



DEBATE PACK

Number CDP-2019/0095, 18 April 2019

Expert Working Group report on hormone pregnancy tests

This pack has been prepared ahead of the debate to be held in Westminster Hall on 23 April 2019 at 11.30am on the Expert Working Group report on hormone pregnancy tests. The debate will be led by Yasmin Qureshi MP.

The House of Commons Library prepares a briefing in hard copy and/or online for most non-legislative debates in the Chamber and Westminster Hall other than half-hour debates. Debate Packs are produced quickly after the announcement of parliamentary business. They are intended to provide a summary or overview of the issue being debated and identify relevant briefings and useful documents, including press and parliamentary material. More detailed briefing can be prepared for Members on request to the Library.

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1. Summary

Drugs containing synthetic versions of progesterone and oestrogen were taken as a form of pregnancy test from the late 1950s until 1970s; the most commonly used of these in the UK was Primodos. Concerns have been expressed for many years that these hormone pregnancy tests may have caused congenital anomalies and miscarriage. In 2014, the then Minister for Life Sciences, George Freeman, announced that the Commission for Human Medicines would establish an expert working group to look at the evidence relating to hormone pregnancy tests.

The Commission on Human Medicines expert working group published a report of its findings on hormone pregnancy tests in November 2017. This concluded that:

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.¹

The report sets out a number of recommendations for the evaluation and reporting on the safety of medicine use in pregnancy. The Government said that the report presents the findings of a thorough review of all the relevant evidence. Departmental Ministers accepted the conclusions and recommendations.² However, the report received criticism following publication, from campaigners in this area, such as the Association for Children Damaged by Hormone Pregnancy Tests, and from MPs in Parliamentary debates. It was labelled as a 'whitewash' and there have been calls for a statutory inquiry to review the evidence and to consider whether there were regulatory failures.

In February 2018, the then Secretary of State for Health and Social care, Jeremy Hunt announced the establishment of a medicines and medical device safety review. This review is chaired by Baroness Cumberlege, and is looking at three issues of concern, including the use of Primodos, the hormone pregnancy test. The review has started to take evidence from patients, patient groups, healthcare professional and others.

A new systematic review of the evidence on hormone pregnancy tests was published in November 2018. The authors have concluded that that "the use of oral HPTs in pregnancy is associated with increased risks of congenital malformations."³ The Government have said that the Commission on Human Medicines has convened an Expert group to look at the new study.

¹ Commission on Human Medicines, [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](#), 15 November 2017

² [HC Written Question 114880: Hormone pregnancy tests](#), 29 November 2017

³ Heneghan C, Aronson JK, Spencer E *et al*. Oral hormone pregnancy tests and the risks of congenital malformations: a systematic review and meta-analysis [version 2; peer review: 3 approved]. *F1000Research* 2019, 7:1725 (<https://doi.org/10.12688/f1000research.16758.2>)

2. Background

Drugs containing synthetic versions of progesterone and oestrogen were taken as a form of pregnancy test from the late 1950s until 1970s. Primodos was the most commonly used of these medications in the UK, others included Norlestrin and Amenorone. They were used for both the investigation/treatment of menstrual irregularities and the diagnosis of early pregnancy (usually between five and ten weeks). It is the latter use which has proved controversial.

For diagnosing pregnancy, Primodos was usually given as two doses 12 hours apart. If the woman taking the tablets did not subsequently have an episode of bleeding the test was positive (i.e. she was pregnant).⁴

At the time hormone pregnancy tests were introduced, pregnancy was usually medically diagnosed later than it is today, without chemical tests, once it was obvious that there had been two or more missed periods and a pregnant uterus could be felt. Hormone pregnancy tests were thought to allow a relatively confident diagnosis of pregnancy.⁵

Studies in the UK and elsewhere from the late 1960s to early 1970s suggested a link between use of hormone pregnancy tests and a wide range of serious congenital anomalies, including cleft lip and palate, limb reduction deformities and heart disease.⁶

Although the evidence was not conclusive on this, the Committee on Safety of Medicines (CSM) (an independent advisory committee to the UK medicines licencing authority) published [a letter in the British Medical Journal](#) (BMJ) on 26 April 1975 that agreed with an [earlier leading article](#)⁷, stating that:

[...] there is little justification for the continued use of withdrawal-type pregnancy tests when alternative methods are available.⁸

In June 1975, the CSM sent [an alert letter](#) to all doctors in the UK in which it advised of a possible association between hormonal pregnancy tests and an increased incidence of congenital abnormalities. It recommended that doctors “should not normally prescribe” these products as pregnancy tests:⁹

⁴ Dewhurst CJ, *Current Practice: Obstetrics in general practice*, British Medical Journal, 7 March 1964 Volume I, p 612

⁵ Dewhurst CJ, *Current Practice: Obstetrics in general practice*, British Medical Journal, 7 March 1964 Volume I, p 612

⁶ Gal I, *Hormonal pregnancy tests and congenital malformations*, *British Medical Journal*, 23 October 1976 pp 1014-5

⁷ BMJ, *Synthetic sex hormones and Infants*, 30 November 1974 pg. 485

⁸ Greenberg G et al, *Hormonal Pregnancy Tests and Congenital Malformations*, British Medical Journal, 26 April 1975, p 191-2

⁹ [Committee on the Safety of Medicines, Hormone pregnancy tests: A possible association with congenital abnormalities, June 1975](#)

A number of studies have shown a possible association between taking mixtures of an oestrogen and a progestogen as a means of diagnosing pregnancy and an increased incidence of congenital abnormalities.

