Malta, 23 January 2009
Circular No. P01/2009

Re: The EMEA makes recommendations for safer use of Ritalin and other methylphenidate-containing medicines in the EU

The European Medicines Agency (EMEA) has concluded that methylphenidate-containing medicines remain suitable for the treatment of children aged six years or older and adolescents with attention deficit/hyperactivity disorder (ADHD). It has also recommended that the product information be made consistent across the European Union (EU) so that all patients, carers and prescribers have the same information for safer and more appropriate use of these medicines.

Methylphenidate has been available in the EU since the 1950s under various trade names, including Ritalin, Concerta, Equasym, Medikinet and Rubifen. In ADHD, it is used as part of a comprehensive treatment programme that includes psychological, educational and social interventions, when other measures have not been effective in changing behaviour.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) has reviewed methylphenidate due to concerns over cardiovascular risks (hypertension, heart rate increases and arrhythmias) and cerebrovascular risks (migraine, cerebrovascular accident, stroke, cerebral infarction cerebral vasculitis and cerebral ischaemia). In addition to these concerns, CHMP looked at the risk of psychiatric disorders, the effect of methylphenidate on growth and sexual maturation, and the effects of long-term treatment.

Following review of the available data, the Committee concluded that there was no need for an urgent restriction to the use of methylphenidate-containing medicines, but that new recommendations on prescribing the medicines and on pre-treatment screening and ongoing monitoring of patients are needed to maximise the safe use of these medicines.

Because information about their safety is not consistent across the EU, the CHMP concluded that the product information of all methylphenidate-containing medicines authorised in the Member States should contain the following information:

- before treatment, all patients should be screened to see if they have any problems with their blood pressure or heart rate. The family history of cardiovascular problems should also be checked. Any patients with these problems should not be treated without specialist evaluation;
- during treatment, blood pressure and heart rate should be monitored regularly. Any problems that develop should be investigated promptly;
- there is a lack of information on the long-term effects of methylphenidate. For patients who take methylphenidate for more than a year, doctors should interrupt treatment at least once a year to determine whether continued treatment with methylphenidate is necessary;
- the use of methylphenidate could cause or worsen some psychiatric disorders such as depression, suicidal thoughts, hostility, psychosis and mania. All patients should be carefully screened for these disorders before treatment and monitored regularly for psychiatric symptoms during treatment;
- the height and weight of patients treated with methylphenidate should be monitored during treatment.

In addition, the CHMP also asked that further risk minimisation measures, including educational material for doctors, be put in place and that further studies be carried out, particularly into the long-term effects of methylphenidate.

The CHMP opinion has now been sent to the European Commission for the adoption of a legally binding decision, applicable in all EU countries.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full **press release** and **Q&A document** issued by the EMEA, attached here for your perusal.

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