pharmacy controls on the potential misuse of PSE and EPH, since their implementation. From the available evidence it appears that the measures implemented

are helping to contain the potential problem of misuse and that there has been a reduction in sales.

In light of this evidence, the CHM agreed with the Working Group that medicines containing PSE or EPH may continue to be sold as OTC pharmacy medicines, provided the measures put in place to contain their misuse continue to be adequate. The CHM also recommended that: the present levels of monitoring, education and awareness measures by pharmacies should be maintained; liaison with stakeholders such as the Home Office, the Association of Chief Police Officers (ACPO) and the Serious (SOCA) should continue; and the Working Group should be reconstituted to review the situation as necessary, and in any case on a yearly basis.

1. INTRODUCTION

(See glossary for explanation of terms)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating the effectiveness and safety of medicines and medical devices in the UK. We continually review the safety of all medicines in the UK and inform healthcare professionals and the public of the latest updates on the balance of risks and benefits associated with medicines. The following MHRA Public Assessment Report presents an update on the impact of measures introduced to control the potential misuse of medicines that contain pseudoephedrine (PSE) and ephedrine (EPH), in the manufacture of the Class A controlled drug methylamphetamine.

2. BACKGROUND

PSE and EPH are nasal decongestants contained in many cough and cold medicines sold over-the-counter (OTC) in UK pharmacies. There has been increasing concern that PSE and EPH can be extracted relatively easily from over-the-counter (OTC) medicines and used in the illicit manufacture of methylamphetamine (commonly known as "methamphetamine", "crystal meth" or "ice"). Methylamphetamine is a highly addictive, potent stimulant which affects the central nervous system, and can cause serious physical and psychological harm. Methylamphetamine was reclassified on 18 January 2007 by the Home Office as a Class A controlled drug, based on the recommendation of the Advisory Council on the Misuse of Drugs¹ (ACMD).

A <u>public consultation</u> was carried out in March 2007 on minimising the risk of misuse of medicines containing PSE or EPH in the manufacture of methylamphetamine. In this consultation, the MHRA sought views on potentially restricting the availability of these medicines by changing their legal status from pharmacy (P) to prescription-only medicines (POM), together with a restriction in their pack size.

In July 2007, the Commission on Human Medicines (CHM; an independent body who give advice to government Ministers about the safety, quality, and efficacy of medicines) considered the responses to the consultation. They advised that the legal status of medicinal products containing PSE or EPH should be reclassified from P to POM in July 2009, unless the risk of misuse of these OTC medicines in the illicit manufacture of methylamphetamine was contained. They also advised that these products could be reclassified at any time before this date if evidence emerged that misuse had not been contained. The CHM provided advice on pack size restrictions and other measures to control the supply of OTC medicines containing PSE or EPH and advised that a working group should be set up to advise on implementation of these measures (see press release and weblinked minutes). Accordingly, the CHM Working Group on PSE and EPH (Working Group) was set up in September 2007 to advise the CHM on the implementation of measures that should be put in place to minimise the misuse of OTC medicines containing PSE or EPH in the illicit manufacture of methylamphetamine.

Following CHM advice to restrict pack sizes of PSE and EPH, a further <u>public consultation</u> in October 2007 considered specific amendments to the <u>Prescription Only Medicines Order 1997</u> (POM Order) to make the sale and supply of products containing more than 720 mg of PSE or 180 mg EPH prescription-only. This legislation was established on 1st April 2008 (see next section).

¹ An independent expert body that advises the government on drug-related issues in the UK

3. AMENDMENT OF LEGISLATION

The following legislation (SI 2008/464) was put in place from 1st April 2008 to restrict the sales of PSE and EPH:

- It became illegal to sell or supply any product that contains more than 720 mg
 PSE or 180 mg EPH without a prescription
- It became illegal to sell or supply a combination of products that between them add up to more than 720 mg PSE or 180 mg EPH without a prescription in one transaction
- It became illegal to sell or supply a product that contains PSE and a product that contains EPH in one transaction

Professional guidance was also issued by the <u>Royal Pharmaceutical Society of Great Britain</u> (RPSGB) for PSE or EPH-containing products to be supplied personally by a pharmacist or a trained staff member under the supervision of a pharmacist (see section 3.1 below).

