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DEBATE PACK

Number CDP 2016/0171, 11 October 2016

Inquiry into hormone pregnancy tests

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This pack has been prepared ahead of the debate to be held on Thursday 13 October 2016 on the Expert Panel Working Group Inquiry into hormone pregnancy tests. The subject for the debate has been selected by the Backbench Business Committee and the Members in charge are Yasmin Qureshi and Hannah Bardell.
The motion for the debate is:

> That this House notes that an Expert Working Panel Group Inquiry was set up by the Government to investigate and assess evidence on children born with serious deformities due to hormone pregnancy test drugs taken by expectant mothers between 1953 and 1975; further notes with concern that the terms of reference as set out by the Medicines and Healthcare Products Regulatory Agency do not clearly allow for an investigation into the systematic regulatory failures of government bodies at the time; notes the conflict of interest of some panel members; further notes that all evidence must be presented to expert panel members as set out in the term of reference; calls on the Inquiry to ensure that all evidence is presented to the expert panel with sufficient time for due consideration; further calls on the inquiry to guarantee thorough background checks on all panel members; calls for the terms of reference to be amended to include an investigation into the conduct of the Committee on Safety of Medicines; further calls on the Government to ensure that the inquiry has the trust and confidence of the victims for whom it was set up; and believes that, unless these changes are made, the ability of the Inquiry to achieve a fair outcome will be significantly compromised.

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1. Inquiry into hormone pregnancy tests

A Backbench Business Committee debate on the inquiry into hormone pregnancy tests has been tabled for 13 October 2016. It will be led by Yasmin Qureshi and Hannah Bardell. The debate will focus on concerns that have been raised regarding the purpose and scope of the inquiry into hormone pregnancy tests and the membership of the expert panel leading the inquiry at the Medicines and Healthcare Products Regulatory Agency (MHRA).

The motion provides further information on these concerns:

> That this House notes that an Expert Working Panel Group Inquiry was set up by the Government to investigate and assess evidence on children born with serious deformities due to hormone pregnancy test drugs taken by expectant mothers between 1953 and 1975; further notes with concern that the terms of reference as set out by the Medicines and Healthcare Products Regulatory Agency do not clearly allow for an investigation into the systematic regulatory failures of government bodies at the time; notes the conflict of interest of some panel members; further notes that all evidence must be presented to expert panel members as set out in the term of reference; calls on the Inquiry to ensure that all evidence is presented to the expert panel with sufficient time for due consideration; further calls on the inquiry to guarantee thorough background checks on all panel members; calls for the terms of reference to be amended to include an investigation into the conduct of the Committee on Safety of Medicines; further calls on the Government to ensure that the inquiry has the trust and confidence of the victims for whom it was set up; and believes that, unless these changes are made, the ability of the Inquiry to achieve a fair outcome will be significantly compromised.

1.1 Background

Drugs containing progestogens and oestrogens were taken as a form of pregnancy test in the NHS 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 in the NHS 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).[1]

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

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

periods and a pregnant uterus could be felt. Hormone pregnancy tests were thought to allow a relatively confident diagnosis of pregnancy.[2]

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.[3]

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[4], stating that:

> [...] there is little justification for the continued use of withdrawal-type pregnancy tests when alternative methods are available.[5]

In June 1975, the CSM sent an alert letter to all doctors in the UK in which 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[6]:

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	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

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

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

4 BMJ, Synthetic sex hormones and Infants, 30 Novermber 1974 pg 485

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

6 PIMS Deposited Paper 26.10.10 UID 73935

used with varying frequency as a pregnancy test within the NHS until withdrawal from the market by Schering in 1978.[7] [8]

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.[9]

1.2 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 achieved wide publicity for 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.[10]

In 1980, the Association initiated legal proceedings against Schering Chemicals Limited on behalf of two children with heart defects.[11,12] The damage claims were discontinued on 2 July 1982 after the judge found there was insufficient evidence linking Primodos and the conditions.[13]

In early 2014, a new campaign called for an independent public inquiry into hormone pregnancy tests. This had been 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.[14]

