MHRA UK PUBLIC ASSESSMENT REPORT

Pseudoephedrine- and ephedrine-containing medicines: 2012 review of actions to manage the risk of misuse

October 2012

PLAIN LANGUAGE SUMMARY

Key message: In 2008, legal measures were introduced in the UK to manage the misuse of medicines containing pseudoephedrine or ephedrine. A review of evidence conducted in 2012 shows that the measures are continuing to effectively manage the risk of misuse of these medicines.

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating medicines and medical devices in the UK. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public assessment reports.

The following report presents the 2012 review of the impact of measures introduced to control the potential misuse of medicines containing pseudoephedrine (PSE), or ephedrine (EPH), in the manufacture of the Class A controlled drug methylamphetamine. These measures were introduced in 2007–2008, and their impact has been reviewed yearly.

PSE and EPH are nasal decongestants[a] 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[b] – a highly addictive drug which affects the central nervous system and can cause serious physical and psychological harm. This concern prompted a public consultation in 2007, following which the Commission on Human Medicines[c] (CHM) 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.

The CHM also advised that a Working Group should be set up to monitor the effectiveness of the pharmacy controls, and to advise the CHM on other measures that could be put in place to minimise the misuse of OTC medicines containing PSE or EPH. The Working Group was established in September 2007. Based on recommendations from CHM, legal sales restrictions were put in place in the UK on April 1st 2008 which made it illegal to sell or supply:

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

In addition, the Royal Pharmaceutical Society (RPS), formerly known as the Royal Pharmaceutical Society of Great Britain, issued guidance that the sale and supply of products containing PSE or EPH must only be carried out by pharmacists or suitably trained pharmacy staff under the supervision of a pharmacist.

---

[a] Drugs which help to clear a blocked nose

[b] Commonly known as ‘methamphetamine’, ‘crystal meth’ or ‘ice’

[c] An independent body which gives advice to UK government Ministers about the safety, quality, and efficacy of medicines

Impact of restrictions and CHM recommendations

Each year from 2009, the CHM has reviewed the evidence of the impact of these measures to control the misuse of PSE or EPH-containing medicines. Three public assessment reports giving full details of the evidence, and the CHM's conclusions are available on our website: Controlling the risk of misuse of medicines containing pseudoephedrine and ephedrine, Pseudoephedrine and ephedrine: managing the risk of misuse of medicines – July 2010 update and Pseudoephedrine- and ephedrine-containing medicines: 2011 review of actions to manage the risk of misuse. The evidence presented in these reports showed that the measures were helping to contain the potential problem of misuse, and that the sale of PSE and EPH products had reduced.

Stakeholders including the pharmacy profession, the General Pharmaceutical Council (GPhC)[a], the Home Office, the Association of Chief Police Officers (ACPO) and the Serious Organised Crime Agency (SOCA) have continued to take measures to minimise the misuse of medicines containing PSE and EPH. They report that these measures are continuing to be successful, and, for our 2012 review, have recently provided updated information on the impact of these measures, such as:

- The RPS, the Pharmaceutical Society of Northern Ireland (PSNI), the National Pharmacy Association (NPA), the Company Chemists Association (CCA) and the Proprietary Association of Great Britain (PAGB) continue to raise and maintain awareness in the pharmacy profession of the indirect abuse potential of medicines containing PSE or EPH.

- In a survey conducted in June 2011 of 409 NPA members, over 97% were aware of the rules regarding sales of PSE. This level of awareness is unchanged from last year.

- Sales figures provided by the PAGB show that wholesale purchases of PSE products by pharmacies were stable from April 2010 to March 2011.

The ACPO have reported only one incidence of small-scale manufacture of methylamphetamine. There was no evidence that this one report was indicative of a trend.

The number of registered methylamphetamine addicts remains small. The ACPO's assessment, based on findings to date, is that there is little to suggest a problem with methylamphetamine misuse across the UK.

Conclusions

In July 2012, the CHM considered the above feedback from stakeholders and concluded that the regulatory measures implemented in 2009 and 2010 to manage the risk of misuse of OTC medicines containing PSE or EPH were continuing to be effective. The CHM recommended that:

- the present levels of monitoring, education and awareness measures by pharmacists should be maintained

[a] The regulatory body for pharmacists, pharmacy technicians and pharmacy premises in the UK

- liaison with stakeholders including the Home Office, the Association of Chief Police Officers (ACPO) and the Serious Organised Crime Agency (SOCA) should continue

- a Working Group should be established as necessary to review the situation if any new concerns arise[a].

- MHRA should continue to monitor the situation and report only significant adverse changes to CHM.

We thank the pharmacy profession for their substantial contribution to managing the risk of misuse of these products.

[a] Please note that the majority of the members of the original 2007 Working Group are no longer members of the CHM

1. INTRODUCTION

(See glossary for explanation of terms used in this report)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating 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. The following report summarises the latest review of the impact of measures introduced to control potential misuse of medicines that contain pseudoephedrine (PSE)) or 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 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 (colloquially known as 'methamphetamine', 'crystal meth' or 'ice'). Methylamphetamine was classified 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 Drugs[a] (ACMD).

