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4th June 2019

Ms Joanna Wood
Review Team
Independent Medicines and Medical Devices Safety Review
King's College, London
Shepherd's House
Room 3.25b
London SE1 1UL

Dear Ms Wood

Thank you for your letter of 24 May, offering me, as Chair of the Expert Working Group (EWG) on Hormone Pregnancy Tests (HPTs), an opportunity to respond to comments made by the All-Party Parliamentary Group (APPG) at its oral hearing on 14th May.

No new issues have been raised by the APPG that I need to respond to specifically; my response to the evidence provided by the Chair of the Association for Children Damaged by HPTs, dated 1st May, and the evidence we provided at the oral hearing cover most of the issues raised.

I would nonetheless like to take this opportunity to re-emphasise that the EWG had a clear mandate and scope and that members brought together a wealth of independent expertise in the relevant disciplines including teratology, embryology, clinical genetics, neonatology and epidemiology. This enabled the group to ensure that all the available evidence was evaluated rigorously and that all aspects of the review were explored in a way that was thorough, impartial and objective. I can attest that the group took on this important work with a completely open mind regarding the outcome.


The Expert Group was given a well-defined scientific remit, but we also recognised how important it was to familiarise ourselves with some of the broader, non-scientific issues in order to provide the context and perspective for the review. To achieve this, we had complete access to the substantial amount of information that the MHRA Secretariat had gathered for the review, including translations of all the documents from the German archives that had been provided for the review by the Chair of the Association for Children Damaged by HPTs.

I would also like to emphasise the important work of the Group in recommending where regulation can be strengthened in relation to medicines used by pregnant women to better support informed decisions by women and their healthcare providers. I am pleased to report that this programme of work is now well under way.

A number of the specific comments in the transcript relate to the procedural aspects of the review or to broader points about medicines regulation and I have forwarded these to the MHRA to respond to in their role as Secretariat to the Group.

Thank you again for providing the opportunity to respond, and I would be happy to provide any further clarification which would be helpful to the Review.

Yours sincerely



Dr Ailsa Gebbie FRCOG FRCP(Edin) FFSRH
Chair of Expert Working Group (EWG) on Hormone Pregnancy Tests
Consultant Gynaecologist [REDACTED]