HOUSE OF COMMONS LIBRARY

DEBATE PACK

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Hormone pregnancy tests

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This pack has been prepared ahead of the debate to be held in the Commons Chamber on Thursday 14 November 2017 on hormone pregnancy tests. The subject for the debate has been selected by the Backbench Business Committee, and it will be opened by Sir Mike Penning MP. The motion for the debate is

> That this House regrets that the terms of reference for the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests were to consider evidence on a possible association between exposure in pregnancy to hormone pregnancy tests and adverse outcomes in pregnancy, but the Commission's Report concluded that there was no causal association between the use of hormone pregnancy tests and babies born with deformities between 1953–1975, even though it was not asked to find a causal link; believes that the inquiry was flawed because it did not consider systematic regulatory failures of the Committee on Safety in Medicines and did not give careful consideration to the evidence presented to it; and calls on the Government, after consultation with the families affected so they have confidence in the process, to establish a statutory inquiry under the Inquiries Act 2005 to review the evidence on a causal association between hormone pregnancy tests on pregnancies and to consider the regulatory failures of the Committee on Safety in Medicines.

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 fetal abnormalities 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.

Following this review, 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 have said that the report presents the findings of a thorough review of all the relevant evidence. Departmental Ministers have accepted the conclusions and recommendations.[2] However, the report has received criticism following publication, from campaigners in this area, such as the Association for Children Damaged by Hormone Pregnancy Tests, and from MPs in an Urgent Question to the Minister. It has been 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. A Backbench Business Committee debate on Hormone pregnancy tests has been tabled for 14 December 2018. It will be led by Sir Mike Penning.

The debate is likely to focus on the expert working group report. In the application to the Backbench Business Committee, Sir Mike Penning raised a number of concerns about the recently published report, including that it did not look at a 'possible association' between the drug and the fetal abnormalities as set out in the terms of reference but instead, made its conclusions on a 'causal association' and that it did not look at regulatory issues.[3]

More information is provided in the motion for the debate:

> That this House regrets that the terms of reference for the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests were to consider evidence on a possible association between exposure in pregnancy to hormone

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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 Backbench Business Committee, Proposals for backbench debate, 21 November 2017

pregnancy tests and adverse outcomes in pregnancy, but the Commission's Report concluded that there was no causal association between the use of hormone pregnancy tests and babies born with deformities between 1953–1975, even though it was not asked to find a causal link; believes that the inquiry was flawed because it did not consider systematic regulatory failures of the Committee on Safety in Medicines and did not give careful consideration to the evidence presented to it; and calls on the Government, after consultation with the families affected so they have confidence in the process, to establish a statutory inquiry under the Inquiries Act 2005 to review the evidence on a causal association between hormone pregnancy tests on pregnancies and to consider the regulatory failures of the Committee on Safety in Medicines.

This briefing provides background information on hormone pregnancy tests, an overview of the working group review and responses to the report.

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 fetal abnormalities, including cleft lip and palate, limb reduction deformities and heart abnormalities.[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 them 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]

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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 o 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	Secrodyl

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 abnormalities 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]

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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 that reportedly show that studies suggested that the drugs caused miscarriages and abnormalities 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 abnormalities.

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 positon was that the data is not sufficient to show a causal link between the tests and congenital abnormalities:

> 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

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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 the congenital abnormalities.

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]

Information on the membership of the expert working group is also provided in the final report.

3.1 Backbench Business debate October 2016

In October 2016, the Backbench Business Committee tabled a debate on hormone pregnancy tests that was led by Yasmin Qureshi and Hannah Bardell. The motion to the debate raised concerns about the terms of reference of the review on hormone pregnancy tests and that

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

it would not look into reports of regulatory failure by Government bodies in the 1960s and 1970s.

Ms Qureshi expressed concerns about the way witnesses to the inquiry had been treated and about the independence of the working group members.[22] A number of members from both sides of the House raised similar issues.

