



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

Dear Ms Wood

Thank you for your letter of 11 July 2019 enclosing an extract of the transcript of evidence given by Marie Lyon at one of your oral hearings.

We note that you wish to give Bayer plc the opportunity to respond to specific critical comments made by Marie Lyon about Bayer plc and also Schering, but I have to say that it was neither clear to us what criticism was being made in this extract, nor what evidence (as opposed to speculation) was being advanced to support that criticism. However, as a factual matter, we wish to make clear the following:


1. Primodos (Duogynon Oral) has not been on the market in the UK or elsewhere for very many years but, as noted by the CHMP at paragraph 3 of its opinion of April 2019 concerning norethisterone and ethinylestradiol (EMA/245512/2019), norethisterone and several other progestogens are still marketed by various companies as monotherapy or in combination with an oestrogen for the treatment of menstrual bleeding irregularities and for endometriosis.
2. At various times there may have been a popular belief, based on the fact that hormone pregnancy tests induced a withdrawal bleeding in those who were not pregnant, that such products would act as an abortifacient. This is noted in the EWG Report of 2017. However, the scientific evidence does not support this supposition, which is counter-intuitive given the role of oestrogens and progestogens in supporting pregnancy (see our answer to Question 3 of your list of questions of May 2019). The EWG's Report notes at paragraph 6.4, after a detailed review of the available scientific evidence, that there is "no evidence that administration of these hormones at the licensed doses used in Primodos during early pregnancy were associated with an increased risk of miscarriage".



18 July 2019

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Thank you for giving us the opportunity to respond in this way.

Yours sincerely



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