

By email only to: jan.olov.larsson@telia.com

7th October 2008

Dear Mr. Larsson,

Re: open letter to Pr. Kent Woods (10th August 2008)

Thank you for writing to us on a number of occasions about the safety of Strattera.

The decision to recommend that a marketing authorisation (product licence) should be granted for a medicine is only made after detailed evaluation of the available data from clinical trials and is subject to input from our independent scientific expert advisory committee, the Commission on Human Medicines. The marketing authorisation for Strattera was only granted once we were convinced that the benefits of its use in the treatment of Attention Deficit Hyperactivity Disorder outweighed its potential risks.

Post-marketing surveillance is also of paramount importance and I note the concerns regarding Strattera that you have expressed in your recent letters. I am confident that the VRMM division of the MHRA continues to keep the safety of Strattera under close review and any new safety signals are evaluated in an independent, scientifically robust manner. The decision about the need for regulatory action is taken along with the other European member states where Strattera is licensed; all member states are committed to ensuring that the balance of benefits and risks associated with its use are optimal.

The MHRA is committed to ensuring that all safety concerns are subject to robust scientific assessment and the best possible regulatory action is taken in a timely manner. We strive to maintain the highest standards of work and review our practices to ensure these standards are maintained or improved upon where necessary. An important aspect of this is ensuring that data from all available sources have been considered and we do appreciate the information you have submitted to us in relation to Strattera, even though we have been unable to verify the sources or accuracy of all your data.

We accept that there are, and will continue to be, divergent views on this issue. However, please be reassured that the MHRA is acting with other European regulatory authorities to ensure that Strattera is used in Europe as safely as possible using regulatory and scientific pharmacovigilance processes, according to national and European legislation.

I understand that the relevant lead assessor from the Vigilance and Risk Management of Medicines (VRMM) division of the MHRA has written to you in response to some outstanding



questions you had raised about the Agency's role in monitoring the safety of Strattera within Europe. I hope that has clarified our position in relation to the regulation of Strattera.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'K Woods', written over a light grey rectangular background.

Kent Woods
Chief Executive