The Committee on Safety of Medicines wish to draw attention to these studies and to the preliminary results of their own case-control study. The early results suggest that a relatively greater proportion of mothers of abnormal babies had been tested in this way. A letter describing these preliminary results was published in the *British Medical Journal* on April 26 1975. (Greenberg, et al, ii, 191). The Committee will present their further conclusions later in the year, when their study is completed.

On the present evidence, the Committee believe that it is possible that the use of these preparations for the diagnosis of pregnancy could on occasion lead to abnormalities in the foetus. There are other means of diagnosing pregnancy which do not require the administration of hormones, and the Committee consider that in view of this possible hazard this method should not now normally be used.

As the data began to accumulate it was felt advisable to inform the companies known to be concerned and it was ascertained either that they had ceased to promote the products for this use, or that the product had been removed from the market. With this further evidence of this possible hazard, the Committee have advised the Health Departments that measures should be taken to ensure that this indication is not included in licences for such products and to require the insertion in all promotional literature of a warning about this possible hazard in pregnancy.

As far as is known the hormone preparations which have been, at some time, used or recommended for this purpose are:

Amenorone	Norlestrin	Paralut
Amenorone Forte	Norlutin A	Pregornot
Disecron	Norone	Primodos
Menstrogen	Orasecron	Secrolyl

Some of these products are no longer on the market, whilst others will continue to be marketed for the treatment of a variety of conditions in women who are not pregnant.

Following this, there were subsequent notifications from the CSM (November 1977), and a yellow warning notice was provided on the products' containers from 1975 onwards to avoid use in pregnant patients. However, it has been reported that Primodos continued to be used with varying frequency as a pregnancy test within the NHS until withdrawal from the market by Schering in 1978.^{10 11}

The CSM's letters on the safety of a number of hormonal preparations, including Primodos in 1975 and 1977 and other relevant documentation is available in House of Lords Deposited Papers online.¹²

2.1 Campaigns and legal cases

The [Association for Children Damaged by Hormone Pregnancy Tests](#) was formed in 1978 by Valerie Williams, the mother of a child with congenital anomalies attributed to Primodos. With support from Jack Ashley MP and others, the Association pursued its aims of obtaining compensation and justice for its member families. Mr Ashley secured an Adjournment Debate on hormone pregnancy tests on 26 May 1978, calling for a public inquiry.¹³

In 1980, the Association initiated legal proceedings against Schering Chemicals Limited on behalf of two children with heart defects.^{14,15} The damage claims were discontinued on 2 July 1982 after the judge found there was insufficient evidence linking Primodos and the conditions.¹⁶

¹⁰ Brewer C, [Continued use of hormonal pregnancy tests](#), *British Medical Journal*, 18 February 1978, p 437

¹¹ The Times, [Pregnancy test drug 'still prescribed after babies-at-risk warning](#), 17 April 1978

¹² [House of Lords Deposited paper on the Committee on the Safety of Medicines and hormone pregnancy tests, 26 October 2010](#)

¹³ HC Deb 2 March 1978 c390-392W and HC Deb 26 May 1978 c2002-9

¹⁴ Times, [Group to sue firm over hormone pregnancy tests](#), 30 November 1978, p 5 (subscription required)

¹⁵ Times, [Primodos actions to go ahead](#), June 10 1980, p 16 (subscription required)

¹⁶ Times, [Claims dropped](#), 3 July 1982, p 3 (subscription required)

In early 2014, a new campaign called for an independent public inquiry into hormone pregnancy tests. This was prompted by the discovery of documents from the 1960s that reportedly show that studies suggested that the drugs caused miscarriages and congenital anomalies at that time.¹⁷

2.2 Medicine and Healthcare products Regulatory Agency review 2014

The Medicine and Healthcare products Regulatory Agency (MHRA) conducted a [review of the historical evidence on hormone pregnancy tests and birth defects in 2014](#). The review considered 36 studies and further unpublished data and reviews.

The review findings were published in March 2014. The MHRA reported that the studies reviewed were “inconsistent in their findings for an association between use of HPTs and congenital anomalies and are not considered sufficient to conclude that an association exists.”¹⁸ The authors expressed concerns about significant limitations with the studies used, mainly related to them being conducted over 20 years ago, when the standards for research were not as high as they are now. They also highlighted that a number of the subsequent evidence reviews expressed similar comments about poor quality of the data in the studies and that most concluded that the evidence does not support a causal association between hormonal pregnancy tests and congenital anomalies.

The conclusion from the synopsis of the MHRA report is included below. This states that the evidence on this issue is mixed but having considered all the available published evidence, the MHRA position was that the data is not sufficient to show a causal link between the tests and congenital anomalies:

The body of evidence for an association between HPTs and congenital anomalies is mixed, with some studies finding a strong association, some finding a weak association and many others finding no association.

Although it is understandable to suspect that there may be an association between a medicine and a condition that develops after taking it, particularly when that medicine is taken during pregnancy, this may not necessarily be the case. The timing of exposure is critical and needs to occur during the period of gestation when the fetus is susceptible to the observed outcome. The association also needs to be plausible; in this case the observation of isolated but different anomalies in different studies is particularly difficult to interpret. If HPTs really were teratogenic, all studies should have observed increased numbers of all the observed that have been anomalies because women were exposed to HPTs at random times throughout gestation. In addition the scientific methodology needs to be sufficiently robust as to exclude false positive findings ie the possibility that other

¹⁷ The Telegraph, '[Is this the forgotten thalidomide?](#)', 12 May 2014

¹⁸ MHRA, [Assessment of historical evidence on Primodos and congenital malformations – a synopsis](#), March 2014

factors could have been responsible for the observed finding - this is not the case for the vast majority of studies.

