Safeguarding public health

Press release

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Nasal decongestants get new sales restrictions

The Medicines and Healthcare products Regulatory Agency (MHRA) has announced today that pseudoephedrine and ephedrine contained in nasal decongestants in cold and flu remedies are to have tighter controls. This follows a public consultation initiated by the MHRA as there has been an increasing concern about the potential for pseudoephedrine and ephedrine to be extracted from over-the-counter (OTC) medicines and used in the illegal manufacture of methylamphetamine (crystal meth).

The MHRA received views from industry, other organisations and public bodies about the continuing availability of pseudoephedrine and ephedrine. The consultation ended on the 29 June 2007. The Commission on Human Medicines (CHM) considered the responses to the consultation and proposals from interested parties.

The Commission has recommended that large packs of pseudoephedrine and ephedrine will be replaced by smaller packs of 720mg (the equivalent of 12 tablets or capsules of 60 mg or 24 tablets or capsules of 30mg) and there will be a limit to one pack per customer. The Commission also recommended to the pharmacy professions that the sale should be carried out by a pharmacist.

An Expert Group of CHM is to be set up to advise on the practical aspects of the measures proposed. The impact of the strengthened pharmacy controls will be regularly monitored and evaluated by this group. The group will also carry out a full review of all decongestants in this class, looking at the effectiveness and potential safety concerns of these medicines and their alternatives.

The legal status of products containing pseudoephedrine and ephedrine should be reclassified from pharmacy only to prescription only (POM) in 24 months time (2009) or earlier if necessary, unless the risk of the misuse of these OTC medicines in the illicit manufacture of methylamphetamine is contained by the measures outlined.

Dr. June Raine, Director of Vigilance and Risk Management of Medicines at the MHRA, said “The MHRA is introducing these measures to protect the public health following concern that was highlighted during the consultation process. All stakeholders will be working together to ensure the controls are effective. The Expert Group will be carrying out a continuous programme to monitor the situation.”

Notes to Editors

1. On 18 January 2007, the CHM considered the availability of Pseudoephedrine and ephedrine in OTC medicines and advised that a public consultation exercise be carried out

2. There are 97 authorised products containing pseudoephedrine and 17 containing ephedrine.

3. The MHRA consultation document.
   www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2030434&ssTargetNodeId=373

4. The CHM is a statutory body under the Medicines Act, with a duty to advise ministers on matters relating to human medicines.
   www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=863

   The CHM recommendations and minutes are available from the MHRA website.
   www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2030434&ssTargetNodeId=373

5. Methlyamphetamine was rescheduled to a Class A drug on 18 January 2007 to reflect the true harms of the drug when it is misused. Please refer to the Home Office for queries about Methlyamphetamine (crystal Meths)
   www.homeoffice.gov.uk

Ends