In July 2009, the CHM considered a paper from the Working Group which gave an update on the measures to control the misuse of PSE and EPH-containing medicines. CHM were asked to consider the impact of these measures, and to advise on whether small packs of these medicines should continue to be available as P medicines. The following MHRA Public Assessment Report presents the findings from this paper, and the recommendations based on the paper from CHM.

4. SUMMARY OF IMPLEMENTATION OF MEASURES

The CHM Working Group met five times since its start in September 2007. Their progress on implementation of measures to minimise the misuse of PSE or EPH-containing OTC medicines in the illicit manufacture of methylamphetamine is summarised below:

4.1 Pharmacy supervision plus education and awareness initiative

- 4.1.1 The Working Group established close links with the RPSGB, the National Pharmacy Association (NPA), the Company Chemists Association (CCA) and the Proprietary Association of Great Britain (PAGB). This was to raise awareness in the pharmacy profession of the indirect potential for abuse of medicines containing PSE or EPH, through training programmes and numerous articles in the pharmaceutical press/trade magazines. A list of key publications is given in section 9 (references) of this report. The Working Group also considered the possibility of pharmacy recordings of sales and for customer identities to be checked; however, based on current evidence of misuse of PSE or EPH products, such a proposal was not considered to be a proportionate measure.
- 4.1.2 The RPSGB advised that sale and supply of PSE or EPH products must be made by a pharmacist or by suitably trained pharmacy staff under the supervision of the pharmacist. They also issued guidance about the dangers of multiple sales of PSE or EPH products. The RPSGB are also developing a type of clinical audit which aims to improve the quality of advice provided when pharmacists and pharmacy staff interact with patients in a variety of self-care scenarios (called a "Simulated Patient Project"). Supply of PSE or EPH OTC products will be included as a scenario in this project.
- 4.1.3 A high-street pharmacy chain reported that checkout tills in their shops have been modified so staff cannot sell more than one pack of PSE or EPH-containing OTC medicines.
- 4.1.5 The CCA in association with LearnSomething¹ developed the <u>MethGuard UK</u> <u>awareness programme</u>, a learning course for pharmacists and their staff to help combat the potential threat of methylamphetamine manufacture with PSE or EPH-containing medicines. The NPA has developed a specific awareness training resource for all its members, in total about 12 000 pharmacies.

4.2 Pharmacy reporting of suspicions

In discussion with the RPSGB and the Department of Health, the Working Group developed a <u>'Reporting Your Suspicions'</u> card containing key messages for UK pharmacists to help identify suspicious activity, and a possible route for community pharmacists to report inappropriate sales requests for PSE and EPH. After discussion with the Chief Pharmaceutical Officers, the RPSGB and the <u>Pharmaceutical Society of Northern Ireland</u> issued the final version as a laminated card to members of the profession in April 2008.

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¹ A company which offers training courses for pharmacies

4.3 Sales tracking and other measures to monitor evidence of use of OTC medicines in the manufacture of methylamphetamine

- 4.3.1 The Working Group evaluated the potential of using a database to monitor sales of PSE- or EPH-containing products. They concluded that the data would not be sufficiently sensitive to identify unusual increases in sales due to coordinated 'smurfing' activities (purchasing the maximum legally-allowed amounts of these drugs in multiple pharmacies).
- 4.3.2 PAGB provided sales figures for one brand of a PSE-containing product which showed that sales of individual tablets for the year ending May 2009 were 24% less than corresponding sales for the year ending May 2008. Other data from PAGB show that the numbers of individual tablets of this branded PSE-product and its generic equivalent of PSE tablets sold by a major pharmacy chain were 26% less in the year 2008/2009 compared to 2007/2008.
- 4.3.3 In relation to advertising, PAGB approved 84 pieces of advertising copy on OTC products containing PSE or EPH in 2007, which reduced to 52 pieces approved in 2008. However, they commented that there is no correlation between advertising and sales as sales of generic PSE products, for which there is no advertising, are higher than any other product.
- 4.3.4 The Working Group developed close working relationships with the <u>Association of Chief Police Officers</u> (ACPO) and the <u>Serious Organised Crime Agency</u> (SOCA), who provided intelligence on methylamphetamine abuse, in particular cases where OTC PSE or EPH had been used in its manufacture. Three confirmed cases were reported by ACPO/SOCA where OTC PSE was used to manufacture methylamphetamine, the most recent in June 2008. Two other cases from 2007 remain unconfirmed.

