Medicines & Healthcare products Regulatory Agency

MHRA

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Dear Ms Wood

Thank you for your letter of 1 July and for providing me with the opportunity to respond to the transcript of the oral hearings of 22 May 2019 with representatives of OACS and OACS Ireland. I would like to provide the following points of clarification.

The representative from OACS, Ms Lapidge, says that the manufacturer had made the recommendation to prescribe valproate where no other medication works and that the regulator ignored that advice.

I refer to page 6 of the follow up information provided following the oral hearing of 19th February which outlines in detail the licensing process for valproate[1]. I would like to highlight the minutes of the meeting of the Committee on Safety of Medicines in August 1974 which advised that valproate could be marketed on condition that the following warnings were added to the licence:

'In women of childbearing age it should only be used for severe cases or those resistant to other treatments.'

'Women of child-bearing age This compound has been shown to be teratogenic in animals. Any benefit which may be expected from its use should be weighed against the hazards suggested by these findings.'

In relation to Ms Lapidge's criticisms in passage 1 about monitoring and evaluation, page 177 of the follow up information provided following the oral hearing outlines the regulator's response to the accumulating data on the risks of valproate in pregnancy.

The representative of OACS Ireland, Ms Keeley, mentions the article in Current Problems in Pharmacovigilance issued in 1983 and says that this was produced by Abbott Laboratories Pharmaceutical Division. To clarify, Current Problems in Pharmacovigilance was a bulletin produced by the Committee on Safety of Medicines and the Medicines Control Agency and was sent to healthcare professionals in the UK.

[1] http://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20-%20Evidence%20Submitted%20Following%20Oral%20Hearings.pdf p183

Thank you again for the opportunity to clarify these points.

Yours sincerely

Dr June Raine
Director – Vigilance and Risk Management of Medicines

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