

Submission by the Irish Pharmacy Union to the Health Products Regulatory Authority on the Pseudoephedrine Consultation, June 2015

Background

In December 2014, the Health Products Regulatory Authority (HPRA) wrote to 11 Marketing Authorisation Holders (MAHs) of pseudoephedrine-containing medicines. In the correspondence, the HPRA indicated that An Garda Síochána had expressed concern about the increased production of methamphetamine using pseudoephedrine sourced from pharmacies and had requested that pharmacists be vigilant in the sale and supply of pseudoephedrine. It was acknowledged that this information had been communicated to pharmacists by the Pharmaceutical Society of Ireland (PSI).

The MAHs were reminded that UK Medicines & Healthcare products Regulatory Agency (MHRA) had imposed a restriction of 720mg of pseudoephedrine as the maximum quantity per pack for pseudoephedrine-containing medicines and that other countries had taken similar measures.

In order to ensure the appropriate sale and supply of OTC pseudoephedrine, the HPRA proposed the following:

1. Limit pharmacy sales of pseudoephedrine-containing medicines to one pack per transaction.
2. Impose a maximum quantity per pack of 720mg pseudoephedrine. Packs containing more than 720mg would not be marketed for pharmacy sale without a prescription and, alternatively, be made available only subject to prescription control.
3. Where the only available pack size has a quantity of pseudoephedrine greater than 720mg, as is the case with Zirtek plus Decongestant, restrict the promotion of this product to healthcare professionals. According to pharmacy and medicines legislation, all medicines sold/supplied from a pharmacy are sold/supplied under the personal supervision of the pharmacist.

At a meeting with the Irish Pharmacy Union (IPU), on 12 June 2015, the HPRA asked the IPU to make a formal submission on these proposals.

Introduction

Pseudoephedrine and ephedrine are nasal decongestants used either alone or in combination with analgesics or other active ingredients for the symptomatic relief of colds, flu and other similar conditions. The majority of products are available without prescription and there is a range of pack sizes available covering solid dosage forms and liquid formulations.

Pharmacies in Australia and the USA have long been battling against criminals who divert pseudoephedrine-based products to illegally produce amphetamine-type stimulants (ATS) such as the drug methamphetamine (or methylamphetamine) also known as 'Crystal Meth' or 'Ice'. In 2011, the United Nations Office on Drugs and Crime ranked ATS as the world's second most widely abused drug type after cannabis. It reported that the expansion of illicit trade in such substances and the high profit generated by that trade pose an increasing threat to security and health worldwide.

Methamphetamine

Methamphetamine is a highly addictive, potent stimulant which affects the central nervous system. It can cause serious physical and psychological harm and can be injected, snorted, smoked or ingested orally. Methamphetamine can be in powder form (speed), paste (base) or crystalline form (ice). When smoked in its crystalline form, it can produce effects similar to crack cocaine though considerably longer lasting – 12 hours or more. Use of Crystal Meth can cause rapid heart rate, increased blood pressure and damage to the small blood vessels in the brain. Evidence also suggests that chronic use can lead to psychotic behaviour, characterised by paranoia and violent behaviour.

In Europe, several countries have reported increases in the use and production of methamphetamine, while the discovery of clandestine laboratories in West Africa indicates that that sub-region is also being drawn into the trade in ATS. Use of ATS is greater in Oceania than in any other region of the world.

Owing to their affordability and the relative ease with which they are manufactured, ATS are attractive drugs of choice for millions of drug abusers in all regions of the world and, unlike plant-based drugs, can be manufactured anywhere with little initial investment required on the part of criminals.

Methamphetamine is produced in clandestine laboratories using pseudoephedrine and ephedrine diverted from cold and flu preparations. Laboratories for making Crystal Meth have been found in suburban houses, garages and warehouses. Some laboratories are small enough to fit into a car boot or even inside a suitcase.

The production of Crystal Meth is profitable and mark-ups are significant. Just 30 tablets, each containing 60mg of pseudoephedrine, can produce more than 300 doses of methamphetamine. The substance abusers have even developed a method of making Crystal Meth with only four tablets of pseudoephedrine.

International Experience

USA

The US Government passed federal legislation, in 2011, that made it illegal to purchase more than 3g (50 tablets) per month for individual use. Many states have passed stricter laws that make it illegal to purchase the drug without proper identification. Other states only allow the purchase from a pharmacy, despite the fact that all other non-prescription medicines can be sold outside pharmacies. This has ensured that genuine patients still have access to pseudoephedrine. The number of methamphetamine labs has reduced in those states that have stricter rules and has increased in states that have less rigorous rules. It is believed that most of the pseudoephedrine used in illegal methamphetamine production is now smuggled in from Mexico.

Australia

Australia's prevalence rate for amphetamine usage is the third highest internationally, at around five times the global average. Prior to 2000, most supply was imported from overseas. However, this changed substantially with ATS the most common illicit drugs manufactured in clandestine laboratories in Australia. Now it is estimated that 90% of methamphetamine production occurs locally, principally using pseudoephedrine.