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."[23] He said that the Association for Children damaged by hormone Pregnancy tests did not have confidence in the inquiry and that this was "unsatisfactory." He went on to address some of the concerns raised in the debate:

> On the first issue, we have heard that there was a regulatory failure and that the inquiry should look at it. I say to the House that if, when the expert group reports next spring, it finds a clear causal link, that will be the time to take further action on issues such as regulation and liability, and everything that goes with that. The first step we are taking is to establish the science. The group that has been set up is an expert group. It is science-led. It is important to make it clear in the House that we are not criticising individual members, because they are striving to get to the truth. It is a group of eminent people.
>
> It would be quite wrong if we conflated the possible eventual need to look at the regulatory actions that were taken, the legal liabilities and everything that goes with that, with the first step of the process, which is to establish whether the science leads us to that link. In spite of some of the comments that have been made today, that has not been done yet in any country. The first serious attempt to do it is the one that is going on now.
>
> 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.[24]

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22 HC Deb 13 October 2016 C520
23 HC Deb 13 October 2016 c 544
24 HC Deb 13 October 2016 C546

3.2 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 findings of studies on the adverse effects associated with these drugs were not made publicly available.[25] 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.
>
> […][26]

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.

3.3 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."[27]

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):

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25 Sky News, Primodos: Sky News exposes pregnancy drug cover-up, March 2017
26 HL Written Question HL6207: Primodos, 29 March 2017
27 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

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.[28]

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

[28] Commission on Human medicines, Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests, November

> • 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. [29]

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.[30]

3.4 Responses to the report

There has been widely reported criticism of the expert working group report. This has 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 have called the review a 'whitewash' and a 'cover-up'.[31]

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 no faith in government health agencies now. I am distraught for our members, who still haven't had the answers they need."[32]

3.5 Urgent Question

An Urgent Question on the report was granted to the Chair of the APPG on Hormone pregnancy tests, Yasmin Qureshi, on 16 November 2017:

> To ask the Secretary of State for Health to make a statement on the recently published "Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests".

The Under-Secretary of State for Health, Steve Brine, set out the purpose of the review and the content of the final report. He also said that he recognised that the report would be a disappointment to some:

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29 Ibid.

30 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

31 Primodos pregnancy test report criticised as 'whitewash' by MPs, the Guardian, 16 November 2017

32 Ibid.

> The purpose of the review was to ascertain whether the totality of the available data, on balance, supported a casual 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 other factors.
>
> 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. The evidence reviewed by the expert working group will be published in the new year, once it has been rightly checked in line with the legal duties of data protection and confidentiality.
>
> 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 about the use of medicines in early pregnancy. I recognise that the conclusion of the report will be a disappointment to some, but I hope that they will see the recommendations as positive. They are a credit to the efforts of the Association for Children Damaged by Hormone Pregnancy Tests and the all-party group on oral hormone pregnancy tests, which is chaired by the hon. Lady, and also a lasting legacy.[33]

Members from across the House expressed criticisms of the report. These 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. Yasmin Qureshi said:

> In 2014, an expert working group was set up to look at a possible association—not a casual link or a causal link. I am sure that hon. Members agree that that means that a lesser burden of proof is required. The first thing that the commission did was to say that it had found no causal connection, but it was never asked to do that—it was asked to look for a possible association. In 2014, the then Minister made promises about statutory oversight. From the papers we had, there appeared to be a clear criminal responsibility regarding of the statutory body, the Committee on the Safety of Medicines, and the people who ran it, given that so much evidence was adduced to them. They were alerted to the fact that Primodos was causing deformities and miscarriages in women, but they totally ignored that evidence. In fact, the person in charge actually said that he wanted to cover it up so that nobody could be sued. It is therefore highly surprising that the commission has come up with this recommendation.[34]

Justin Madders said that campaign groups had called the review "a whitewash, an injustice and a betrayal." He reported that an October draft of the expert working group report included a sentence that was removed from the published report and asked why this had been removed:

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33 HC Deb 16 November 2017 C578
34 HC Deb 16 November 2017 C579

> A draft of the report, which was published in October, stated
>
> "Limitations of the methodology of the time and the relative scarcity of the evidence means it is not possible to reach a definitive conclusion."
>
> However, that sentence was removed from the final version. It is critical that the Minister answers these questions: why was the sentence removed; why was there a delay of a month; and did he speak to the authors of the report about the sentence before its removal? The inquiry has answered a question that it was not asked to answer, and it has reached a conclusion not supported by the evidence. What is the Minister's view of the various studies that have been referred to that do show a causal connection?[…][35]

The Minister set out that the review was comprehensive, independent and scientific:

> The hon. Gentleman referred to a "whitewash". As I have said, this was a comprehensive, independent, scientific review of all available evidence by experts on a broad range of specialisms who, with respect, are far more qualified to consider the subject than either him or me. It was a rigorous, important and impartial review conducted over the best part of two years, and the experts were given access to all the available documents. [36]