4.4 Triggers for a review of the availability of PSE or EPH OTC medicines

The CHM endorsed a paper by the Working Group on potential triggers for a review of the pharmacy/OTC availability of PSE or EPH-containing medicines in June 2008. The triggers are:

- The number and scale of methylamphetamine laboratories found, which use OTC PSE or EPH to manufacture methylamphetamine. There are currently five such cases (see 4.3.4): three confirmed, two unconfirmed.
- The number and scale of non-OTC-related methylamphetamine laboratories found in the UK (information provided by ACPO). The actual seizures of methylamphetamine using non-OTC PSE or EPH remains low. Illicit drug laboratories found by police are rare and numbers of individuals in treatment are similarly limited. The main supply appears to be import rather than local manufacture, with bulk precursor chemical purchase being the easier source of pseudoephedrine and, in particular, ephedrine. Based on findings to date, ACPO assessed that there is a small availability of methylamphetamine across the UK.
- Suspicious requests for OTC PSE or EPH-containing medicines reported by
 pharmacists to RPSGB/SOCA via the reporting system. There have been three
 such reports to date, which are considered by the RPSGB to be a direct result of
 their 'Reporting Your Suspicions' card. It is difficult to know whether the relatively
 low number of reports is due either to few people trying to buy PSE
 inappropriately, or to a lack of reporting.

- The number of pharmacy 'break ins' where PSE or EPH-containing products were stolen or targeted for use in the manufacture of methylamphetamine. This information is provided by ACPO/SOCA, and there have been no such cases reported to date.
- The number of reported methylamphetamine addicts provided by the National Treatment Agency to the Home Office. These numbers have remained small.

Developments in other countries concerning the use of PSE or EPH to illicitly manufacture methylamphetamine have been monitored, as a number of other countries have also recognised the need to restrict the availability of these substances (see section 5).

Liaison with relevant stakeholders such as ACPO, SOCA, and the RPSGB will continue to provide information as it arises. Overall, SOCA and ACPO have indicated that the issue of methylamphetamine abuse is under control, and consider that the steps taken to minimise the risk of misuse of PSE or EPH in the illicit manufacture of this drug are proportionate.

5. INTERNATIONAL POSITION

In the *Czech Republic* there has been increasing abuse of PSE for some years. From May 2009 the <u>Czech Regulatory Authority</u> switched PSE products to a new category – 'OTC with a sales restriction'. Dispensing is limited as follows:

- One pack containing a maximum of 720 mg PSE per person per week
- A maximum quantity of 1800 mg per person per month
- Pharmacies must enter sales in a central register to verify that the product has not been sold to that particular person in the same week
- Purchase of these products over the internet by mail order is prohibited

There is also an ongoing debate in the Czech parliament on a proposal to switch all PSE-containing products to prescription only.

In *France* EPH products are more restricted than PSE products, probably because of their historical abuse as a slimming aid. A French national survey on medicinal products containing PSE or EPH was conducted between 2000–2007. The results showed only one isolated case of misuse of these medicines in the illicit manufacture of methylamphetamine. However, in April 2008, considering the recommendations of the International Narcotics Control Board and to prevent diversion of PSE or EPH-containing products to illicit use, the following measures were implemented:

- OTC products containing PSE or EPH were banned from being placed directly in the sales areas of pharmacies (however, since summer 2008, a decree allows some PSE or EPH OTC medicinal products to be placed directly in the sales areas of pharmacies)
- Pharmaceutical laboratories have to:
 - report any theft of these medicines to the <u>French Regulatory Authority</u> (AFSSAPS)
 - report any suspicion of diversion to illicit use to the <u>National Mission for</u> the <u>Control of the Chemical Precursors</u>
 - o produce an annual statement of production, exportation, importation and sales information for AFSSAPS.

In Sweden, Finland and Norway, PSE and EPH are prescription only medicines.