1.3 Review of the evidence regarding hormone pregnancy tests and congenital abnormalities

The 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.*" 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

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7 Brewer C, *Continued use of hormonal pregnancy tests*, British Medical Journal, 18 February 1978, p 437
8 The Times, Pregnancy test drug 'still prescribed after babies-at –risk warning, 17 April 1978
9 House of Lords Deposited paper on the Committee on the Safety of Medicines and hormone pregnancy tests, 26 October 2010
10 HC Deb 2 March 1978 c390-392W and HC Deb 26 May 1978 c2002-9
11 Times, *Group to sue firm over hormone pregnancy tests*, 30 November 1978, p 5
12 Times, *Primodos actions to go ahead*, June 10 1980, p 16
13 Times, *Claim dropped*, 3 July 1982, p 3
14 The Telegraph, 'Is this the forgotten thalidomide?', 12 May 2014

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 remains that the data is not sufficient to show a causal link between the tests and the 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 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.[15]

1.4 Hormone pregnancy tests inquiry

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.[16]

A call for evidence was published in March 2015. This stated that the Commission on Human Medicines (CHM) 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. 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.

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15 MHRA, Assessment of historical evidence on Primodos and congenital malformations – a synopsis, March 2014

16 HC Deb 23 October 2014, c1138

The CHM *Human Medicines Regulations 2012 Advisory Bodies Annual Report 2015* contains further information on the Hormonal Pregnancy Tests Working Group:

> Hormonal Pregnancy Tests Working Group
>
> 150. In 2015 the Commission convened an Expert Working Group (EWG) to review the available data on a possible association between Hormone Pregnancy tests (HPTs) and congenital anomalies. HPTs were used in the 1950's-1970's but licenses were withdrawn in the late 1970's.
>
> 151. The EWG met first in October 2015 to consider the remit and work plan for the Group, and whether any additional expertise was required and noted a review of the social, medical and legal perspective from the time that HPTs were available, together with a chronology of events from 1958 to the present day. The Group agreed that its terms of reference should focus on the scientific evidence on the possible association between exposure in pregnancy to HPTs and adverse effects in pregnancy (including birth defects in the child, abortion and stillbirth), what lessons may be learned for improving existing regulatory systems in relation to medicines used in pregnancy, and whether the findings have any implications for currently licensed medicines.
>
> A second meeting of the Group was held in December 2015 to consider the information from spontaneous case reports including Yellow Card data and testimonials from a number of individuals who consider they have been affected by HPTs. Further meetings to consider the basic science and epidemiological evidence are planned for 2016.[17]

In response to Parliamentary questions in January 2016, the Under-Secretary of State for Health, Lord Prior of Brampton, reported that the group conducting the inquiry had met twice in 2015, and a number of further meetings were planned for 2016. At the time of the answer the report of the group's findings was expected before the end of the year (2016).[18]

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17 MHRA, *Human Medicines Regulations 2012 Advisory Bodies Annual Report 2015*
18 HL Deb 21 January 2016, c897

2. News Articles

BBC News

Pregnancy drug Primodos inquiry meeting 'disappointment'

7 March 2015

http://www.bbc.co.uk/news/uk-wales-31769020

Daily Telegraph

'Is this the forgotten Thalidomide?'

Sarah Rainey 24 May 2014

http://www.telegraph.co.uk/news/health/10819186/Is-this-the-forgotten-thalidomide.html

BBC News Online

23 October 2014

Pregnancy drug Primodos papers will be published

http://www.bbc.co.uk/news/uk-politics-29745910

3. Press releases

Yasmin Qureshi MP

February 03, 2015

Primodos pregnancy test drug inquiry 'must be transparent', says MP Yasmin Qureshi

The independent inquiry into controversial hormone pregnancy test Primodos must be transparent, campaigners have said.

Bolton South East MP Yasmin Qureshi, who campaigned for the inquiry, said a meeting this week with Health Minister George Freeman had been "reassuring".

Primodos was a hormone-packed drug that used similar compounds to the contraceptive pill, but in much stronger doses.

