European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends lifting of supply and treatment restrictions for Neupro

The European Medicines Agency has recommended that the supply and treatment restrictions for Neupro (rotigotine transdermal patch), from Schwarz Pharma Ltd, be lifted. Once this recommendation is endorsed by the European Commission, the ban on prescribing Neupro to patients not yet taking the medicine will be reversed. Doctors in the European Union will then be able to prescribe Neupro to all patients in accordance with the approved product information and prescriptions will no longer be limited to one month.

Neupro is currently indicated for the treatment of Parkinson's disease and restless legs syndrome. It is applied as transdermal patches that deliver the active substance, rotigotine, across the skin.

At its May 2008 meeting, the Agency's Committee for Medicinal Products for Human Use (CHMP) recommended immediate changes to the storage conditions for Neupro following reports of crystallisation of the active substance in some patches. The recommendations included the requirement that the medicine be stored in a refrigerator at a temperature of between 2 and 8ºC.

While the company was implementing a cold-chain storage and distribution system to comply with the new storage conditions, restrictions were put in place to manage potential shortages. These stated that Neupro could only be prescribed to patients who had already been taking the medicine, with prescriptions limited to one month at a time.

Following assessment of the cold-chain system that has been put in place by the company, the CHMP is now re-assured that no significant crystallisation should occur under these storage conditions and that Neupro supplied to patients now meets the required quality standards.

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Notes:

1. More information on the restrictions recommended in June 2008 is available in a question-and-answer document.
2. The CHMP reviewed the marketing authorisation of Neupro on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.
3. Neupro was first authorised in February 2006 for the treatment of Parkinson's disease. Since August 2008 it has also been authorised for the treatment of restless legs syndrome. It is currently available in Austria, the Czech Republic, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Poland, Spain, Slovakia, Sweden and the United Kingdom.
4. More information is available in the European Public Assessment Report (EPAR) at http://www.emea.europa.eu/humandocs/Humans/EPAR/neupro/neupro.htm.
5. This press release, together with other information on the work of the Agency, can be found on the Agency's website: www.emea.europa.eu

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