He went on to say that the MHRA would be keen to look at any new work published in this area:

> The hon. Gentleman mentioned other research. He might have been referring to Dr Vargesson, an Aberdeen-based researcher who is, I believe, working on the components of Primodos in fish. He was invited to give evidence to the group, and he did so, but he did not want to leave his work and the evidence, which he said would shortly be published, with the expert working group. As far I am aware, that work has still not been published, but I know that the MHRA will be keen to look at any new work that is published.[37]

Concerns were also expressed about the treatment of the families who were invited to give evidence to the review.[38] Mr Brine acknowledged that the way families were treated could have been a lot better.[39]

35 HC Deb 16 November 2017 c581
36 HC Deb 16 November 2017 c581
37 Ibid.
38 HC Deb 16 November 2017 C581
39 HC Deb November 2017 C581

4. News items

Pharmaceutical Journal

Report into HPT link to birth deformities branded a whitewash

24 November 2017

http://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/report-into-hpt-link-to-birth-deformities-branded-a-whitewash/20204003.article

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-8rf8g9dzr

Guardian

Anger after report finds birth defects not caused by hormone pregnancy tests

15 November 2017

https://www.theguardian.com/society/2017/nov/15/1960s-hormone-pregnancy-test-did-not-cause-birth-defects-review-finds

BBC News Online

Hormone pregnancy test 'no link to harm'

15 November 2017

http://www.bbc.co.uk/news/health-41996712

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

Guardian

Pregnancy test's alleged link to birth defects to be reviewed by UK regulator

Watchdog to examine new files found by campaigners while Primodos maker Bayer denies it caused abnormalities

19 March 2017

https://www.theguardian.com/science/2017/mar/19/pregnancy-tests-alleged-link-to-birth-defects-to-be-reviewed-by-uk-regulator

Independent

New evidence links 1970s pregnancy test drug to life-changing birth defects

There may have been a 'cover-up' of the effect of the drug on pregnant mothers, say campaigners

19 March 2017

http://www.independent.co.uk/news/uk/home-news/new-evidence-pregancy-drug-hormone-birth-defects-primodos-thalidomide-compensation-yasmin-qureshi-a7637616.html

Guardian

Primodos was a revolutionary oral pregnancy test. But was it safe?

In the 1950s, laboratory pregnancy tests involved urine and a toad. Primodos was a breakthrough, but campaigners say there is evidence of serious side effects

13 October 2016

https://www.theguardian.com/science/the-h-word/2016/oct/13/primodos-was-a-revolutionary-oral-pregnancy-test-but-was-it-safe

5. Press release

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.

6. Parliamentary material

Statements

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

Debates

Commons Urgent Question: Hormone pregnancy tests

HC Deb 16 November 2017 | Vol 631 cc578-

https://hansard.parliament.uk/Commons/2017-11-16/debates/DF363AFF-7FA2-4F72-8A83-0DACB6EA1D0C/HormonePregnancyTests#contribution-636D70A1-CEDD-44BD-A73A-914F1389EA00

Backbench Debate: Hormone Pregnancy Tests

HC Deb 13 October 2016 | Vol 615 cc519-550

https://hansard.parliament.uk/Commons/2016-10-13/debates/8520B85A-2A57-4CCB-ABB4-73DB74A51D27/HormonePregnancyTests

PQs

Hormones: Pregnancy Tests

Asked by: Gwynne, Andrew

To ask the Secretary of State for Health, pursuant to the Answer of 22 November 2017 to Question 112845, if he will meet with external experts on hormone pregnancy tests.

Answering member: Steve Brine | Department: Department of Health

The Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests included experts in a wide range of relevant scientific disciplines and took evidence from visiting experts. After consideration of a broad range of data, the consensus conclusion of Group members was that the available scientific evidence, taking all aspects into consideration, did not support a causal association between the use of hormone pregnancy tests during early pregnancy. This conclusion was endorsed by the Commission on Human Medicines which comprises independent scientific experts of international standing. There are no plans to meet other external experts.

30 November 2017 | PQ 115443

Hormones: Pregnancy Tests

Asked by: Jenrick, Robert

To ask the Secretary of State for Health, what the Government's policy is on the conclusions of the Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests, published in November 2017.