Having carefully considered the available published evidence, our position therefore remains that the data are not sufficient to conclude that there is a causal association between the use of Primodos (or any HPT) and congenital abnormalities.¹⁹

¹⁹ MHRA, [Assessment of historical evidence on Primodos and congenital malformations – a synopsis](#), March 2014

3. Commission on Human Medicines expert working group review

In response to a Backbench Business Committee debate on oral hormone pregnancy tests in October 2014, the then Minister for Life Sciences, George Freeman confirmed that there would be an independent review of the papers and all the evidence on this issue.²⁰

A [call for evidence](#) was published in March 2015. This stated that the Commission on Human Medicines (the body that advises ministers on the safety, efficacy and quality of medicinal products) had endorsed a need for a review of the evidence relating to hormone pregnancy tests and had agreed the terms of reference for a panel of independent experts. It also stated that the review would not be a political inquiry but would examine the evidence to see if there are grounds for accepting a link between the medication and adverse outcomes in pregnancy.

The terms of reference for the review were agreed by the expert working group in 2015, and were set out in the 2017 report:

1. To consider all available evidence on the possible association between exposure in pregnancy to hormone pregnancy tests (HPTs) and adverse outcomes in pregnancy (in particular congenital anomalies, miscarriage and stillbirth) including consideration of any potential mechanism of action.
2. To consider whether the EWG's findings have any implications for currently licensed medicines in the UK or elsewhere.
3. To draw any lessons for how drug safety issues in pregnancy are identified, assessed and communicated in the present regulatory system and how the effectiveness of risk management is monitored.
4. To make recommendations.²¹

In an October 2016 Backbench Business Committee debate concerns were raised about the terms of reference of the review on hormone pregnancy tests and that it would not look into reports of regulatory failure by Government bodies in the 1960s and 1970s.

In response to the debate, the then Under-Secretary of State for Health, David Mowat, said that "nobody on the Government side of the House has any interest in anything other than getting to the truth, and the process that was put in place two years ago had that at its heart."²² He noted that the Association for Children damaged by Hormone Pregnancy Tests did not have confidence in the inquiry and that this was

²⁰ [HC Deb 23 October 2014, c1138](#)

²¹ Commission on Human Medicines, [Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests](#), November 2017 (page 2)

²² [HC Deb 13 October 2016 c 544](#)

“unsatisfactory.” He said that if the expert group found a clear causal link, then further action would be taken on regulation and liability.

He went on to address concerns that the working group were not impartial:

The second concern is that the expert working group is not impartial. The MHRA has taken a vigorous approach to evaluating and handling potential conflicts of interest. No member of the expert working group can have any interest in any of the companies that were involved or their predecessors. Members should not have publicly expressed a strong opinion, favourable or unfavourable, about the possibility of birth defects arising from these drugs. We heard that one of the members had tweeted. If there is evidence of that, we will follow it up. It is true that one member not of the expert group, but of the advisory group was removed because it was felt that he had a conflict of interest that was not properly declared. Action was taken very quickly in respect of that.

The inquiry is chaired by a consultant gynaecologist from the Chalmers centre in Edinburgh. The group has 14 scientists drawn from some of the best universities in the UK. We have no reason to believe that any of them have any more reason not to want to get to the truth than Members on both sides of this House.²³

Box 1: Sky News documentary

In March 2017, a *Sky News* documentary, *Primodos: The Secret Drug Scandal* provided an account of a six year investigation into the history of hormone pregnancy tests. This included reviewing archived documents from a number of organisations.

The programme expressed concerns regarding the actions of the then regulator, the Committee on the Safety of Medicines, at the time of the use of hormone pregnancy tests and reported that the findings of studies on the adverse effects associated with these drugs were not made publicly available.²⁴ The documents reviewed by the documentary team were submitted to the Expert Working Group.

A March 2017 Lord’s Parliamentary Question asked about the Government’s response to the documentary. The Under-Secretary of State for Health, Lord O’Shaughnessy stated that any new evidence identified would be provided to the expert working group for consideration:

An Expert Working Group of the Commission on Human Medicines is conducting a comprehensive scientific review on the evidence for a possible causal association between Hormone Pregnancy Tests (HPTs), including Primodos, and birth defects. Any important new evidence identified in the Sky News documentary will be reviewed by the Medicines and Healthcare products Regulatory Agency and provided to the Expert Working Group for their consideration and advice.

While the evidence for any association between HPTs and congenital defects is still under consideration it would be premature to comment on the need for a public inquiry.[...]²⁵

More information about the investigation can be found on the [Sky News website](#), and the documentary can be viewed on the [Sky News YouTube webpage](#).

²³ [HC Deb 13 October 2016 C546](#)

²⁴ Sky News, *Primodos: Sky News exposes pregnancy drug cover-up*, March 2017

²⁵ [HL Written Question HL6207: Primodos](#), 29 March 2017

3.1 Publication of the Expert Working Group report

The report of the Commission on Human Medicines' expert working group review on hormone pregnancy tests was published on 15 November 2017. The group's overall conclusion was that "the scientific evidence does not support a causal association between the use of HPTs such as Primodos and birth defects or miscarriage."²⁶

The report's summary sets out the three key issues addressed by the group in relation to hormone pregnancy test and the conclusions that in relation to these (bold retained from original):

1. To consider all available evidence on the possible association between exposure in pregnancy to HPTs and adverse outcomes in pregnancy (in particular congenital anomalies, miscarriage and stillbirth) including consideration of any potential mechanism of action

The EWG's overall finding is that the available scientific evidence, taking all aspects into consideration, does not support a causal association between the use of HPTs, such as Primodos, during early pregnancy and adverse outcomes, either with regard to miscarriage, stillbirth or congenital anomalies. All the available relevant evidence on a possible association has been extensively and thoroughly reviewed with the benefit of up-to-date knowledge by experts from the relevant specialisms.

