20 Greenacre Court
Lancaster
LA1 4LE

20th May 2010

Dear Devyani Fowler,

Thank you for your response to my letter of 21st April regarding Ativan.

My initial prescribing doctor would not have had all relevant information at his disposal in 1975 as you say. In the UK at that time the best source of information which would enable a doctor to decide if and how a product should be used was the ABPI data sheet. The Ativan data sheet for the first 15 years failed to refer to the evidence of withdrawal seizures found in the De Buck clinical trials in 1972 or to the fact that UK recommended dosages for Ativan were double those recommended in North America and elsewhere. UK dosages were changed in 2007 from 10mg maximum to 4mg. **What evidence did Wyeth submit to back up this application?**

There is very good evidence that doctors would have acted quite differently had Wyeth reflected in the data sheet Dr De Buck's finding that seizures might result from discontinuation of Ativan taken at therapeutic doses after only a few weeks. **Can you confirm that Wyeth disclosed De Buck's findings to the Licensing Authority in its product licence application for Ativan submitted in April 1972?**

If, however, the cases of epileptic seizures mentioned in De Buck's paper were part of his discussion of his **subsequent** clinical experience and did not form part of his study results and were not included in the product licence application, then **when was this new information submitted to the MCA?**

Also, as I mentioned in my previous letter, the 1974 data sheet warns against abrupt withdrawal 'as some sleep disturbance may result.' **What was the evidence for this?**

I am currently corresponding with the MHRA, Dept of Health and the Sec of State Health regarding these issues and I reserve the right to contact you further regarding the safety of Ativan.

Yours sincerely

John Perrott