Until 1975 it was prescribed by GPs as a pregnancy test. Two pills were taken and, if the woman was not pregnant, it would induce a period.

It has since been argued the high-dose hormones sometimes caused abnormalities to the foetus or a miscarriage.

Ms Qureshi led a debate in October last year to argue that thousands of babies would not have been left disabled if the government of the day had taken action.

The government agreed to set up an independent panel to look into the evidence.

Ms Qureshi said: "I had a reassuring meeting with George Freeman on my campaign for Primodos victims and I thanked him for agreeing to set up a panel of inquiry.

"I'm pleased he strongly agreed with me that the process must be transparent and one of trust and confidence for victims who have been denied justice and understandably have lost confidence in the process.

"Appointed panel members must be impartial and be thoroughly vetted.

"We have seen conflict of interests emerge with inquiries into other areas and it is only right and proper that Primodos victims are reassured.

"A chair for the panel has now been appointed and I look forward to meeting with her to discuss the constitution and objectives of the panel."

Ms Qureshi took up the campaign after meeting Little Lever mum Nichola Williams.

Miss Williams was born with life-threatening congenital health issues, which she claims were caused by the drug Primodos that her mother was prescribed while pregnant.

The hormone drug produced by Schering, a German company later taken over by Bayer, was given to women in the UK by GPs in the 1960s and 1970s as a pregnancy test.

Bayer denies that Primodos was responsible for causing any deformities in children.

A timeline for the Panel Inquiry has not yet been set.

Medicines and Healthcare Products Regulatory Authority

Medicines regulator launches call for evidence on previously licensed oral hormonal pregnancy tests

25 March 2015

The Medicines and Healthcare products Regulatory Agency (MHRA) has today launched a public call for evidence relating to the use of oral hormonal pregnancy tests (HPTs, which are no longer prescribed in the UK) and adverse effects relating to pregnancy including possible birth defects.

HPTs such as Primodos were available in the 1960s and 1970s and were widely used to diagnose pregnancy. In 1967, a study raised initial concern that use of HPTs may be associated with birth defects. The then Committee on Safety of Medicines (CSM) kept this issue under review and in 1975 recommended that in view of the possible concern, and the availability of alternative methods, doctors should not use HPTs. These products were withdrawn from the market in the late 1970s.

In October 2014, the government committed to an independent review of the evidence relating to HPTs and the possible risk of birth defects. The review is not a political inquiry intended to demonstrate liability, but to examine the evidence to assess whether there are grounds for accepting a link between the use of HPTs and the conditions experienced by some patients.

A group of experts in relevant scientific disciplines is currently being convened to conduct the review, which is expected to be completed by the beginning of 2016.

To ensure all the available evidence is reviewed, the MHRA is currently in the process of obtaining all relevant documents. As part of this process, the MHRA is asking any individual or organisation with information they feel is relevant to submit it for consideration by the experts during the review. All evidence submitted will be included in the review and a report (including a public summary) will be made publicly available once the review is complete.

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

"We encourage people to send us any information they consider is relevant to previously used hormonal pregnancy tests and potential

adverse effects that they think may have been associated with these drugs.

"It is important that we hear from people who feel they or their child have been affected adversely by hormonal pregnancy tests. We encourage anyone who wants to provide information about a suspected adverse effect from use of a HPT to submit it to us via a Yellow Card report.

"We would also welcome any other published or unpublished evidence you consider relevant and wish to submit for the review and ask that you send this to us by the end of June 2015.

Background

Information on how to submit information to the review.

The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are as safe as is reasonably possible. Underpinning all our work lies strong and evidence-based judgements to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health.

All evidence reviewed will be made publicly available (subject to considerations of the Freedom of Information Act and Data Protection Act).

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4. Parliamentary material

PQs

Health: Hormone Pregnancy Tests – Lords exchange of questions

Asked by Lord Kennedy of Southwark

To ask Her Majesty's Government what is the timeframe for the inquiry into the safety of hormone pregnancy tests, and when they expect the report to be published.