2. On whether the Expert Working Group's findings have any implications for currently licensed medicines

The findings of the review for HPTs, including Primodos, on a possible association between exposure in pregnancy to HPTs and adverse outcomes in pregnancy do not have implications for any currently licensed medicines. They are in fact considered to be reassuring for women who may inadvertently become pregnant whilst taking these hormones for contraception or gynaecological indications.

3. To draw any lessons for how drug safety issues in pregnancy are identified, assessed, and communicated in the present regulatory system and how the effectiveness of risk management is monitored

There have been substantial and far-reaching advances in all areas of the development, regulation, study and use of medicines in pregnancy since HPTs were available in the UK, whereas there was a lack of transparency in the past. Nevertheless, ways to strengthen further how safety concerns in pregnancy are detected, managed, evaluated and communicated should be taken forward.²⁷

The expert working group also made a number of recommendations. This included undertaking an annual review of congenital anomalies, and where there has been an adverse pregnancy outcome following the use of hormone pregnancy tests, that families should be offered up-to-

²⁶ Commission on Human Medicines, [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](#), 15 November 2017

²⁷ Commission on Human medicines, [Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests](#), November

date genetic testing to determine whether there is an underlying genetic cause:

The EWG considered that a number of steps could be taken to safeguard future generations through strengthening the systems in place for detecting, evaluating, managing and communicating risk with exposure to medicines in early pregnancy.

These include:

- undertaking an annual review of all reported congenital anomalies with independent scientific advice of CHM, published in its annual report
- facilitating research by optimising the collection of, access to and use of data on medicines in pregnancy
- safeguarding future generations through improved training and guidance of healthcare professionals
- working to improve the impact of safety messages on the risks of medicines in pregnancy.

In addition, families of the Association for Children Damaged by HPTs, whose lives have been impacted by adverse pregnancy outcomes and who were given HPTs to diagnose pregnancy should be offered a full up-to-date genetic clinical evaluation.²⁸

The Chair of the Commission on Human Medicines (CHM), Professor Stuart Ralston, reported that the review was comprehensive and wide ranging and that it was reviewed and endorsed by the Commission on Human Medicines:

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.²⁹

3.2 Initial responses to the report

There were widely reported criticisms of the expert working group report. These included that the report did not look at regulatory issues and that a number of documents had not been included in the review.

Families who believe they have been affected by hormone pregnancy tests called the review a 'whitewash' and a 'cover-up'.³⁰

The Guardian reported:

Marie Lyon, chair of the Association for Children Damaged by Hormone Pregnancy Tests, said: "It's truly shocking and I am appalled by the report. We all feel betrayed, and I feel like I have

²⁸ Ibid.

²⁹ Commission on Human Medicines, [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](#), 15 November 2017

³⁰ [Primodos pregnancy test report criticised as 'whitewash' by MPs](#), the Guardian, 16 November 2017

no faith in government health agencies now. I am distraught for our members, who still haven't had the answers they need."³¹

3.3 Parliamentary debate on the expert group report

In an Urgent Question debate shortly after the publication of the report, and a Backbench Business Committee debate in December 2017, Members from across the House expressed criticisms of the report. Content from both of these debates is included below.

Concerns raised in the debates included that the review was asked to look at a "possible association" but reported on a "causal association" and that evidence relating to the actions of the Committee on the Safety of Medicines in the 1960s and 1970s had not been looked at by the expert working group. In response to these criticisms in the Backbench Business Committee debate, the then Under-Secretary of State for Health, Steve Brine, said that he did not think that the terms of reference of the review had changed:

The terms of reference set out the scope of the review, and I do not believe that they changed. They were endorsed by the CHM in December 2014 a few weeks after the previous debate, and confirmed by the then Minister, my hon. Friend the Member for Mid Norfolk, in a letter to the all-party group in September 2015. In the same letter, the all-party group was informed:

"it is important to review the scientific evidence to establish whether there is any causal association between use of HPTs and subsequent birth defects in the child."

It is implicit and integral to any scientific assessment of evidence on medicines and associated harms to see whether the medicine is actually responsible for causing the harm rather than simply being associated with it.³²

He also reiterated that historic regulatory issues were outside of the scope of the expert group's review.³³

Members also stated that patients and campaigners had described the review as a whitewash.^{34, 35} They expressed concerns about a sentence that had been removed from the draft report before the final version had been published.³⁶ The Minister acknowledged these concerns and said that the report had been revised to better reflect the scientific conclusions:

[..] I know that many Members are concerned about differences in the draft and final reports, and especially over the removal of the sentence that said:

"limitations of the methodology of the time and the relative scarcity of the evidence means it is not possible to reach a definitive conclusion."

³¹ Ibid.

³² [HC Deb 14 December 2017 c714](#)

³³ [HC Deb 14 December 2017 c714](#)

³⁴ [HC Deb 16 November 2017 c581](#)

³⁵ [HC Deb 14 December 2017 c693](#)

³⁶ [HC Deb 14 December 2017 c701](#)

That sentence in the draft report was followed immediately by the group's overall finding

"that the available scientific evidence does not support a causal association between the use of HPTs such as Primodos, during early pregnancy and adverse outcomes."