Answering member: Steve Brine | Department: Department of Health

The Commission on Human Medicines published the report of its Expert Working Group on Hormone Pregnancy Tests on 15 November 2017. This was the culmination of an extensive and thorough review of all the available relevant evidence on a possible association between Hormone Pregnancy Tests and adverse outcomes of pregnancy by a panel comprising independent experts of international standing in relevant scientific and medical specialisms.

The Expert Working Group's overall finding, endorsed by the Commission on Human Medicines, was that the available scientific evidence, taking all aspects into consideration, did not support a causal association between the use of Hormone Pregnancy Tests, such as Primodos, during early pregnancy and adverse outcomes of pregnancy, including miscarriage, stillbirth or congenital anomalies. The Expert Working Group also made a number of important, forward-looking recommendations to further strengthen the systems in place for detecting, evaluating, managing and communicating safety concerns associated with use of medicines in early pregnancy.

Departmental ministers have accepted the report's conclusions and recommendations. The focus is now on implementing these recommendations.

HC Deb 29 November 2017 | PQ 114880

Primodos

Asked by: Elliott, Julie

To ask the Secretary of State for Health, if he will bring forward proposals for a review of the findings of the Report of the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests, published in October 2017.

Answering member: Steve Brine | Department: Department of Health

The Commission on Human Medicines published the report of its Expert Working Group on Hormone Pregnancy Tests on 15 November 2017. Departmental ministers have accepted the report's conclusions and recommendations.

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, including miscarriage, stillbirth or congenital anomalies. In addition to the overall conclusion, the Expert Working Group has made a number of recommendations to safeguard future generations through further strengthening the systems in place

for detecting, evaluating, managing and communicating safety concerns associated with the use of medicines in early pregnancy.

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. There are no proposals for a review of the report's findings and the Medicines and Healthcare products Regulatory Agency will now take forward the recommendations.

HC Deb 23 November 2017 | PQ 113646

Hormones: Pregnancy Tests

Asked by: Gwynne, Andrew

To ask the Secretary of State for Health, what the timetable is for the Expert Panel Working Group Inquiry into hormone pregnancy tests to release its report.

To ask the Secretary of State for Health, what meetings he has had with external experts on hormone pregnancy tests in each of the last 12 months.

Answering member: Steve Brine | Department: Department of Health

My Rt. hon. Friend the Secretary of State has not met with external experts on Hormone Pregnancy tests in the last 12 months. The Government committed to an independent review of the available evidence relating to Hormone Pregnancy Tests and the possible risk of birth defects in October 2014. The review was carried out by an Expert Working Group of the Commission on Human Medicines, the Government's independent advisory body on medicines. Careful consideration was given to the membership of the Expert Working Group to make sure the panel was well qualified and of sufficient breadth of exercise to conduct a rigorous scientific review. The Expert Working Group was comprised of a Chair and 15 members who are experts in a wide range of relevant scientific disciplines. The membership of the Expert Working Group included expertise in: pharmacoepidemiology; toxicology; pharmacology; family planning; embryology; neonatal development; reproductive endocrinology; clinical genetics, gynaecology; obstetrics; perinatal epidemiology; paediatric epidemiology; and medical statistics.

The Expert Working Group on Hormone Pregnancy Tests (HPTs) invited seven external experts to present evidence for consideration during its review of the available evidence on a possible association between exposure to HPTs and adverse outcomes of pregnancy.

The report of the Expert Working Group was published on 15 November 2017. Based on this extensive and rigorous review, their overall conclusion was that, based on the totality of the data, the scientific evidence does not support a causal association between the use of HPTs such as Primodos and birth defects or miscarriage.

HC Deb 22 November 2017 | PQ 112846; PQ 112845

Patients: Disclosure of Information

Asked by: McGinn, Conor

To ask the Secretary of State for Health, what the criteria was for the issue of a confidentiality agreement with a Primodos patient; and if he will make a statement.

Answering member: Steve Brine | Department: Department of Health

We have interpreted that the Hon. Member's question relates to confidentiality agreements for those who participated in the Expert Working Group on Hormone Pregnancy Tests.

Under the Human Medicines Regulations 2012, express restrictions are placed on the disclosure of any information by a person who obtains it by virtue of those Regulations (which includes those participating in meetings of the Commission on Human Medicines and its Expert Working Groups).

All participants of the Expert Working Group on Hormone Pregnancy Tests were required to sign a confidentiality declaration form to confirm their understanding that the paperwork, any other correspondence and discussions of the Group are strictly confidential, and must not be disclosed. Observers on the Expert Working Group, including patient representatives, were also asked to sign the form.