Answering member: The Parliamentary Under-Secretary of State, Department of Health (Lord Prior of Brampton) (Con): My Lords, an expert working group of the Commission on Human Medicines has been convened to review all available evidence on whether use of hormone pregnancy tests may have been associated with adverse outcomes in pregnancy. The group met twice in 2015 and a number of further meetings will be held in 2016. A report of the group's findings will be published once the review is complete, which is expected before the end of the year.

Lord Kennedy of Southwark (Lab): My Lords, the terms of reference of the inquiry still do not include past regulatory failures and the campaigners fear a veil of secrecy and an inability to get to the truth. What can the Minister say today to alleviate people's fears? Will he agree to meet a delegation of campaigners and interested Peers to discuss how we can shine a light on what happened to learn the lessons of the past so that they are there for the future?

Lord Prior of Brampton: My Lords, this issue goes back to the 1950s, so trawling back over that period may not be that helpful. What is helpful is that we learn lessons from the past so that the existing regulatory system can learn from those errors. I am, however, very happy to meet the noble Lord and others who are interested to discuss this further, if they wish to do so.

Baroness Walmsley (LD): My Lords, given that many of the survivors of Primodos, the drug in question here, were not told that they were taking part in a clinical trial, will the noble Lord assure us that today nobody would take part in a clinical trial without their knowledge?

Lord Prior of Brampton: My Lords, I understand that to be the case but I will double-check and, if it is not, I will of course write to the noble Baroness.

Lord Hunt of Kings Heath (Lab): My Lords, is it absolutely clear that there will be full disclosure of all public documents and the regulators' documents for this review?

Lord Prior of Brampton: I understand that all the relevant documents are being made available to the expert working group. The chair of the

association looking after the children who have been damaged by these pregnancies is an observer on that committee.

Lord Winston (Lab): My Lords, with deference to my noble friend's Question, is it not a fact that 40 years on—it is actually more than 40 years because the last letter in the *British Medical Journal* was in 1977 on things that had happened previously—it is now really impossible to decide the precise nature of what happened after the dosage of Primodos? While an inquiry might be helpful to some people, it is very unlikely that we will uncover anything that will be really useful in the future. Is not the message to pregnant women that they are not advised to take any kind of drug during pregnancy?

Lord Prior of Brampton: My Lords, the noble Lord is clearly an expert in this field. If the advice is that pregnant women should not take any kind of drug during pregnancy, that must be the right advice. I agree with him that many of these documents go right back to the early 1950s and many are in German rather than English. The quantity of documentation is enormous. That is one reason why this review has taken so long. However, the people on the expert working group are very distinguished clinicians and are doing the best they can in very difficult circumstances.

Baroness Gardner of Parkes (Con): My Lords, will the Minister confirm the reply he gave that no one will be asked to take any of these experimental things without being aware of doing so, because pregnancy is a time of great anxiety, particularly in view of the accidents that have happened in the past?

Lord Prior of Brampton: All I can do is entirely agree with what my noble friend says. That must be right.

Baroness Deech (CB): My Lords, there has been great fuss about the Prime Minister's wish to ensure that all women, particularly Muslim women, learn English. What steps can the Government take to make sure that all pregnant women receive directly the medical advice that they need during pregnancy?

Lord Prior of Brampton: Much advice is available on NHS Choices and elsewhere. Clearly, GPs have a primary responsibility in giving initial advice to women, of whatever nationality, when they become pregnant.

HL Deb 21 January 2016 | Vol 768 cc 897-8

http://www.publications.parliament.uk/pa/ld201516/ldhansrd/text/160121-0001.htm#16012126000924

Deposited Paper Dep2016-0094 Letter dated 02/02/2016 from Lord Prior of Brampton to Lord Kennedy of Southwark and others regarding the Expert Working Group on Hormonal Pregnancy Tests (HPTs). 2p.

https://depositedpapers.parliament.uk/depositedpaper/view/2276551

Pregnancy Tests

Asked by: Lord Kennedy of Southwark

To ask Her Majesty's Government how people and organisations can make representations to the inquiry into the safety of hormone pregnancy tests.