The CHM quite rightly considered the two sentences together to be misleading, and advised that the report should be revised to better reflect the scientific—I stress, scientific—conclusion of the group, and that is set out on page 100 of the final report.

Concerns were also expressed about the treatment of the families who were invited to give evidence to the review.³⁷ Mr Brine acknowledged that the way families were treated could have been a lot better.³⁸ In response to the Backbench Business Committee debate he said that he had discussed this with the expert group and asked them to "report back to me as to how they will do things better next time."³⁹

³⁷ [HC Deb 16 November 2017 C581](#)

³⁸ [HC Deb November 2017 C581](#)

³⁹ HC Deb 14 December 2017 c

4. The Independent Medicines and Medical Devices Safety Review

In February 2018, the then Secretary of State for Health and Social Care, Jeremy Hunt, announced a Government review on medicines and medical device safety. The review would look at three issues of concern: the use of Primodos; use of the anti-epileptic drug sodium valproate in pregnancy; and the use of vaginal mesh.

[The Independent Medicines and Medical devices Safety Review](#) is being chaired by Baroness Cumberlege. The purpose of the review is set out on the website:

The Review will focus on what has happened in response to safety concerns raised about three medical interventions: surgical mesh, Primodos and sodium valproate. We will consider whether the processes pursued and actions taken by the healthcare system to date in relation to these concerns have been sufficient and satisfactory. We will make recommendations for action, as we deem necessary.

The Review will also make recommendations for improving the healthcare system's ability to respond in future when concerns are raised about the safety of treatments or technologies, be they medicines or medical devices.⁴⁰

The specific questions of interest for the review in relation to Primodos are:

1. where the science is not broadly acknowledged or accepted, whether the available historic and scientific evidence (and its assessment to date) can reasonably preclude 'a possible association' between Hormone Pregnancy Tests and their teratogenic effects, and/or needs to be revisited, in the opinion of the Review;
2. given the knowledge on Hormone Pregnancy Tests available to the manufacturers, regulators and clinicians at the time, the consideration, advice and practice with regard to the use of alternative, non-invasive pregnancy tests.⁴¹

The review has taken written and oral evidence from those affected by these medicines and devices, healthcare professionals and regulators, more information about the work so far is provided on [the review website](#). The Review's [evidence webpage](#) includes links to the written submissions, and videos of the oral evidence sessions on Primodos.

⁴⁰ The Independent Medicines and Medical devices Safety Review, [FAQs](#) [accessed 17 April 2019]

⁴¹ The Independent Medicines and Medical devices Safety Review, [Terms of Reference](#)

5. A new systematic review of the research

[A new systematic review](#) and meta-analysis of the research on hormone pregnancy tests was published in November 2018. This concluded that:

[...] use of oral HPTs in pregnancy is associated with increased risks of congenital malformations⁴²

One of the authors of the study, Professor Carl Heneghan, raised concerns about the 2017 Expert Working group review in [an interview with Sky News](#). He said that there had been a failure to undertake a systematic review:

"What has clearly gone wrong here is complete failure to do the right approach for systematic reviews.

"That was missing in the EWG's report - that's why we've now done that piece of work and actually put it out there so that people can look at it and come to their conclusions on what the balance of probability is."

He added: "Once you start looking at more specific malformations, you start to see the threshold which is doubling the risk which UK law courts say 'but for' this wouldn't have happened." ⁴³

A spokesperson from the MHRA responded to these comments. They said that the new publication was a reanalysis of the existing data rather than including new data, and that the expert group review was comprehensive and scientifically robust:

"This publication, which is currently awaiting peer review, does not contain new data. It is a different approach to the analysis of existing historic observational data which was reviewed by the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests.

"The review by the Expert Working Group was comprehensive, scientifically robust and independent. Based on the totality of the data, the review concluded the available scientific evidence did not support a causal association between the use of HPTs such as Primodos during early pregnancy and birth defects or miscarriage.

"In line with our commitment to review any new evidence, we will be consulting independent scientific experts for their views." ⁴⁴

The study has now been peer reviewed.

In response to [an April 2019 Parliamentary question](#) on this issue, the Under-Secretary of State for Health, Jackie Doyle-Price reported that the Commission on Human medicines had convened an Expert group to look at the new study and that the European Medicines Agency were also conducting a review of the publication:

⁴² Heneghan C, Aronson JK, Spencer E *et al.* Oral hormone pregnancy tests and the risks of congenital malformations: a systematic review and meta-analysis [version 2; peer review: 3 approved]. *F1000Research* 2019, 7:1725 (<https://doi.org/10.12688/f1000research.16758.2>)

⁴³ Jason Farrell, [Oxford University study links pregnancy drug Primodos to birth defects](#), Sky News,

⁴⁴ Jason Farrell, [Oxford University study links pregnancy drug Primodos to birth defects](#), Sky News,

Since publication of the report of the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests (HPTs) the Government has committed to review any important new evidence that arises. In response to publication of the study by Heneghan et al. the Commission on Human Medicines convened an Expert Group to advise on the suitability and robustness of the methodology (including the selection and application of the data quality score) and any clinical implications.

To ensure impartiality none of the members of the Group was involved in the previous review by the Expert Working Group on HPTs. A specific conflict of interest policy was developed and all participants were required to complete and sign a declaration of interests form. Participants were asked to declare personal or non-personal interests in the companies who marketed HPTs or whose predecessors marketed them, current or previous involvement in any studies or reviews on HPTs, the expression in public of a strong opinion about HPTs or any of the companies that produced them, and direct or indirect involvement with, or peer review of, the publication by Heneghan et al. The conflict of interest policy and declarations of participants will be made public in due course.