Because of this concern, a public consultation 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 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 UK government Ministers about the safety, quality, and efficacy of medicines) considered the responses to the consultation. They advised that the legal status of medicines containing (PSE) and ephedrine (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. The CHM provided advice on pack size restrictions and other measures to control supply of OTC medicines containing PSE and EPH, and advised that a Working Group should be set up to advise on implementation of the measures (see press release and weblinked minutes).

Accordingly, the CHM Working Group on PSE and EPH (Working Group) was established 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 public consultation in October 2007 considered specific amendments to the Prescription Only Medicines Order 1997 (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 came into force in the UK on 1st April 2008, after which it became illegal to sell or supply:

- any product that contains more than 720 mg PSE or 180 mg EPH without a prescription.
- a combination of products that between them add up to more than 720 mg PSE or 180 mg EPH without a prescription

[a] An independent expert body that advises the government on drug-related issues in the UK

- a product that contains PSE and a product that contains EPH in one transaction

Professional guidance was also issued by the Royal Pharmaceutical Society [RPS], formerly known as the Royal Pharmaceutical Society of Great Britain (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, July 2010, and again in July 2011, the CHM considered the impact of measures which had been put in place to minimise the risk of misuse of PSE and EPH-containing products and recommended that: the existing levels of monitoring, education and awareness measures by pharmacists should be maintained; liaison with stakeholders including the Home Office (HO), Association of Chief Police Officers (ACPO) and the Serious Organised Crime Agency (SOCA) should continue; the Working Group should be reconstituted as necessary, and in any case to review the situation on a yearly basis.

Three public assessment reports published in July 2009, July 2010 and September 2011 giving full details of the evidence and the CHM's conclusions are available on our website: Controlling the risk of misuse of medicines containing pseudoephedrine and ephedrine, Pseudoephedrine and ephedrine: managing the risk of misuse of medicines – July 2010 update and Pseudoephedrine- and ephedrine-containing medicines: 2011 review of actions to manage the risk of misuse. Articles on this issue were also published in the September 2009, September 2010 and September 2011 editions of Drug Safety Update, the MHRA monthly bulletin for health professionals on the safety of medicines.

3. UPDATE ON IMPLEMENTATION OF MEASURES

In light of the CHM's recommendations above, stakeholders have continued to take measures to help minimise the misuse of OTC medicines containing PSE or EPH in the illicit manufacture of methylamphetamine. Information provided recently is summarised below.

3.1 Pharmacy supervision plus education and awareness initiatives

Close links have been maintained with the RPS, the Pharmaceutical Society of Northern Ireland (PSNI) the National Pharmacy Association (NPA) the Company Chemists Association (CCA) and the Proprietary Association of Great Britain (PAGB). These organisations have provided updated information to the MHRA on the continuing measures to maintain awareness by the pharmacy profession of the indirect abuse potential of medicines containing PSE or EPH.

The RPS is committed to supporting pharmacists in relation to the misuse of PSE or EPH and issues regular communications to members to ensure they maintain vigilance with these products. These include a 'Look, Listen and Report your suspicions' guide and advice on "Supplying over-the-counter analgesics" and "Dealing with requests for large quantities of medicines over-the-counter".

The PSNI has placed guidance on its website relating to PSE sales. Monitoring the website shows there is constant access of this information by either professionals or the public. The PSNI liaises with the Northern Ireland Department of Health, Social Services and Public Safety (DHSSPS) and its pharmaceutical inspectorate, and they report no evidence of misuse or abuse of PSE/EPH containing products to date in Northern Ireland.

The NPA continues to maintain and develop an awareness training resource for members to download from the NPA website. It is now available in various formats to suit the users, eg, group training or individual learner, and also for use with an MP3 player. Through regular NPA promotion, eg, via superintendant email alerts and the NPA member magazine, pharmacists are encouraged to record staff training as part of an audit trail; in particular, newly appointed staff are made aware of the current rules. In a survey conducted in May 2012 of 409 members, over 97% of members responded that they are aware of the rules regarding sales of PSE-containing products. Training packs will be sent to those members who responded that were not aware of these rules. The NPA are reassured by the high level of awareness, which remains unchanged from last year.

The CCA continues to operate the MethGuard UK awareness training programme. The vast majority of members have however developed their own in-house resource, including several major high-street pharmacy stores. Companies report that awareness training on the rules regarding sales of products containing PSE or EPH is part of the standard training for all relevant staff (eg, medicines counter assistants) and new staff. Some companies provide refresher training prior to the autumn/winter cough and cold season, and audit compliance through different schemes (eg, a mystery shopper scheme).

3.2 Pharmacy reporting of suspicions

The 'Look, Listen and Report your suspicions' guide is available to members on the RPS website. The GPhC are not aware of any cases of pharmacists reporting the inappropriate sale of PSE or EPH products over the last year, nor of any reports of suspicious behaviour. They report that pharmacists are aware and alert to the potential abuse of products containing these medicines.