Methylamphetamine misuse is a major problem in *Australia*. As a result all PSE-containing products are now classified as Schedule 3 pharmacist only, requiring a pharmacist to be involved in each sale. All preparations containing more than 720 mg PSE per pack were moved to prescription only, requiring a doctor's prescription for sales. Patients have to provide photographic identification and pharmacists have to log purchases on a <u>real-time online database</u>, which alerts the pharmacist to previous purchases made by the same individual.

Methylamphetamine misuse is a major problem in the *USA*. In response to this problem, the Food and Drug Administration introduced in 2006 the following restrictions:

- PSE has to be stored behind the counter or in locked cabinets (in pharmacies and non-pharmacy outlets)
- Purchasers have to provide identification
- Retailers must keep a written record of the sale
- Pack sizes are limited to 1.8 g and transactions limited to one pack
- The quantity purchased per day is limited to 3.6 g a day (two packs)

No more than 9 g can be purchased per month (five packs)

In addition to federal laws, around half of the states have individual state laws which restrict PSE to pharmacy sale, and Oregon has reclassified PSE and EPH as Schedule III controlled substances, available only as POM.

Mexico is the primary foreign source of methylamphetamine to the USA and has become one of its largest producers since the suppression of laboratories in the USA. SOCA recently informed the Agency that from February 2009 the sale of PSE was banned in Mexico and Guatemala.

Following police investigations, the <u>Peruvian Medicines Agency</u> restricted the legal status of all products containing PSE to "POM retained" (referring to the prescription storage requirements for items to be kept in the pharmacy for 2 years). From April 15th 2008 all such products produced and imported are dispensed in registered pharmacies only as "POM retained". Batches of PSE-containing medicines manufactured before April 2008 can be sold without medical prescription from pharmacies for a 1-year period only.

6. ACTION UNDER MISUSE OF DRUGS LEGISLATION

The Working Group considered information from Home Office representatives outlining the technical requirements to include PSE and EPH under the <u>Controlled Drugs</u> <u>legislation</u>. This action would need to be taken forward by the Home Office through Parliament following consultation with the <u>Advisory Council on the Misuse of Drugs</u> (ACMD).

ACMD views on action to minimise risk of OTC PSE or EPH abuse

The Working Group asked the ACMD to note the progress on measures to contain the illicit manufacture of methylamphetamine from OTC PSE or EPH-containing medicines, and for their views on:

- The scale of methylamphetamine abuse and illicit manufacture in the UK
- Any additional measures which should be implemented to minimise the misuse of PSE or EPH-containing medicines if they were to remain OTC
- The on-going monitoring and triggers for further review of OTC PSE or EPH if they were to continue to be available.

The ACMD confirmed that overall production of methylamphetamine in the UK is relatively stable and the total number of seizures is low. They welcomed the measures put in place to control misuse of OTC PSE or EPH medicines and considered the current measures are proportionate. They also acknowledged the importance of ongoing monitoring and a commitment to continuing liaisons with the ACPO and the Home Office to keep MHRA updated.

7. SUMMARY AND DISCUSSION ON IMPACT OF ACTION

The various measures recommended by the CHM in 2007 to help minimise the risk of misuse of OTC medicines containing PSE or EPH were implemented where practical. Legislation has been amended to reduce the pack sizes of PSE and EPH medicines available OTC. The pharmacy profession through representative organisations has taken steps to educate staff and improve awareness of the issues associated with misuse of PSE and EPH and the links to methylamphetamine misuse.

As a direct result of the 'Reporting Your Suspicions' cards provided by the RPSGB, there have been three reported instances of suspicious activity. It is difficult to know whether the relatively low number is due to few people trying to buy PSE inappropriately or to a lack of reporting. However the RPSGB have concluded that "these measures have been effective and the issue is well understood by pharmacists and their staff".

The Working Group developed a series of indicators which would trigger a review of the continuing availability of OTC PSE and EPH products and reclassification to POM. Based on these triggers (see Section 4.4), there has only been one report of misuse since the legislation was amended. The ACMD reports no change in the wider situation related to the scale of misuse of methylamphetamine.