The regulatory body in Australia, the National Drugs and Poisons Schedule Committee, decided in January 2006 that all products containing pseudoephedrine would become a Schedule 3 Medicine. This means that a pharmacist must personally be involved in every purchase and that the products are stored out of reach from customers. They also agreed that all products containing more than 800mg of pseudoephedrine per pack (liquids) or 720mg of pseudoephedrine per pack (tablets/capsules) become Schedule 4. Medicines in this category are only available with a doctor's prescription.

In addition, Project Stop was developed by the Pharmacy Guild of Australia and funded by the Government to provide pharmacy-to-pharmacy information sharing. Rolled out nationally in 2007, Project Stop is an online recording system that is accessible to all pharmacies, allowing the tracking of criminals across borders and jurisdictions. Pharmacists using Project Stop record all pseudoephedrine product sales and obtain photo ID for every purchase. Once an individual has exceeded a predefined number of pseudoephedrine product requests within a specified time frame, an alert is immediately displayed on a secure website used by enforcement agencies.

UK

In 2008, the MHRA announced new laws in relation to pseudoephedrine-containing products. Large packs of pseudoephedrine and ephedrine were made prescription-only. Smaller packs containing 720mg (the equivalent of 12 tablets/capsules of 60 mg or 24 tablets/capsules of 30mg) remain non-prescription and are limited to one pack per customer. Furthermore, the Royal Pharmaceutical Society advised that the sale and supply of these products must be made by a pharmacist or suitably trained pharmacy staff under the supervision of a pharmacist.

The MHRA reviewed these restrictions in August 2011 and concluded that the measures were helping to contain the potential problem of misuse and that the sale of pseudoephedrine-containing medicines had reduced. The number of registered methamphetamine addicts remains small and there is low availability of methamphetamine across the UK. Implementation of measures to regulate sales, together with the additional voluntary actions overseen by the pharmacy profession, has made an important contribution to managing the risk of misuse. The Commission on Human Medicines commended the pharmacy profession for their continued significant contribution to managing the risk of misuse of medicines containing pseudoephedrine and recommended that existing levels of monitoring, education, and awareness measures by pharmacists be maintained.

Irish Experience

The diversion of pseudoephedrine and manufacture of methamphetamine in Ireland does not yet appear to be operating anywhere near the scale of operations in Australia or the United States. However, this does not mean we have become complacent. In 2012, the HSE South issued a number of alerts to pharmacies in Cork, Kerry and Limerick regarding customer requests for excessive quantities of pseudoephedrine. On one occasion, as a result of a pharmacist's vigilance, the Gardaí arrested four men who were found to be producing Crystal Meth in their house. Following this alert, the IPU highlighted the issue to pharmacists in our eNewsletter and General Memorandum.

In 2012, the PSI issued advice to pharmacists in relation to sale of pseudoephedrine-containing products. It recommended that consideration should be given to the location and storage of these medicines, that requests for these products be referred to the pharmacist and that pharmacists should use their professional judgment and discretion in deciding whether a genuine clinical need exists and the medicine is appropriate for the patient.

In January 2015, the IPU spoke with the Garda Drug Squad who indicated that Crystal Meth production is not a big problem in Ireland; indeed, only four 'box' labs have been found in recent years. The Gardaí believe that manufacturers of Crystal Meth prefer to use benzyl methyl ketone (BMK) to manufacture methamphetamine as it is cheaper and more readily available in bulk than pseudoephedrine.

Next Steps

If pseudoephedrine were to become a prescription-only medicine, there would be a significant increase in the number of patients requiring doctors' appointments to receive medication to treat common medical complaints such as cold or sinusitis. While there would potentially be a decrease in costs for law enforcement through lab reductions, there would be an immediate greater increase in healthcare costs; this would be a cost-shifting exercise rather than a solution.

It is worth noting that in Australia, where all sales of pseudoephedrine-containing products are recorded in real time, only 1.5% of sales are denied, meaning that 98.5% of people who present at a pharmacy leave with the medicine they require. If just 75% of transactions recorded in Australia had been forced to go to a doctor first, it would have required 365,000 man hours in GP consultation time and added \$73 million to the taxpayer or healthcare service.

Community pharmacists are in a strong position to exercise professional judgment and refuse to supply pseudoephedrine-containing products, if deemed necessary. Pseudoephedrine products are useful and effective medicines that should remain available to the public for legitimate purposes through community pharmacies.

Community pharmacists continue to provide consumer education at the pharmacy level to advise consumers that the reason for the increased vigilance is to discourage the diversion of pseudoephedrine-containing products for illicit purposes. To support this, the IPU would be in favour of a nationally coordinated education and awareness campaign. Such a campaign needs to address prevention, intervention, treatment, research and education, particularly targeting individuals who are at high risk of drug abuse and dependence.

Conclusion

The IPU regularly advises its members to be vigilant in regard to purchases of pseudoephedrine and to ensure that sales are limited to one pack per person. If pharmacists are suspicious of any of their customers purchasing or attempting to purchase an excessive amount of pseudoephedrine-based products or requesting multiple packets they are advised to notify their local Garda Drug Squad. This will enable the Gardaí to build up a picture of the extent of the problem in Ireland.

We would be happy to meet with the HPRA to discuss or clarify any of the issues raised in this submission.