Medicines & Healthcare products Regulatory Agency

MHRA

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

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Dear Ms Wood

Thank you for your letter of 26 June enclosing a transcript from the evidence given to the review by the Chair of the Association for Children Damaged by Hormone Pregnancy Tests (HPTs) on 20th May 2019. I am grateful for the opportunity to provide a response which is set out in Annex 1.

There is some overlap between this transcript and the one sent to Dr Ailsa Gebbie, Chair of the Expert Working Group on Hormone Pregnancy Tests (EWG) and the one sent to Professor Ralston, Chair of the Commission on Human Medicines (CHM). As the MHRA provides the Secretariat to CHM and its EWGs, Professor Ralston and Dr Gebbie have asked me to respond to any new process-related points that have been raised. These points are also covered in Annex 1.

The MHRA takes very seriously the issues raised in these and previous transcripts concerning the Agency's conflicts of interest policy. The approach to conflicts of interest in our expert committee system is based on self-declaration of interests and transparency. However, we accept the need to review our policies and processes in light of the concerns expressed in the context of the Review.

I would be happy to provide any further clarification, if that would be helpful.

Yours sincerely

June M. Raine

Dr June Raine
Director – Vigilance and Risk Management of Medicines

[redacted]

Annex 1

Passage 2 - Authority of the regulatory system relating to data from studies

Since the introduction of the amended pharmacovigilance legislation in 2012[1] the marketing authorisation holder is legally obliged to bring to the attention of the regulator any information or data it is aware of that could impact on the balance of benefits and risks of a currently authorised product, including the results of studies. Similarly, if the regulator has a concern it can impose on marketing authorisation holders the obligation to conduct a study.

Passage 3 - Data provision to the EWG

The MHRA provided the secretariat function to the EWG, organising its meetings and providing the attendees with summaries of the evidence under consideration in accordance with a programme of work agreed with the Group at its first meeting.

In addition to detailed summaries of the relevant scientific data, the EWG asked for access to all information provided to the Agency for the purpose of the review. In accordance with this request, a substantial package of data that included all evidence that had been reviewed to that point, was sent to the Group in July 2016. A listing of this data can be provided on request (see Annex 2).

On 20th February 2017, once translation of all the documents in German from the Landesarchiv Berlin was complete, these were also sent to the Group, together with a summary. Mrs Lyon was invited to give a presentation to the EWG at its meeting on 24th April on areas of importance within the Landesarchiv Berlin documents.

Observer status

At a meeting on 18th August 2015 between MHRA, Mrs Lyon and Mr Dobrik, the roles of the various participants in the Expert Working Group were discussed. The MHRA clarified at that meeting that observers would usually be able to respond to questions from members and the Chair and would be able to contribute to the discussions of the Expert Working Group at the Chair's discretion. The role of Mr Dobrik was subsequently changed to 'invited expert', which meant he was able to contribute freely to the discussions though not to the final recommendations.

My letter of 24th April 2019 provides further details with regard to the level of participation Mrs Lyon at the EWG meetings[2].

Passage 4

Mrs Lyon wrote to the MHRA after the first two meetings, requesting that we pass on her letter to the Chair of the EWG as she did not have a contact address for Dr Gebbie. The Secretariat duly forwarded the letter to Dr Gebbie. The points raised in the letter were discussed at the next EWG meeting.

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[1] Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

[2] http://immdsreview.org.uk/downloads/IMMDSReview%20response%20to%20Mrs%20Lyon%20evidence%20190424_redacted.pdf