

6<sup>th</sup> March 2008

Dr Jean-Pierre Garnier  
GlaxoSmithKline  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS

Dear Dr Garnier

I am writing to advise you that the Medicines and Healthcare products Regulatory Agency is today announcing the conclusion and outcome of its investigation into a number of allegations regarding GSK, in particular that the company withheld from the MHRA important clinical trial data relating to the safety and efficacy of Seroxat in children and adolescents, and promoted that product for use in this age group despite safety and efficacy concerns.

In immediate practical terms, the outcome of the investigation is that, having considered our investigation report, government lawyers have decided not to pursue a prosecution of GSK. Their view is that the law at the time these events took place did not require a pharmaceutical company to inform the regulator of clinical trials data in groups for whom the medicine was not licensed, and that there is insufficient evidence of GSK promoting the product for "off-label" use in under 18s. We will today be issuing a press release to confirm that, and will be publishing on our website a short report setting out the conduct and conclusions of the investigation. I am attaching both the press release and the report for your records.

That is the immediate practical outcome but there are a number of other issues arising from this process. There is obviously a need to tighten the law to make it absolutely clear that pharmaceutical companies have a legal responsibility to inform the regulator of any information that changes the benefit: risk profile of their products, regardless of whether the information relates to a licensed indication. We will be using the current European Commission consultation on pharmacovigilance regulations and other opportunities to press for changes to the law in this area.

Such a course of action should be unnecessary in an industry which relies so heavily on public trust and aspires to high ethical standards. I would have thought it self-evident that such information should be made available promptly to the regulator in order that action can



be taken to protect public health. However, that moral responsibility now needs to be insisted upon by the unambiguous force of law.

You will be aware that we have reviewed a large quantity of documents from GSK. Legal provisions prevent us from releasing publicly any information gained under our statutory powers in the course of a criminal investigation. However, there has been a significant level of quite legitimate public interest in this case, and I would therefore like to release that information into the public domain. This of course requires your consent. GSK has regularly asserted that it has nothing to hide in this matter, and so I should be grateful if you could confirm in writing your consent to the release.

Finally, I have no doubt that the content of this letter will be the subject of numerous Freedom of Information requests to the Agency in the coming weeks. The MHRA takes the view that any considerations of confidentiality are outweighed by the public interest in its disclosure, and we will therefore be publishing this letter today alongside our investigation report.

If you have any queries about the content of this letter, please do not hesitate to contact me.

Yours sincerely

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

Professor Kent Woods  
CEO