EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Janne Larsson
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EMA/634897/2012
Patient Health Protection

Subject: Your correspondence of 23 September 2012 and 6 January 2013

Dear Mr Larsson

Thank you for your e-mails of 23 September 2012 and 6 January 2013 addressed to the chair of the Committee for Medicinal Products for Human Use (CHMP), Dr Tomas Salmonson, regarding the use of Concerta (methylphenidate containing medicinal product) in adults in Europe.

As per our previous correspondence with you we would like to reiterate that methylphenidate containing medicinal products are authorised in the European Union through national procedures. No methylphenidate containing medicines have been authorised through the centralised procedure. For nationally authorised medicines the Agency's Committees in particular the CHMP and the new Pharmacovigilance and Risk Assessment Committee (PRAC) only get involved in the assessment of such products in specific situations at the request of the Member States or the European Commission.

As you are aware the CHMP was previously involved in a review procedure of methylphenidate at the request of a member state over concerns on the safety of these medicines in children. Once this procedure was concluded and the Commission Decision was issued, it became the responsibility of national competent authorities of the Member States to ensure the implementation of changes and conditions agreed. This review procedure did not address the issue of use of methylphenidate in adults as this was not a population for which these medicines were authorised at the end of the review, nor to the best of our knowledge since.

In view of your continued interest in methylphenidate we would like however to bring to your attention that a European funded study is being undertaken by the ADDUCE consortium. The main objective of this study is to investigate the long term adverse effects of methylphenidate on growth, neurological system, psychiatric status and cardiovascular system in children and young adults. For further information on this study please refer to http://adhd-adduce.org.

We have in addition forwarded the information you sent us to the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) which is a regulatory body that represents national medicines regulatory authorities of the EU Member States and specifically to the Medicines and Healthcare products Regulatory Agency (MHRA) as UK acts as Reference Member State for Concerta.

Yours sincerely,

Anthony Humphreys
Head of Regulatory, Procedural and Committee Support
Patient Health Protection