The report of the Group was published on 15 November 2017. All the supporting evidence, will be published once it has been reviewed in line with duties under data protection legislation, and common law duty of confidence.

HC Deb 16 November 2017 | 112563

Commons oral questions: Primodos

Hannah Bardell (Livingston) (SNP)

What the timetable is for the publication of the report of the expert working group on Primodos. [901818]

The Parliamentary Under-Secretary of State for Health (Steve Brine)

This is an incredibly sensitive subject. The report of the expert working group on hormone pregnancy tests will be published tomorrow. There will be a written ministerial statement with a copy of the report. This follows a rigorous review of all the available data on this subject by a panel with expertise in the relevant fields of science and healthcare.

Hannah Bardell

I welcome the Minister's statement, although there are some questions about the opaqueness of the inquiry and many other concerns. The lives

of my constituents Wilma and Kirsteen Ord and many others have been blighted by the hormone pregnancy drug Primodos. Will he appear in front of the Health Committee, look at the way in which that inquiry was conducted and consider a public inquiry into Primodos so that the families can get truth and justice about how they have been affected by this drug?

Steve Brine

I thank the hon. Lady for her question. I am open to offers from any Select Committee. It would be premature to consider issues of liability before considering the strength of the evidence and seeing the report, which we will study carefully. The report will conclude whether there is a causal association between the use of HPDs such as Primodos and adverse outcomes of pregnancy. We look forward to seeing its outcomes and its recommendations.

HC Deb 14 November 2017 | Volume 631 c144

Engagements

Asked by: Mims Davies

In the 1960s and 1970s, thousands of women were prescribed Primodos as a pregnancy test, which resulted in profound effects for the babies that followed. Alongside elderly parents, my constituent Charlotte Fensome cares for her brother Steven, who was profoundly affected. Does the Prime Minister agree that those families now deserve justice and that there should be a chance to launch a public inquiry into this terrible scandal?

Answered by: The Prime Minister | Department: Prime Minister

My hon. Friend has raised an important issue, and she is absolutely right to do so. We should recognise the impact that this had on those women who took this hormone pregnancy test during pregnancy from the late 1950s into the 1970s—I believe 1978 was the last time. An expert working group has been set up to look into this issue and it is due to publish its findings in the autumn, but I would be very happy to meet my hon. Friend to discuss this issue with her.

HC Deb 06 September 2017 | Vol 628 cc156-7

Pregnancy: Drugs

Asked by: Lord Alton of Liverpool

To ask Her Majesty's Government, further to the Written Answer by Lord O'Shaughnessy on 28 March (HL6261), whether the Expert Working Group on Hormonal Pregnancy Tests will review (1) the terms of reference of (a) the Committee on the Safety of Medicines, and (b) the Metabolic Research Unit, when determining what lessons may be learnt for further improving existing regulatory systems to identify, monitor and minimise any adverse effects of medicines in pregnancy, (2) the need to assemble and assess reports of adverse reactions to drugs

trials, and (3) how ministers should be advised of the outcomes of those trials.

To ask Her Majesty's Government, further to the Written Answer by Lord O'Shaughnessy on 28 March (HL6261), whether they will meet with Marie Lyon and representatives of the Primodos victims support group.

Answering member: Lord O'Shaughnessy | Department: Department of Health

One of the terms of reference of the Expert Working Group on Hormonal Pregnancy Tests is to consider what lessons may be learnt for further improving existing regulatory systems to identify, monitor and minimise any adverse effects of medicines in pregnancy. The regulatory, legal and social landscape has changed significantly since hormonal pregnancy tests were on the market; many of these changes have been driven by previous experience. The Group will consider the processes and tools that were available to the United Kingdom regulator when hormonal pregnancy tests were on the market and make recommendations for any changes necessary to further improve the capability of current regulatory systems to identify, monitor and minimise any adverse effects of medicines in pregnancy. This will include all aspects of medicines regulation, from the assessment of safety pre-authorisation to communication of an identified risk.

There has been continued engagement with the Association for Children Damaged by Hormonal Pregnancy Tests throughout the Expert Working Group review process. I am meeting the All Party Parliamentary Group on Hormone Pregnancy Tests and representatives of the Association in the near future.

HL Deb 06 April 2017 | PQ HL6515; PQ HL6511

Primodos

Asked by: Lord Alton of Liverpool

To ask Her Majesty's Government what funding they are providing to researchers based in (1) Cambridge, and (2) Aberdeen, who are examining the composition of the drug Primodos and its likely effects on the child in the womb.

