Press release: Independent Expert Working Group finds totality of scientific evidence does not support a causal association between the use of hormone pregnancy tests and birth defects

Following this extensive and rigorous review the overall conclusion, based on the totality of the available data, is that the scientific evidence does not support a causal association between the use of HPTs such as Primodos and birth defects or miscarriage.

HPTs such as Primodos were available in the 1960s and 1970s and were widely used to diagnose pregnancy. They were withdrawn from the market in the UK in the late 1970s.

In 2014, the government committed to an independent review and having thoroughly examined all the evidence, the conclusion of the review is that the use of HPTs, including Primodos, in early pregnancy was not responsible for the serious birth defects experienced by some people.

Science and clinical practice has moved on since the 1970s and far-reaching advances in the regulation of medicines have taken place. However, this was a valuable opportunity to make recommendations to further strengthen the systems in place for detecting, evaluating and communicating safety concerns with use of medicines in pregnancy.

The recommendations include:

- a full genetic clinical evaluation offered to those who were given a HPT for diagnosing pregnancy and whose lives have been impacted by an adverse pregnancy outcome, to see if an underlying genetic cause can be identified
- a Working Group to advise on better ways to collect, monitor and use data on the safety of medicines during pregnancy
- electronic Yellow Card reporting to be made available at point of care, including at early scanning, to all those who suspect an adverse outcome of pregnancy with use of a medicine
- a strategy to co-ordinate research on mechanisms of teratogenicity in early embryonic development to be taken forward with appropriate experts
- improving the impact of safety messages, monitoring their effect, and ensuring healthcare professionals and patients receive the best available information and feel empowered to make informed decisions about medicines in pregnancy

Professor Stuart Ralston, Chair of the Commission on Human Medicines, said:

> This was a comprehensive and wide ranging scientific review of all the available evidence on the possible association between HPTs and birth defects by internationally leading experts across a broad range of specialisms.
>
> The report of the EWG was carefully reviewed and discussed by the Commission on Human Medicines CHM who fully endorsed the EWGs conclusions and recommendations.

Dr Ailsa Gebbie, Chair of the EWG, said:

> Our recommendations will strengthen further the systems in place for detecting, evaluating and communicating risk with use of medicines in pregnancy and help safeguard future generations.
>
> Many women use these same hormones on a daily basis for contraception and heavy periods who may experience an unintended pregnancy. So our findings are also very reassuring for them.
>
> I wish to express my thanks to the group and to observers and invited experts, and my heartfelt thanks go especially to the families who shared their experiences in difficult circumstances.

Mr Nick Dobrik, an invited expert of the EWG, said:

> As an invited expert I called for the Expert Working Group to consider what recommendations it could make to further strengthen existing systems to monitor and detect harms in relation to medicines that have the potential to disturb the development of the fetus.
>
> The core of the recommendations made in the report are focused on doing just that and the outcome of this important scientific review will help to safeguard future generations.
>
> What happens next to deliver these recommendations is therefore vitally important. Together these initiatives have the potential to make a real difference to the safety of future generations, and they will have my fullest backing.

Dr June Raine, MHRA’s Director of Vigilance and Risk Management of Medicines, said:

> While the publication of this report cannot take away from the very real suffering experienced by these families, it helps shape the

path to further strengthen existing regulatory systems relating to medicines used in pregnancy.

Our focus now will be how best to take forward these recommendations and to make sure, working closely and collaboratively with professional bodies, health system organisations and the ‘Association of Children Damaged by Hormone Pregnancy Tests’, that they are appropriately implemented.

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