For complete transparency the meeting was observed by the Chair of the Association for Children Damaged by HPTs, an advocate for those affected by thalidomide, a Lay representative and a representative from the Independent Medicines and Medical Devices Safety Review.

In parallel, the European Medicines Agency is conducting an independent review of the publication by Heneghan et al. Both reviews are ongoing, and we expect the conclusions to be made public within a month of their completion, likely to be May 2019.⁴⁵

⁴⁵ [HC Written Question 237674 \[pregnancy tests\] 4 April 2019](#)

6. News items

Sky News

Primodos: Drug linked to birth defects 'not assessed properly' in UK review

5 April 2019

<https://news.sky.com/story/primodos-drug-linked-to-birth-defects-not-assessed-properly-in-uk-review-11684027>

BBC News

Review ordered into epilepsy drug, vaginal mesh and Primodos

21 February 2018

<https://www.bbc.co.uk/news/health-43143319>

BMJ

Campaigners vow to fight on after report finds no link between hormone test and birth defects

17 November 2017

BMJ 2017; 359 doi: <https://doi.org/10.1136/bmj.j5352> Cite this as: BMJ 2017;359:j5352

<http://www.bmj.com/content/359/bmj.j5352>

Guardian

Primodos pregnancy test report criticised as 'whitewash' by MPs

16 November 2017

<https://www.theguardian.com/science/2017/nov/16/primodos-pregnancy-test-report-criticised-whitewash-mps>

The Times [subscription]

Hormone pregnancy test did not cause birth defects

16 November 2017

<https://www.thetimes.co.uk/article/hormone-pregnancy-test-did-not-cause-birth-defects-8rf8g9dzt>

Sky News

Primodos: Sky News exposes pregnancy drug cover-up

March 2017

<https://news.sky.com/story/primodos-sky-news-exposes-pregnancy-drug-cover-up-10807338>

7. Press release

Department of Health and Social Care

Review launched to respond to patient concerns about NHS treatments

The review will focus on 3 NHS treatments: Primodos, vaginal mesh implants and the anti-epilepsy drug sodium valproate.

22 February 2018

Health and Social Care Secretary Jeremy Hunt has announced a review into how the health system responds to reports from patients about side effects from treatments.

The review comes after patient-led campaigns on 3 NHS treatments:

- the hormone pregnancy test Primodos, which was used up until 1978
- the anti-epileptic drug sodium valproate
- the use of vaginal mesh

Mr Hunt said that the response these groups of patients received from the NHS and its regulators was “not good enough”.

Baroness Julia Cumberlege will lead the review. She will consider:

- whether any further action is needed relating to the complaints around Primodos, sodium valproate and vaginal mesh
- the processes followed by the NHS and its regulators when patients report a problem
- how to make sure communication between the different groups involved is good

Mr Hunt has asked the review to set up an independent committee to help ministers decide on the best approach to resolving these issues.

He said:

Over the years, there have been significant concerns raised by individuals and campaign groups about the potentially harmful effects of 3 products used by the NHS. The response they have received from those in positions of authority has not always been good enough.

From Primodos to mesh and sodium valproate, patients and their families have had to spend too much time and energy campaigning for answers in a way that has added insult to injury for many. I want to see if we can establish a fairer and quicker way of resolving these concerns both now and in the future.

Chair of the review, Baroness Cumberlege, said:

I look forward to undertaking this tremendously important review and in particular to working with patients to ensure that our health system learns from those it may have failed. It's essential that voices aren't just listened to, but properly heard, and that whenever appropriate, the system promptly learns lessons and makes changes.

Commission on Human Medicines

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

15 November 2017

An Expert Working Group (EWG) of the UK's Commission on Human Medicines (CHM) has published their report on the use of hormone pregnancy tests (HPTs) and adverse effects relating to pregnancy including possible 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.

8. Parliamentary material

Statements

Medicines and Medical Devices Safety Review

21 Feb 2018 | Vol 636 c165-

<http://bit.ly/2KtutqA>

Written Statement: [Report of the Expert Working Group on Hormone Pregnancy Tests](#) HCWS245

Today, the Commission on Human Medicines has published the report of its Expert Working Group on Hormone Pregnancy Tests. Based on its extensive and thorough review, the Expert Working Group's overall finding, endorsed by the Commission on Human Medicines, is that the available scientific evidence, taking all aspects into consideration, does not support a causal association between the use of Hormone Pregnancy Tests, such as Primodos, during early pregnancy and adverse outcomes of pregnancy, either with regard to miscarriage, stillbirth or congenital anomalies.

In the UK, Hormone Pregnancy Tests first became available for diagnosing pregnancy in the 1950s. Between the 1950s and 1978, when Primodos was withdrawn from the market in the UK, a number of studies were published which investigated a possible link between women being given a Hormone Pregnancy Test to diagnose pregnancy and the occurrence of a range of congenital anomalies in the offspring.

Although there was never any reliable evidence that HPTs were unsafe, concern about this issue, coupled with the development of better pregnancy tests meant that a number of precautionary actions were taken to restrict the use of HPTs. The tests were voluntarily removed from the market by the manufacturers.

The body of information subsequently accrued by the 'Association for Children Damaged by Hormone Pregnancy Tests' and other campaigners, led to a Parliamentary debate in 2014 during which the then Minister for Life Sciences, George Freeman MP, stated that he would instruct that all relevant documents held by the Department of Health be released. In addition, he determined that an independent review of the papers and all the available evidence was justified.

