

# Pharmacy must make measures work

Tom Moberly and Mike Thompson report on what new restrictions for products containing pseudoephedrine and ephedrine mean for pharmacy

Pharmacists will have to shoulder the burden of ensuring that new restrictions announced last week relating to products containing pseudoephedrine and ephedrine work so that these products continue to be available over-the-counter, the Medicines and Healthcare products Regulatory Agency says.

Speaking about the pack size and sales restrictions, June Raine, director of vigilance and risk management of medicines at the MHRA, elaborates: "The new measures are part of a comprehensive package advised by the Commission on Human Medicines.

"At the end of a two-year period, a decision will be made as to whether those measures have had the desired effect and are retained, or whether it is necessary for these products to be reclassified to prescription-only medicines."

She explains that the MHRA has listened to pharmacists who are confident that the risk can be managed in pharmacy. "Now it is over to pharmacy to make the measures work."

Commenting on the voluntary nature of the controls and the deferral of reclassification, Dr Raine says: "This is a strong signal from Government in support of the role of pharmacists in medicines supply."

She adds that the MHRA will liaise with the Royal Pharmaceutical Society to make sure that pharmacists have the guidance that they need to control sales effectively.

"Pharmacists need to take advantage of the training packages that are becoming available, follow the guidance and be alert and responsive," Dr Raine says. But she admits: "No-one thinks that an entire methylamphetamine epidemic will be created from OTC sales."

Dr Raine also suggests that other controls might be considered before triggering full prescription control of pseudoephedrine, if the current proposed restrictions prove to be insufficient.

One possibility will be to use the Misuse of Drugs Regulations to require records of sales to be kept and to restrict the total amount that individuals can buy over a period of time. This would shift the threat of



Pseudoephedrine products

prosecution away from pharmacists making supplies and on to individuals who might buy too much.

Sadia Khan, the Society's lead pharmacist for self care, stresses that pharmacists should, with immediate effect, be ensuring that sales of any pseudoephedrine- and ephedrine-containing medicines are restricted to one pack per sales transaction.

"Adequate procedures to prevent multiple pack sales should be implemented and all staff involved in the sale or supply of these products should also be appropriately trained," she says. "The Society will be giving urgent consideration to the issue of personal sales by a pharmacist and will provide further guidance once the implications of the CHM advice have been fully considered".

The restrictions (*PJ*, 1 September, p221) were proposed in response to concerns that decongestant products containing pseudoephedrine and ephedrine could be used in the illegal manufacture of methylamphetamine (crystal meth).

Colette McCreedy, director of practice at the NPA, believes that the way in which pharmacy deals with these restrictions will have long-term implications for the profession. "If we can demonstrate that we can handle this public health issue, it will demonstrate

to the MHRA and Committee on Human Medicines that they can have faith in pharmacy," she says.

Although dates for phasing out pack sizes larger than 720mg have yet to be determined, Sheila Kelly, executive director of the Proprietary Association of Great Britain, believes that a number of factors will have an impact on this. These include the need to ensure supplies are not disrupted during the cold season and legal requirements for a 12-week consultation process and a 42-day period while the Regulations lie before parliament.

A Commission on Human Medicines working group is being established to advise on the practical aspects of the measures proposed (see Panel).

## Scottish controls

Community pharmacists in Scotland have also been urged to ensure that sales of nasal decongestant products containing pseudoephedrine and ephedrine are more tightly controlled. As part of this, Community Pharmacy Scotland is encouraging pharmacists to carry out the sale themselves, or at least to supervise the sale closely, to minimise the inappropriate use of the products.

Harry McQuillan, chief executive of CPS, comments: "We would like to see pharmacists implement immediately the proposed measures to restrict and control sales, and we will be strongly encouraging our members to do so.

"The alternative — to make these products prescription only medicines, only able to be prescribed by a GP — would have had a detrimental effect on all of the efforts to improve patient access to pharmaceutical care and medicines for minor ailments, and in doing so would have increased the pressure on GPs.

"In our view pharmacists are the right people to ensure and control the sale of these products."

## Monitoring the new restrictions

New controls over the sale of products containing pseudoephedrine and ephedrine are to be monitored by an expert group of the Commission on Human Medicines to see whether they are sufficient to stop a threatened prohibition on over-the-counter sales of all such products.

June Raine, director of vigilance and risk management of medicines at the Medicines and Healthcare products Regulatory Agency, says that the group, in conjunction with enforcement agencies, will first consider what information will be available after the new controls come into effect and then define indicators that could be used to monitor their effectiveness. These would then be used to decide whether to trigger the threatened POM reclassification of all pseudoephedrine products in 2009.

The expert group is expected to be up and running by October, with its membership being finalised in September.