In the UK to date, reports of three illicit methylamphetamine labs using OTC PSE products have been confirmed and two further reports await confirmation. The actual seizures of methylamphetamine remain low, illicit drugs laboratories found by police are rare and number of individuals receiving treatment for this drug are similarly limited. The main supply appears to be import rather than local manufacture, with bulk precursor chemical purchase being the easier source of pseudoephedrine and, in particular ephedrine. Based on findings to date, ACPO's assessment is that there is a small availability of methylamphetamine across the UK. On the evidence available it appears that the measures put in place to reduce the illicit manufacture of methylamphetamine from OTC PSE or EPH-containing medicines are helping to contain the potential problem. The ACMD agree with this view; they support the range of measures and consider they are proportionate.

There is a great diversity in the extent to which different countries restrict sale and supply of PSE and EPH-containing products, from no action through to full prescription restrictions. Some countries, including the UK, have adopted a restrictive supply approach (see section 3 of this report for restrictions), whereas others have supply registers and require identification to be shown upon purchase.

8. RECOMMENDATIONS AND CONCLUSIONS

In light of the report from the Working Group, the CHM agreed that medicines containing PSE or EPH may continue to be sold as OTC pharmacy medicines, provided the present measures for controlling their misuse continue to be adequate. Such measures include the current legislation:

- It is illegal to sell or supply any product that contains more than 720 mg pseudoephedrine or 180 mg ephedrine without a prescription
- It is illegal to sell or supply a combination of products that between them add up to more than 720 mg pseudoephedrine or 180 mg ephedrine in one transaction
- It is illegal to sell or supply a product that contains pseudoephedrine and a product that contains ephedrine in one transaction

The CHM also recommended that: the levels of monitoring, education and awareness measures by pharmacies should be maintained; liaison with stakeholders such as the Home Office, the ACPO and SOCA should continue; and that the Working Group should be reconstituted to review the situation as necessary and in any case on a yearly basis.

9. REFERENCES

1. Look, listen, report your suspicions card (RPSGB, April 2008) http://www.rpsqb.org/pdfs/psephquide.pdf (accessed July 2009)

2. Law and Ethics Bulletins:

Reminder of the restrictions on the sale of products containing pseudoephedrine or ephedrine (RPSGB, November 2008)

http://www.rpsgb.org/pdfs/LEBpsephreminder.pdf (accessed July 2009)

Restriction on the sale of pseudoephedrine and ephedrine products (RPSGB, March 2008)

http://www.rpsgb.org/pdfs/LEBrestrictsalepsephprod.pdf (accessed July 2009)

Update on sale and supply of pseudoephedrine and ephedrine containing medicines (RPSGB, November 2007)

http://www.rpsgb.org/pdfs/LEBupdatepsephmeds.pdf (accessed July 2009)

Restriction on sale or supply of pseudoephedrine and ephedrine containing medicines (RPSGB, September 2007)

http://www.rpsgb.org/pdfs/LEBrestrictpsephmeds.pdf (accessed July 2009)

3. Pharmaceutical Journal Articles:

Remain vigilant over pseudoephedrine sales following discovery of illegal drug laboratory. 2008 (Oct 11): **281**: 411

CD and pseudoephedrine changes reflected in new MEP. 2008 (July 19); 281: 59

Pseudoephedrine. 2008 (Apr 26); 280: 503

Ephedrine/pseudoephedrine restrictions start 1 April. 2008 (Mar 29); 280: 377

New pseudoephedrine sales restrictions confirmed. 2008 (Jan 5/12); 280: 10

Update on sale and supply of pseudoephedrine and ephedrine containing medicines. 2007 (Dec 8); **279**: 662

Society opposes MHRA stance on pseudoephedrine. 2007 (Nov 24); 279: 577

NPA launches pseudoephedrine/ephedrine training package. 2007 (Nov 17); **279**: 550

Council decides restricting sale of pseudoephedrine would be overkill. 2007 (Oct 13); **279**: 415

No need to restrict pseudoephedrine sales to pharmacists, Society says. 2007 (Oct 13); **279**: 391

Decongestant pack size limits proposed. 2007 (Oct 6); 279: 373

Clarification of the "Controlled Drugs in hospital" section of Medicines, ethics and practice: a guide for pharmacists and pharmacy technicians, issue 31 and restriction

on sale or supply of pseudoephedrine and ephedrine containing medicines. 2007 (Sept 8); **279**: 271–272