Answering member: Lord Prior of Brampton | Department: Department of Health

The terms of reference for the inquiry into the safety of Hormone Pregnancy Tests (HPTs) state that the Expert Working Group (EWG) of the Commission on Human Medicines will 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). This will include scientific studies as well as wider sources of evidence.

The Medicines and Healthcare products Regulatory Agency (MHRA) is providing the secretariat to the review and is compiling all the available information. To date, the MHRA has requested relevant published and unpublished information from all companies whose predecessors marketed HPTs and has conducted a search of the National Archives with a view to obtaining a complete set of historical documents relevant to this issue. The MHRA will also search for all relevant published literature and review all suspected adverse drug reactions that have been submitted in association with HPTs in the United Kingdom. All of this information will be made available to the EWG.

Interested individuals and organisations were invited to provide any information relevant to a possible association between the use of oral HPTs and adverse outcomes in pregnancy through a public call for evidence between 25 March and 30 June 2015. In addition, the EWG will hear evidence from a number of individuals who feel their lives have been adversely affected by HPTs.

The report of the review and all documents will be made public subject to the usual legal requirements.

HL Deb 30 October 2015 | HL2940

Pregnancy Tests

Asked by: Bebb, Guto

To ask the Secretary of State for Health, what steps his Department is taking to prevent conflicts of interest with the pharmaceutical industry among those chosen to sit on the hormone pregnancy test review panel;

To ask the Secretary of State for Health, what representations his Department has received from Schering/Bayer on the safety of hormone pregnancy tests.

Answering member: George Freeman | Department: Department of Health

Potential members of the Expert Group on Hormone Pregnancy Tests will be asked to declare any interests (financial or non-financial) in relevant pharmaceutical companies or in any other area that could affect their impartiality. All experts' interests will be carefully considered to determine their suitability for membership on the Group. Members will be asked again about potential interests in the meetings to decide on the appropriate level of participation in discussions.

The Medicines and Healthcare products Regulatory Agency (MHRA, in its capacity as the arm's length body of the Department of Health with responsibility for the regulation of medicinal products) has no record of any representations from Schering/Bayer on the safety of hormone pregnancy tests since they were withdrawn in 1978. The MHRA is has asked all companies which marketed hormonal pregnancy tests to fully disclose the research evidence and test results they hold for inclusion in the review.

HC Deb 05 January 2015 | PQ 219183, PQ 219184

Debate

Oral Hormone Pregnancy Tests

Commons backbench debate: Oral Hormone Pregnancy Tests

HC Deb 23 October 2014 | Vol 586 cc1112-1145

> [Motion: That this House notes that children were born with serious deformities due to hormone pregnancy test drugs taken by expectant mothers between 1953 and 1975; also notes with concern that as the surviving victims enter their forties and fifties many of them face a host of new problems as their bodies continue to suffer; further notes that no official warnings were issued about these drugs until eight years after the first reports indicated possible dangers; further notes that some doctors continued to prescribe the drugs for pregnant women after official warnings from the Committee on Safety of Medicines; calls on the Secretary of State for Health to fully disclose all documents relating to the use of Hormone Pregnancy Tests held by the Department from the period between 1953 and 1978; and also calls on the Secretary of State to set up an independent panel to examine these documents.]

5. Useful links and further reading

Medicines and Healthcare Products Regulatory Authority *Hormonal Pregnancy Tests: Call for Evidence*

https://www.gov.uk/government/consultations/hormonal-pregnancy-tests-call-for-evidence

Medicines and Healthcare Products Regulatory Authority *Assessment of historical evidence on Primodos and congenital malformations*

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

Association for Children Damaged by Hormone Pregnancy Tests

http://www.hormonepregnancytests.org.uk/index.php

All-Party Parliamentary Group on Oral Hormone Pregnancy Tests

http://www.publications.parliament.uk/pa/cm/cmallparty/160831/oral-hormone-pregnancy-tests.htm

The Conversation *Is Primodos 'the forgotten thalidomide'?* 8 February 2016

https://theconversation.com/is-primodos-the-forgotten-thalidomide-50673

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