



Department
of Health

*From the Baroness Blackwood
Parliamentary Under Secretary of State (Lords)*

*Department of Health
39 Victoria Street
London
SW1H 0EU
Tel: 020 7210 4850*

Lord Alton
House of Lords
London
SW1A 0AA

Dear Lord Alton

I promised to write to you after the debate in the House of Lords on 28th February on 'Improving the safety of medicines and medical devices'.

During the debate you said that the Medicines and Healthcare products Regulatory Agency (MHRA) had not responded to either an FOI request made by the All-Party Parliamentary Group (APPG) on Hormone Pregnancy Tests (HPTs) or to e-mails from Mrs Lyon requesting the raw data used in the forest plots.

The MHRA has informed me that it has no record of having received an FOI request from the APPG despite searching its mailboxes in response to Mrs Lyon's original email of 4th February. Since subsequently receiving details of the APPG's request the MHRA has sent Mrs Lyon the requested data to pass onto the APPG and Professor Heneghan. I am appending a copy for your records.

In line with the Government's commitment to review any important new evidence that arises with respect to HPTs, Lord O'Shaughnessy asked for a new, independent expert group of the Commission on Human Medicine (CHM) to consider the meta-analysis conducted by Professor Heneghan and his colleagues.

The CHM has set up a new group of experts, none of whom were involved with the original Expert Working Group on HPTs. This group is meeting on 18th

March; Mrs Lyon and a member of the IMMDSR team are attending as observers and Professor Heneghan has been invited to present his work to the group. In parallel the Committee for Medicinal Products for Human Use (CHMP) in Europe will be reviewing the data to determine whether there are any implications for currently authorised medicines. The findings of both reviews will be made public.

The original recommendations of the Expert Working Group on HPTs are being implemented and overseen by the Cross-Sector Group on the Safety of Medicines in Pregnancy. This important work was chaired by Lord O'Shaughnessy and I look forward to taking that forward. On Baroness Cumberlege's Review, while we will need to take her advice on the likely report date, we anticipate that she will report this year. I can assure you that we will look at her recommendations in detail and ensure a system response.

I hope this reply is helpful.

Best wish

Nicola

NICOLA BLACKWOOD