To ask Her Majesty's Government what assessment they have made of the Sky News documentary *Primodos: The Secret Drugs Scandal*; and whether they will consider establishing a public inquiry into the alleged failure of the regulator at that time to protect public safety.

Answering member: Lord O'Shaughnessy | Department: Department of Health

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.

The Government is not providing any funding to researchers in Cambridge or Aberdeen who are examining the composition of the drug Primodos and its likely effects on the child in the womb.

HL Deb 29 March 2017 | PQ HL6208; PQ HL6207

Primodos

Asked by: Lord Alton of Liverpool

To ask Her Majesty's Government, further to the Written Answers by Earl Howe on 26 October 2010 (HL2589, HL2591, HL2592, and HL2593) concerning the drug Primodos, and to the remarks by the Parliamentary Under Secretary of State for Health on 23 October 2014 (HC Deb 1139) concerning oral hormone pregnancy tests, and in the light of the Sky News documentary *Primodos: The Secret Drugs Scandal*, what progress has been made on the independent review of the papers and evidence relating to oral hormone pregnancy tests; what assessment that review has made of the decision by the Committee on Safety of Medicines to ask drug companies to stop promoting pregnancy test drugs to doctors in 1969 but not to advise doctors not to use such drugs until 1975; and whether that review will examine the allegations made in the Sky News documentary, in particular (1) that no toxicology or testing was undertaken prior to the drug Primodos being licensed, (2) that Primodos was being used as an abortifacient in some parts of the world whilst being sold in the UK for the purposes of pregnancy testing, and (3) that there may have been collusion between the drug manufacturer and the regulatory bodies.

Answering member: Lord O'Shaughnessy | Department: Department of Health

Primodos, a hormonal pregnancy test, first became available in the 1950s. At that time there were no legal requirements on companies to ensure that marketed medicines met appropriate standards of safety, quality and efficacy and a licence to market was not required. Any studies performed on a medicine prior to its use were at the discretion of the company. The Medicines Act came into force in 1971.

The terms of reference of the Expert Working Group on Hormonal Pregnancy Tests, adopted by its members and agreed with by the chair of the main patient association in her role as an 'observer' on the Group, are focused on a scientific review of the strength of evidence for a possible association between exposure in pregnancy to hormonal pregnancy tests and adverse outcomes in pregnancy (particularly birth defects, miscarriages and stillbirths). The Group's terms of reference also

include what lessons may be learnt for further improving existing regulatory systems to identify, monitor and minimise any adverse effects of medicines in pregnancy.

HL Deb 28 March 2017 | PQ HL6261

Primodos

Asked by: Kinnock, Stephen

To ask the Secretary of State for Health, what representations he has received on evidence that was made available to the Government on the dangers of the pregnancy testing drug Primodos in 1967; and what steps he has taken as a result of those representations.

Answering member: Nicola Blackwood | Department: Department of Health

The Government has maintained an ongoing and close dialogue with campaigners over the course of the last eight years, involving face to face meetings and extensive correspondence. As a result of these discussions, the Government committed to an independent review of all the evidence relating to a possible link between hormone pregnancy tests and adverse effects on pregnancy. An ad-hoc Expert Working Group of the Commission on Human Medicines is conducting this review and has so far met on five occasions. It is anticipated that the review will be complete early in 2017, at which time a report of the Group's findings will be published.

The Government remains committed to open engagement on this important issue.

HC Deb 26 October 2016 | PQ 49295

Primodos

Asked by: Ellman, Mrs Louise

To ask the Secretary of State for Health, whether he plans to alter the terms of reference of the Expert Working Panel Group Inquiry into Primodos.

Answering member: Nicola Blackwood | Department: Department of Health

The terms of reference of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests were reviewed by the Group at their first meeting on 14 October 2015, endorsed by the Commission on Human Medicines and formally adopted by all members, invited experts and observers of the Expert Working Group at their second meeting on 4 December 2015.

On 13 October 2016 at a Backbench Business Committee debate secured by the All-Party Parliamentary Group (APPG) on Hormone Pregnancy Tests, the Government committed to respond in detail to the concerns raised by the APPG, which include the terms of reference of

the Expert Working Group on Hormone Pregnancy Tests, and to then meet with the APPG to discuss these concerns.

HC Deb 19 October 2016 | PQ 48751

7. Useful links

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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