The purpose of the review was to ascertain whether the totality of the available data, on balance, support a causal association between use of a Hormone Pregnancy Test by the mother and adverse pregnancy outcomes. It also considered whether, alternatively, the anomalies could have been due to chance alone or due to other factors.

An Expert Working Group of the Commission on Human Medicines was established in October 2015 to conduct the review with the benefit of up-to-date scientific expertise.

The Expert Working Group was subject to a strict conflict of interest policy and comprised experts from a broad range of specialisms, together with lay representation. The terms of reference of the Expert Working Group, were as follows:

- To consider all available evidence on the possible association between exposure in pregnancy to hormone pregnancy tests and adverse outcomes in pregnancy (in particular congenital anomalies, miscarriage and stillbirth) including consideration of any potential mechanism of action.
- To consider whether the Expert Working Group's findings have any implications for currently licensed medicines in the UK or elsewhere.
- To draw any lessons for how drug safety issues in pregnancy are identified, assessed and communicated in the present regulatory system and how the effectiveness of risk management is monitored.
- To make recommendations.

The final report summarises the scientific evidence that was considered by the Expert Working Group, its conclusions on the evidence, and its recommendations. All the available relevant evidence on a possible association has been extensively and thoroughly reviewed with the benefit of up-to-date knowledge by experts from the relevant specialisms.

In addition to the overall conclusion, the Expert Working Group has made a number of recommendations to safeguard future generations through strengthening the systems in place for detecting, evaluating, managing and communicating safety concerns with use of medicines in early pregnancy. These recommendations can be found in the report. The Medicines and Healthcare products Regulatory Agency will coordinate their implementation, in collaboration with relevant organisations; and the Commission on Human Medicines, together with its Expert Advisory Group on Medicines' for Women's Health, will ensure progress is regularly monitored.

The evidence which has been reviewed by the Expert Working Group will be published in the New Year once it has been checked in line with the legal duties of data protection and confidentiality.

[I attach a copy of the report.](#)

15 Nov 2017 | Written statements | House of Commons | HCWS245

Lords statement: Hormone pregnancy tests

HL Deb 16 November 2017 | Vol 785 cc2220-

<https://hansard.parliament.uk/Lords/2017-11-16/debates/B44FF058-3C92-4D48-9916->

[D0E6D60432E2/HormonePregnancyTests#contribution-B3DD8500-56ED-438B-A79A-F9EE985D4092](https://www.parliament.nsw.gov.au/committees/committees/HormonePregnancyTests#contribution-B3DD8500-56ED-438B-A79A-F9EE985D4092)

Debates

Commons Debate: Hormone Pregnancy Tests

HC Deb 14 December 2017 | Vol 633 c689-

<http://bit.ly/2le74Ye>

Commons Urgent Question: Hormone pregnancy tests

HC Deb 16 November 2017 | Vol 631 cc578-

<http://bit.ly/2lfz3qv>

PQs

[*Pregnancy Tests*](#)

Asked by: Qureshi, Yasmin

To ask the Secretary of State for Health and Social Care, what plans his Department has for peer review the report of the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests.

To ask the Secretary of State for Health and Social Care, whether a meta-analysis was carried out as part of the Commission on Human Medicines' Expert Working Group review into Hormone Pregnancy Tests.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Commission on Human Medicines' Expert Working Group (EWG) review into Hormone Pregnancy Tests (HPTs) was comprehensive, scientifically robust and independent. Based on the totality of the data, the review concluded the available scientific evidence did not support a causal association between the use of HPTs during early pregnancy and birth defects or miscarriage. All evidence considered by the EWG has been published online.

The EWG did not undertake a meta-analysis as part of the review. The EWG examined a large number of epidemiological studies, many of which were conducted under different designs. The EWG considered whether meta-analysis was possible and ultimately concluded that because the studies were so different such an analysis would not be informative. Meta-analysis was also not considered appropriate because the studies were not sufficiently robust and suffered from extensive limitations.

The EWG comprised independent experts from a wide range of relevant specialisms and its report was further scrutinised by the Commission on

Human Medicines, the Government's independent scientific advisory body on the safety of medicines. There are no plans for further peer review of the report. The Government is committed to reviewing any important new evidence that arises.

HC Deb 09 April 2019 | PQ 239926; PQ 239925

[Pregnancy Tests](#)

Asked by: Qureshi, Yasmin

To ask the Secretary of State for Health and Social Care, what the timetable is for the publication of the findings of the Commission on Human Medicines' independent scientific review of the publication by Professor Carl Heneghan into hormone pregnancy tests.

To ask the Secretary of State for Health and Social Care, what steps he has taken to ensure the (a) impartiality and (b) independence of panels members on the Commission on Human Medicines' independent scientific review of the publication by Professor Carl Heneghan into hormone pregnancy tests.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

Since publication of the report of the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests (HPTs) the Government has committed to review any important new evidence that arises. In response to publication of the study by Heneghan et al. the Commission on Human Medicines convened an Expert Group to advise on the suitability and robustness of the methodology (including the selection and application of the data quality score) and any clinical implications.

To ensure impartiality none of the members of the Group was involved in the previous review by the Expert Working Group on HPTs. A specific conflict of interest policy was developed and all participants were required to complete and sign a declaration of interests form.

Participants were asked to declare personal or non-personal interests in the companies who marketed HPTs or whose predecessors marketed them, current or previous involvement in any studies or reviews on HPTs, the expression in public of a strong opinion about HPTs or any of the companies that produced them, and direct or indirect involvement with, or peer review of, the publication by Heneghan et al. The conflict of interest policy and declarations of participants will be made public in due course.