Pharmacy must make measures work. 2007 (Sept 8); 279: 254

Pseudoephedrine products remain OTC, but with new pack size limits. 2007 (Sept 1); **279**: 221

A threatening cloud has passed. 2007 (Sept 1); 279: 220

Pseudoephedrine. 2007 (Aug 18); 279: 177

US-style methylamphetamine awareness scheme planned. 2007 (July 28); 279: 94

Pharmacy control of pseudoephedrine sales to be scrutinised. 2007 (July 21); **279**: 63

Profession under the spotlight. 2007 (July 21); 279: 60

National Pharmacy Association plans secret checks on pseudoephedrine community sales. 2007 (July 14); **279**: 34

NPA draws up training ahead of pseudoephedrine decision. 2007 (Jun 30); 278: 762

Response to methylamphetamine threat needs balance, MHRA told. 2007 (Jun 30); **278**: 762

Additional pseudoephedrine controls not necessary. 2007 (Jun 23); 278: 726

Society and NPA call on pharmacists to address problem of pseudoephedrine misuse. 2007 (May 26); **278**: 597

Test purchases show flaws in pharmacy medicine controls. 2007 (May 12); 278: 541

Be more vigilant. 2007 (May 12); 278: 540

Decongestant switch is disproportionate to the risk. 2007 (May 5); 278: 517

Reclassification is over-reaction. 2007 (Apr 28); 278: 479

Monitoring of P medicines sales needs to improve. 2007 (Apr 21); 278: 445

NPA opposes reclassifying pseudoephedrine. 2007 (Apr 21); 278: 445

Society to oppose POM control for decongestants. 2007 (Apr 14); 278: 437

Is MHRA's pseudoephedrine P to POM plan a slap in the face for pharmacy? 2007 (Mar 17); **278**: 304

Pseudoephedrine products set to be reclassified POM. 2007 (Mar 10); 278: 269

Methamphetamine: link to cold remedies and reclassification. 2007 (Jan 27); **278**: 114

How reclassifying a CD could affect supplies of cold remedies that work. 2007 (Jan 27); **278**: 102

Query inappropriate requests for ephedrine. 2006 (May 13); 276: 559

10. GLOSSARY

Class A controlled drugs

In the UK, certain drugs are designated as controlled substances (ie, only certain designated persons may manufacture, supply and possess them) and are divided into three classes: A, B and C. Those categorised as Class A are considered to be the most likely to cause harm (see http://www.homeoffice.gov.uk/drugs/drugs-law/Class-a-b-c/ for more information)

Clinical Audit

A process performed by the UK's National Health Service that seeks to improve patient care and outcomes by reviewing performance in the Service

Decongestant

A drug that helps to clear a blocked nose

Ephedrine

A drug that narrows blood vessels and widens airways, used mainly as a nasal *decongestant*

Generic

A drug without a brand name that is sold or identified by its scientific name

Illicit

Illegal

Legislation

A proposed law or group of laws

Methylamphetamine

A Class A controlled drug that is illegal to possess, supply or manufacture. It is a **stimulant** that causes feelings of exhilaration

Misuse (of medicines)

Using a drug for improper purposes (ie, not for treating a condition or disease)

Narcotic

A drug that produces pain relief, sleepiness and addiction

Over-the-counter

Medicines that can be sold to a customer without a prescription

Parenteral

Given to, or taken into the body through a route outside the digestive system, eg, by injection

Pharmacy (referring to medicine classification)

Medicines that can only be sold to a customer by a trained pharmacist

Precursor (chemical)

A chemical that is required in the process of making a drug, which becomes part of the end-product

Prescription Only Medicine

Medicines that can only be sold to a customer if they have a valid prescription from a doctor

Pseudoephedrine

A drug that narrows blood vessels, used as a nasal decongestant

Public Consulation

A process that seeks the public's input on matters that affect them

Stakeholders

A person, group, organisation or system who affects, or can be affected by an organisation's actions

Stimulant

A substance that causes increased activity in the body, particularly in the nervous system and the heart and circulatory system