3.3 Sales monitoring for evidence of use of over-the-counter medicines in the manufacture of methylamphetamine

The PAGB provided wholesale figures for PSE and EPH products. The figures show a decline in wholesale purchases by pharmacies, of 1.6% and 19.2%, respectively, during the financial year April 2011–March 2012. The manufacturers of brand leader products have reported a small increase of 0.6 – 1.3% in sales of PSE-containing products; this would indicate that PSE sales appear to have reached a plateau following significant reductions in previous years. Some branded products have been discontinued.

3.4 Triggers for a review of the availability of pseudoephedrine or ephedrine over-the-counter medicines

The CHM has previously agreed a number of factors which act as potential triggers for a review of the pharmacy/OTC availability of PSE or EPH-containing medicines. The ACPO, SOCA and the Home Office have provided updated information in these areas which is summarised below:

The ACPO reported one incidence of a small-scale manufacture of methylamphetamine, although a link to use of PSE or EPH products has not been confirmed.

Reports of suspicious requests for OTC PSE or EPH-containing medicines by pharmacists to RPSGB/SOCA are documented via the reporting system (the 'Look, Listen and Report your suspicions' guide). Over 2011 – 2012, there have been no pharmacy suspicion reports of customers behaving suspiciously when attempting to purchase quantities of PSE or EPH. Data from the last five years do not indicate a

significant increase in the number of methylamphetamine users, and the numbers of registered methylamphetamine addicts remains small[a].

There have been no other reports of concern from ACPO or SOCA regarding misuse of PSE or EPH products. Based on findings to date, the ACPO considers there is very little evidence of a problem with methylamphetamine misuse across the UK but they continue to monitor the situation.

Liaison with relevant stakeholders including ACPO, SOCA, and the GPhC Pharmacy inspectorate will continue to provide suitable information as it arises. Overall, SOCA and ACPO are aware of the potential dangers of misuse, but at present the indications are that misuse of medicines in relation to methamphetamine production is still not presenting any major problems. They consider that the current restrictions on OTC medicines containing PSE or EPH are sufficient to address the risk of potential misuse and abuse.

4. INTERNATIONAL POSITION

An update of available information on measures implemented in other countries to minimise the risk of misuse of PSE or EPH-containing medicines is provided below.

USA

The situation is stable and there have been no new developments in the marketing of PSE in the USA. It is sold OTC (behind-the-counter) unless individual state laws dictate otherwise where there is legislation that restricts PSE to prescription status.

New Zealand

In 2011, the Government introduced new legislation making ephedrine and pseudoephedrine Class B1 drugs under the Misuse of Drugs Act as part of a range of initiatives targeted on reducing methamphetamine manufacture and abuse. Since then the number of clan labs identified by police and the number of crimes associated with methamphetamine has reduced; although there is no way to link the reduction in manufacture with the decision to reclassify PSE and EPH. As the market had already moved to phenylephrine ahead of the legislation change there has effectively been two full winters where all cough and cold products on the market were free of PSE without major consumer complaint or question.

5. DISCUSSION

The feedback from stakeholders is that the regulatory measures recommended by the CHM to help manage the risk of misuse of OTC medicines containing PSE or EPH are continuing to be implemented effectively. There was one incidence of small scale manufacture of methylamphetamine. There is no evidence from ACPO that this case is indicative of a trend which requires additional measures to control the misuse of PSE-containing products.

The pharmacy representative organisations are maintaining their support and encouragement of education and training by pharmacists and pharmacy staff, to

[a] Data from the British Crime Survey 2010 – 2011 and the National Treatment Agency

ensure awareness of misuse of PSE and EPH and the links to methylamphetamine misuse.

There have been no reports from pharmacies of suspicious requests for unusual quantities of OTC PSE.

The factors that would trigger a review of continued OTC PSE or EPH availability have been reviewed and there are no significant issues of concern.

Other countries are also taking steps to better manage the risk of misuse of PSE and EPH products.

6. RECOMMENDATIONS AND CONCLUSIONS

After reviewing the updated information summarised in this report, the CHM agreed that the measures implemented in 2007 and reviewed yearly since then are continuing to control the supply of OTC products containing PSE or EPH. The CHM recommended that:

- the present level of monitoring and the education and awareness measures by pharmacists should be maintained
- liaison with stakeholders including the Home Office, ACPO and SOCA should continue
- a Working Group should be established as necessary to review the situation if any new concerns arise[a].
- MHRA should continue to monitor the situation and report only significant adverse changes to CHM.

We thank the pharmacy profession for their substantial contribution to managing the risk of misuse of these products.

.

[a] Please note that the majority of the members of the original 2007 Working Group are no longer members of the CHM

7. 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://webarchive.nationalarchives.gov.uk/20100419081707/http:/drugs.homeoffice.gov.uk/drugs-laws/misuse-of-drugs-act/ 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***

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)

Over-the-counter
Medicines that can be sold to a customer without a prescription

Pharmacy (referring to medicine classification)
Medicines that can only be sold to a customer by a trained pharmacist

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

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

Stakeholders
A person, group, organisation or system which 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