For complete transparency the meeting was observed by the Chair of the Association for Children Damaged by HPTs, an advocate for those affected by thalidomide, a Lay representative and a representative from the Independent Medicines and Medical Devices Safety Review.

In parallel, the European Medicines Agency is conducting an independent review of the publication by Heneghan et al. Both reviews

are ongoing, and we expect the conclusions to be made public within a month of their completion, likely to be May 2019.

HC Deb 04 April 2019 | PQ 237674; PQ 237673

[*Pregnancy Tests*](#)

Asked by: Qureshi, Yasmin

To ask the Secretary of State for Health and Social Care, how much was spent from the public purse on the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Commission on Human Medicines (CHM) advises health ministers on the safety, efficacy and quality of medicinal products. Expert Working Groups of the CHM are comprised of independent experts who work on a voluntary basis and receive reasonable expenses. The Medicines and Healthcare products Regulatory Agency provide a secretariat function to the CHM and its Expert Working Groups. This is included in Agency costs. The Agency is an Executive Agency of the Department and it is established as a Government trading fund, with its work predominantly funded by fees charged to the industry it regulates.

HC Deb 02 April 2019 | PQ 238314

[*Pregnancy Tests*](#)

Asked by: Qureshi, Yasmin

To ask the Secretary of State for Health and Social Care, if he will make an assessment of the merits in the conclusions of the 2018 report by Professor Carl Heneghan on oral hormones pregnancy tests and the risks of congenital malformations; and if he will make a statement.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

In line with the Government's commitment to review any new evidence in relation to hormone pregnancy tests, the Commission on Human Medicines is convening a new expert group to conduct an independent scientific review of the publication by Professor Carl Heneghan. In addition, the European Medicines Agency's Committee for Medicinal Products for Human Use is conducting a review of the paper at European Union level, at the request of the Medicines and Healthcare products Regulatory Agency. Once this paper has been fully considered the findings will be made public.

HC Deb 11 January 2019 | PQ 206297

[*Pregnancy Tests*](#)

Asked by: Shapps, Grant

To ask the Secretary of State for Health and Social Care, whether his Department has (a) conducted and (b) is aware of any research into whether women and children in any (i) post code and (ii) county area were disproportionately affected by hormone pregnancy testing.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Department has not conducted research into whether women and children in any post code or county area were disproportionately affected by hormone pregnancy testing, nor is it aware of published scientific research on this topic.

Hormone Pregnancy Tests were available from 1958-1978. The Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests reviewed all the available evidence on the possible association between exposure in pregnancy to hormone pregnancy tests and adverse outcomes in pregnancy. The Group concluded that, taking all aspects into consideration, the available evidence did not support a causal association between the use of hormone pregnancy tests during early pregnancy and birth defects or miscarriage.

The Government's priority, as always, is the safety of patients. The Expert Working Group made a number of forward-looking recommendations to further strengthen the scientific evidence which supports safety monitoring of medicines in pregnancy and current focus is on implementing these recommendations.

HC Deb 22 February 2018 | PQ 128169

[*Pregnancy Tests*](#)

Asked by: Field, Frank

To ask the Secretary of State for Health and Social Care, what plans he has to establish an independent public inquiry into hormone pregnancy tests.

To ask the Secretary of State for Health and Social Care, what steps he is taking to fund independent scientific research into hormone pregnancy tests.

Answering member: Jackie Doyle-Price | Department: Department of Health and Social Care

The Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests was established in 2015 to consider all the available evidence on the possible association between exposure in pregnancy to hormone pregnancy tests and adverse outcomes in pregnancy. The Expert Working Group conducted a comprehensive, scientifically robust and independent review of all available scientific evidence relating to hormone pregnancy tests including the responses to a public call for evidence. In reaching its conclusion that, taking all aspects into consideration, the available evidence did not support a causal association between the use of hormone pregnancy tests during

early pregnancy, the Expert Working Group made a number of forward-looking recommendations to further strengthen the scientific evidence which supports safety monitoring of medicines in pregnancy. The current focus of the Medicines and Healthcare products Regulatory Agency (MHRA) is on implementing these recommendations.

While there are no plans to fund independent scientific research into hormone pregnancy tests (which have not been available since 1978), should any further evidence emerge of direct relevance to hormone pregnancy tests the MHRA will evaluate this. In addition, certain of the Expert Working Group's recommendations are anticipated to encourage relevant research into the safety of medicines in pregnancy.

The Government's priority, as always, is the safety of patients. A comprehensive and independent review of the science has been done but the Government will continue to listen and keep all options for further investigation on the table.

HC Deb 09 February 2018 | PQ 126213; PQ 126210

9. Useful links

The Independent Medicines and Medical Devices Safety Review

<http://immdsreview.org.uk/index.html>

Oral hormone pregnancy tests and the risks of congenital malformations: a systematic review and meta-analysis

Carl Heneghan, Jeffrey K. Aronson, Elizabeth Spencer, Bennett Holman, Kamal R. Mahtani, Rafael Perera, Igho Onakpoya

<https://f1000research.com/articles/7-1725/v2>

Association for Children Damaged by Hormone Pregnancy Tests

<http://www.hormonepregnancytests.org.uk/>

Commission on Human Medicines *Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests*

<https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests>

Medicines and Healthcare Regulatory Agency, *Assessment of historical evidence on Primodos and congenital malformations – a synopsis* March 2014

<http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con404471.pdf>

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